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: 001-15070

RegeneRx Biopharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**52-1253406**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)
15245 Shady Grove Road, Suite 470, Rockville, MD (Address of principal executive offices)	20850 (Zip Code)

Registrant's telephone number, including area code: 301-208-9191

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common	RGRX	OTC

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

Common Stock, $0.001 par value, including associated Series A Participating Cumulative Preferred Stock Purchase Rights

Warrants to Purchase Common Stock, $0.001 par value

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 and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark 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 definitions of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934. (Check one):

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☐

If an emerging growth company, indicate by check mark if registrant has elected not to use the extended transition period for complying with any new or revised 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

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

As of March 10, 2020, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $13 million. Such aggregate market value was computed by reference to the closing price of the Common Stock as quoted on the Over-the-Counter Bulletin Board, or the OTC Bulletin Board, on March 10, 2020.

The number of shares outstanding of the registrant's common stock as of March 10, 2020 was 133,441,788.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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PART I

This Annual Report on Form 10-K, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding us and our business, financial condition, results of operations and prospects within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the words "project," "believe," "anticipate," "plan," "expect," "estimate," "intend," "should," "would," "could," "will," "may" or other similar expressions. In addition, any statements that refer to projections of our future financial performance or capital resources, our clinical development programs and schedules, our anticipated growth and trends in our business, the clinical and pharmaceutical applications of our products, our expectations about our competitive position in the marketplace, potential business relationships and partnerships, and other characterizations of future events or circumstances are forward-looking statements. We cannot guarantee that we will achieve the plans, intentions or expectations expressed or implied in our forward-looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make, including those described under "Risk Factors" set forth below. In addition, any forward-looking statements we make in this report speak only as of the date of this report, and we do not intend to update any such forward-looking statements to reflect events or circumstances that occur after that date.

Item 1. Business.

General

RegeneRx Biopharmaceuticals, Inc. ("RegeneRx" or the "Company") (OTCQB:RGRX) is a biopharmaceutical company focused on the development of a novel therapeutic peptide, Thymosin beta 4, or Tß4, for tissue and organ protection, repair, and regeneration. We have formulated Tß4 into three distinct product candidates in clinical development:

· RGN-259, a preservative-free topical eye drop for regeneration of corneal tissues damaged by injury, disease or other pathology;

· RGN-352, an injectable formulation to treat cardiovascular diseases, central and peripheral nervous system diseases, and other medical indications that may be treated by systemic administration; and

· RGN-137, a topical gel for dermal wounds and reduction of scar tissue.

We are continuing strategic partnership discussions with biotechnology and pharmaceutical companies regarding the further clinical development of all of our product candidates.

Current Financial Status

In February 2019, we sold a series of convertible promissory notes to management, the Company's Board of Directors and accredited investors including Essetifin S.p.A., our largest stockholder (the "2019 Notes"). The sale of the 2019 Notes resulted in gross proceeds to the Company of $1,300,000 over two closings. The first closing in the amount of $650,000 occurred in February 2019 and the second closing, also in the amount of $650,000, occurred on May 13, 2019 after the Company provided notice of the enrollment of the first patent in the ARISE-3 clinical trial in DES sponsored by ReGenTree. The 2019 Notes contain a $0.12 conversion price and the purchasers also received a warrant exercisable at $0.18 to purchase additional shares of common stock equal to 75% of the number of shares into which each note is initially convertible (the "2019 Warrants"). In addition, we received proceeds of $115,625 pursuant to the exercise of warrants held by Sabby Management as well as $125,000 for April 2019 warrant exercises. In January 2020, Sabby exercised their remaining warrants and the Company received proceeds of $241,912. At present, with the receipt of the sale proceeds from the closing on the 2019 Notes and proceeds from the March and April 2019 and January 2020 warrant exercises, we will have sufficient cash to fund planned operations through the third quarter of 2020.

We continue to evaluate options including the licensing of additional rights to commercialize our clinical products as well as raising capital through the capital markets. However, our ability to raise additional capital raises significant concerns about our ability to continue as a going concern. Since inception, and through December 31, 2019, we have an accumulated deficit of $107 million and we had cash and cash equivalents of $639,916 as of December 31, 2019. We anticipate incurring additional operating losses in the future as we continue to explore the potential clinical benefits of Tß4-based product candidates over multiple indications. We have entered into a series of strategic partnerships under licensing and joint venture agreements where our partners are responsible for advancing development of our product candidates by sponsoring multiple clinical trials.

Current Clinical Status

In January 2015, we entered into a Joint Venture Agreement with GtreeBNT whereby we created ReGenTree LLC ("ReGenTree" or "Joint Venture") jointly owned by us and GtreeBNT, which intends to commercialize RGN-259 for treatment of dry eye syndrome and neurotrophic keratitis, an orphan indication in the United States.

To date ReGenTree has completed a Phase 2/3 clinical trial ("ARISE-1") and Phase 3 clinical trials in patients with DES ("ARISE-2"). Currently, it is sponsoring a Phase 3 clinical trial in patients with neurotrophic keratitis ("NK") ("SEER-1"), and a Phase 3 trial in patients with DES (ARISE-3), both in the U.S. In May 2016, we reported the results of the 317-patient ARISE-1 trial and in October 2017, we reported the results of the ARISE-2 trial. The ARISE-2 study, which was sponsored by ReGenTree and managed by Ora, Inc. pursuant to a contract between the parties, demonstrated a number of statistically significant improvements in both signs and symptoms of DES with 0.1% RGN-259 versus placebo, while showing excellent safety, comfort, and tolerability profiles. The ocular discomfort symptom showed a statistically significant reduction in the RGN-259-treated group at day 15 as compared to placebo (p=0.0149) in the change from baseline. For sign, RGN-259 also improved the dry eye patient's ability to withstand an exacerbated condition in a patient subgroup with both compromised corneal fluorescein staining and Schirmer's test at baseline. In this population, RGN-259 showed superiority over placebo in reducing corneal fluorescein staining in the change from baseline at days 15 and 29 (p=0.0207 and 0.0254, respectively). RGN-259 confirmed its global effects on dry eye syndrome and fast onset in multiple sign and symptom efficacies with no safety issues in the ARISE-1 and ARISE-2 studies as well as in the pooled data, although ARISE-2 was not successful in duplicating the results of ARISE-1 where the study population was limited and less diversified. ReGenTree is proceeding with its RGN-259 development plan as discussed with the FDA in April 2018. ReGenTree and Ora, Inc. entered into a contract for management of ARISE-3. ReGenTree has initiated the study, the first patient was enrolled in the second quarter of 2019, and it is expected to be completed in the Summer of 2020.

The NK trial (SEER-1), a smaller study in an orphan population, last reported enrollment of 17 patients. ReGenTree previously disclosed that 7 of 17 patients had completely healed. To participate in the trial the patients were required to have a persistent epithelial defect (non-healing corneal wound). While these preliminary observations are encouraging, it should be noted that the patients and treating physicians remained masked while the trial was on-going, so it was not known whether the healed patients were in the RGN-259 group, placebo group, or distributed among both. We expect ReGenTree to report top line data in the next few months.

GtreeBNT has developed the CMC (chemistry, manufacturing and controls) dossier required for Phase 3 clinical trials and commercialization in the U.S. and in Korea. This comprehensive and critical effort ensures that final drug product manufacturing, packaging, stability, purity, reproducibility, etc., meets regulatory guidelines and product specifications. The product of this activity is the current product formulation being utilized in the U.S. trials being conducted by ReGenTree and will also be utilized in the planned clinical activity to be conducted by GtreeBNT under the RGN-259 license agreement for Pan Asia.

In February 2017, our licensee for RGN-137, GtreeBNT, through its subsidiary, Lenus Therapeutics, LLC, received permission from the U.S. FDA to sponsor a Phase 3 clinical trial using RGN-137 to treat patients with epidermolysis bullosa (EB), a genetic disease that causes severe blistering of the skin and internal organs. In August 2017, the Company amended the license agreement for RGN-137 held by GtreeBNT. Under the amendment the Territory was expanded to include Europe, Canada, South Korea, Australia and Japan. In December 2018, GtreeBNT initiated a small Phase 2 open trial in patients with EB to evaluate RGN-137 in such patients prior to sponsoring a larger Phase 3 trial. Three patients have been enrolled in the open clinical trial to date. It was reported in August 2019, that the first patient had positively responded to RGN-37. It is hoped that 12 additional patients can be enrolled through 2020 now that all the clinical sites have received IRB approval.

Currently, we have active partnerships in four major territories: North America, Europe, China and Pan Asia. Our partners have been moving forward and making progress in each territory. In each case, the cost of development is being borne by our partners with no financial obligation for RegeneRx. We still have significant clinical assets to develop, primarily RGN-352 (injectable formulation of Tß4 for cardiac and CNS disorders) in the U.S., most of Asia, and Europe, and RGN-259 in the EU. In August 2017 we amended the RGN-137 license agreement with GtreeBNT, expanding the territory to include Europe, Canada, South Korea, Australia and Japan. Regarding RGN-259, our goal is to wait until satisfactory results are obtained from the current ophthalmic clinical program in the U.S. before moving into the EU. This should allow us to obtain a higher value for the asset at that time. However, we intend to continue to develop RGN-352, our injectable systemic product candidate for cardiac and central nervous system indications, either by obtaining grants to fund a Phase 2a clinical trial in the cardiovascular or central nervous system fields or finding a suitable partner with the resources and capabilities to develop it as we have with RGN-259.

We anticipate incurring additional operating losses in the future as we continue to explore the potential clinical benefits of Tß4-based product candidates over multiple indications. To fund further development and clinical trials we have entered into a series of strategic partnerships under licensing and joint venture agreements (see "Strategic Partnerships" below) where our partners are responsible for advancing development of our product candidates with multiple clinical trials.

Overview of Tß4

Tß4 is a synthetic copy of a naturally occurring 43-amino acid peptide that was originally isolated from bovine thymus glands. It plays a vital role in cell structure and motility and in the protection, regeneration, remodeling and healing of tissues.

Although it is recognized that wound healing and tissue regeneration are complex processes, most companies working to develop new drugs in this area have focused primarily on the development of growth factors and genetic therapies to stimulate healing and have, to date, failed to demonstrate dramatic improvements in the healing process. Numerous preclinical animal studies, published by independent researchers, have identified several important biological activities involving Tß4 that we believe make it potentially useful as a wound healing, repair and tissue regenerating agent. These activities include:

- ***Progenitor (Stem) Cell Recruitment and Differentiation.*** Independent research published in the journal *Nature* in November 2006 featured the discovery that Tß4 is the key signaling molecule that recruits and triggers adult epicardial progenitor cells, or EPCs, to differentiate into coronary blood vessels. EPCs are partially differentiated stem cells that can further differentiate into specific cell types when needed. Confirmatory research published in 2009 in the *Journal of Molecular and Cellular Cardiology* concluded that Tß4 is responsible for the initiation of the embryonic coronary developmental program and EPC differentiation in adult mice. These publications confirm that Tß4's interaction with EPCs is necessary for the maintenance of a healthy adult animal heart, as well as for normal embryo and fetal heart development in mammals. In Neuroscience (2009 and 2010), and the J. Neurosurgery (2010), Tß4 was shown to similarly stimulate oligodendrogenesis, *i.e.*, the differentiation of oligodendroctye progenitor cells into myelin-producing oligodendrocytes, whereby restoring functional recovery in animal models of multiple sclerosis, stroke, and traumatic brain injury.

- ***Actin Regulation.*** Tß4 regulates actin, which comprises up to 10% of the protein of non-muscle cells in the body and plays a central role in cell structure and in the movement of cells. Independent research studies have indicated that Tß4 stimulates the migration of human keratinocytes, or skin cells, as well as corneal epithelial cells that protect the eye, human endothelial cells and progenitor cells of the heart and brain. Endothelial cells are the major cell type responsible for the formation of new blood vessels, a process known as angiogenesis. Certain of these studies conducted at the National Institutes of Health, or NIH, were the first to suggest the role of Tß4 in wound healing. The data from these studies encouraged us to license the rights to Tß4 from the NIH in 2001 and to launch an initial clinical development program that targeted the use Tß4 for chronic dermal wounds.

- ***Reduction of Inflammation and Scar Tissue Formation.*** Uncontrolled inflammation is the underlying basis of many pathologies and injuries. Independent research has shown that Tß4 is a potent anti-inflammatory agent in skin cells and in corneal epithelial cells in the eye. Tß4 has also been shown to decrease the levels of inflammatory mediators and to significantly reduce the influx of inflammatory cells in the reperfused heart of animals. More recent preclinical research suggests that Tß4 blocks activation of the NFκB pathway, which is involved in DNA activation of inflammatory mediators, thereby modulating inflammation in the body. This anti-inflammatory activity may explain, in part, the mechanism by which Tß4 appeared to improve functional outcome in the mouse multiple sclerosis model described above, as well as promoting repair in the heart and skin. In the skin, it has been shown to reduce scar formation by reduction of infiltration of myofibroblasts. Identifying a factor such as Tß4 that reduces scarring and blocks activation of NFκB suggests that Tß4 could have additional important therapeutic applications for inflammation-related diseases, such as cancer, osteoarthritis, rheumatic diseases, autoimmune diseases, inflammatory pulmonary disease and pancreatitis.

- ***Collagen and Laminin-5 Stimulation.*** Tß4 has a number of additional biological activities shown to reduce inflammation, stimulate the formation of collagen, and up-regulate the expression of laminin-5, a subepithelial basement membrane protein. Both collagen and laminin-5 are central to healthy tissue, wound repair and the prevention of disease. Laminin-5 promotes cell migration and maintains cell-cell and cell-matrix contacts for intact tissues which are important for preventing fluid loss and bacterial infection.

- ***Anti-Apoptosis.*** Tß4 has been shown to prevent apoptosis, or programmed cell death, in two animal models and in two tissue types. In the rodent model, corneal apoptosis, or loss of corneal epithelial cells leading to corneal epithelial thinning, was prevented through topical administration of Tß4 eye drops. In the heart muscle of ischemic animal models, such as in mice and pigs, cell death was prevented by either local or systemic administration of Tß4.

Tß4 has shown efficacy in heart repair and regeneration in numerous animal models. A 2004 paper in *Nature* showed that it could reduce the lesion size, improve cardiac function and promote survival. The 2006 *Nature* publication mentioned above further concluded that Tß4's interaction with EPCs resulted in the formation of cardiomyocytes that repaired damaged myocardium, or heart tissue, in mice after an induced acute myocardial infarction, or AMI, commonly known as a heart attack. Research published in the journal *Circulation* showed Tß4's cardioprotective effects in a pig ischemic-reperfusion model. This pig model is accepted as an important model upon which to base human clinical research, as pigs are larger mammals, the anatomy of the pig heart is similar to that of the human heart, and vascular response processes are completed five to six times faster in pigs than in humans, so that long-term results can be obtained in a relatively short period of time. This research also identified Tß4's interaction with EPCs as the underlying basis of cardioprotection through the differentiation of EPCs into cardiomyocytes, yielding statistically significant cardiac functional recovery results when compared to the administration of placebo.

Similar research in the area of brain and central nervous system tissues also showed efficacy of repair and regeneration was published in the journal Neuroscience in 2009. This publication concluded that Tß4 triggered the differentiation of oligodendrocyte progenitor cells to form myelin-producing oligodendrocytes, which led to the remyelination of axons in the brain of mice with experimental autoimmune encephalomyelitis, or EAE. This mouse model is an accepted small animal model for the study of multiple sclerosis. Research published in the Journal of Neurosurgery in 2010 and also in the Journal of Neurological Science in 2014 showed that Tß4 could improve functional neurological outcome in an animal stroke model. A second study was published in the Journal of Neurosurgery in 2011 demonstrating that administration of Tß4 can significantly improve histological and functional outcomes in rats with traumatic brain injury, or TBI, indicating that Tß4 has considerable therapeutic potential for patients with TBI. More recently, researchers studying Tß4 under a material transfer agreement (MTA) found that Tß4 had beneficial effects in animal models of peripheral neuropathy, one of the major complications of diabetes. This research was published in the Journal of Neurobiology of Disease in December 2012 and appears to corroborate previous findings using Tß4 for repair of central nervous system disorders. A paper in Neuropharmacology in 2014 found many benefits of Tß4 administration in a rat model of spinal cord injury, including decreased lesion size at 7 days, increased neural and oligodendrocyte survival, increase levels of myelin basic protein (a marker of mature oligodendrocytes), decreased ED1 (a marker of activated microglia/macrophages), and decreased proinflammatory cytokines. Thus, Tß4 has efficacy for repair and regeneration in several nervous system injury models including MS, TBI, stroke, peripheral neuropathy, and spinal cord injury and there will likely be additional applications in this area. We believe that these various biological activities work in concert to play a vital role in the healing and repair of injured or damaged tissue and suggest that Tß4 is an essential component of the tissue protection and regeneration process that may lead to many potential medical applications. All of our product candidates utilize Tß4 as the active pharmaceutical ingredient (API), which is manufactured by solid-phase peptide synthesis and is an exact copy of the naturally occurring peptide. We have created three distinct formulations for various routes of administration and medical indications.

Our Product Candidates

RGN-259

RGN-259 is our proprietary preservative-free eye drop formulation of Thymosin beta 4. In September 2011, we completed a Phase 2a exploratory clinical trial evaluating the safety and efficacy of RGN-259 in 72 patients with moderate dry eye syndrome. In November 2011, we reported preliminary safety and efficacy results from the trial. RGN-259 was deemed safe and well-tolerated, with no observed drug-related adverse events.

In June 2012, we reported preliminary results from a double-masked, vehicle-controlled, physician-sponsored Phase 2 clinical trial evaluating RGN-259 for the treatment of nine patients (18 eyes) with severe dry eye. RGN-259 was observed to be safe and well-tolerated and met key efficacy objectives with statistically significant sign and symptom improvements, compared to vehicle control, at various time intervals, including 28 days post-treatment.

Consistent with the reduction of ocular discomfort and fluorescein staining at the 28-day follow-up visit, other improvements seen in the RGN-259-treated patients included tear film breakup time and increased tear volume production. Likewise, these improvements were seen at other time points in the study. These results were published Cornea in 2015.

In September 2015, ReGenTree began the Phase 2/3 ARISE-1 clinical trial in patients with DES and the Phase 3 SEER-1 clinical trial in patients with neurotrophic keratitis (“NK”), both in the U.S. In May 2016, we reported the results of the 317-patient ARISE-1 dry eye trial. In the trial, RGN-259 demonstrated statistically significant improvements in both signs and symptoms of dry eye with 0.05% and 0.1% RGN-259 compared to placebo in a dose dependent manner during a 28-day dosing period. While the primary outcome measures were not met, several key related pre-specified endpoints and subgroups of patients with more severe dry eye showed statistically significant treatment effects. These results confirm the findings from the previous Phase 2 trial providing clear direction for the clinical regulatory pathway and remaining registration trials for RGN-259. Shortly following the ARISE-1 trial, the FDA approved ReGenTree’s Phase 3 ARISE-2 dry eye protocol and we initiated the ARISE-2 trial that enrolled approximately 600 patients.

The ARISE-2 study, which was sponsored by ReGenTree and managed by Ora, Inc., demonstrated a number of statistically significant improvements in both signs and symptoms of dry eye syndrome with 0.1% RGN-259 versus placebo, while showing excellent safety, comfort, and tolerability profiles. The ocular discomfort symptom showed a statistically significant reduction in the RGN-259-treated group at day 15 as compared to placebo (p=0.0149) in the change from baseline. For sign, RGN-259 also improved the dry eye patient’s ability to withstand an exacerbated condition in a patient subgroup with both compromised corneal fluorescein staining and Schirmer’s test at baseline. In this population, RGN-259 showed superiority over placebo in reducing corneal fluorescein staining in the change from baseline at days 15 and 29 (p=0.0207 and 0.0254, respectively). RGN-259 confirmed its global effects on dry eye syndrome and fast onset in multiple sign and symptom efficacies with no safety issues in the ARISE-1 and ARISE-2 studies, as well as in the pooled data, although ARISE-2 was not successful in duplicating the results of ARISE-1 where the study population was limited and less diversified.

In February 2019, ReGenTree initiated a 700-patient ARISE-3 trial in patients with dry eye syndrome to confirm the results observed in ARISE-2. The first patient was enrolled in the second quarter of 2019 and the trial is expected to be completed in the Summer of 2020.

Strategic Partnerships

Lee's Pharmaceuticals. We are a party to a license agreement with Lee's Pharmaceutical for the license of Thymosin Beta 4 in any pharmaceutical form, including our RGN-259, RGN-352 and RGN-137 product candidates, in China, Hong Kong, Macau and Taiwan (Greater China). In February 2019, the license was assigned by Lee's to their affiliate, Zhaoke Ophthalmology Pharmaceutical Limited. Lee's previously filed an IND with the Chinese FDA to conduct a Phase 2, randomized, double-masked, dose-response clinical trial with RGN-259 in China for dry-eye syndrome. Lee's subsequently informed us that it received notice from China's FDA declining its IND application for a Phase 2 dry eye clinical trial because the API was manufactured outside of China. The API was manufactured in the U.S. and provided to Lee's by RegeneRx pursuant to the agreement to develop RGN-259 ophthalmic eye drops in Greater China. However, in mid-2016, we were informed by Lee's that the CFDA modified its manufacturing regulations and would now allow Chinese companies to utilize API manufactured outside of China for Phase 1 and 2 clinical trials. Recently, we have been in ongoing discussions with management of Zhaoke to further refine its development plan for RGN-259. We have not yet been informed of a projected starting date for Phase 2 trials but believe Lee's is awaiting the outcome of the ARISE-3 DES trial prior to initiating clinical trials in China.

GtreeBNT. We are a party to a license agreement with GtreeBNT for the license of RGN-259 related to certain development and commercialization rights for RGN-259, in Asia (excluding Greater China). Separately, we licensed GtreeBNT the rights to RGN-137 which was recently amended as discussed above. GtreeBNT is currently our second largest stockholder. GtreeBNT filed an IND with the Korean Ministry of Food and Drug Safety to conduct a Phase 2/3 study with RGN-259 in patients with dry eye syndrome and in July 2015 received approval to conduct the trial. In late 2016 GtreeBNT informed us that it believes marketing approval in the U.S. will allow expedited marketing in Korea, possibly without the need for a clinical trial and, therefore, will await marketing approval in the U.S.

U.S. Joint Venture (ReGenTree, LLC).

We are a party to a Joint Venture Agreement with GtreeBNT and a license agreement with the Joint Venture Company, ReGenTree, LLC, for the commercialization of RGN-259 for treatment of dry eye and neurotrophic keratitis in the United States, as well as any other relevant ophthalmic indications.

In September 2015, ReGenTree began the Phase 2/3 ARISE-1 clinical trial in patients with dry eye syndrome (and the Phase 3 SEER-1 clinical trial in patients with neurotrophic keratitis ("NK"), both in the U.S. In May 2016, we reported the results of the 317-patient ARISE-1 dry eye trial. In the trial, RGN-259 demonstrated statistically significant improvements in both signs and symptoms of dry eye with 0.05% and 0.1% RGN-259 compared to placebo in a dose dependent manner during a 28-day dosing period. While the primary outcome measures were not met, several key related pre-specified endpoints and subgroups of patients with more severe dry eye showed statistically significant treatment effects. These results confirmed the findings from the previous Phase 2 trial providing clear direction for the clinical regulatory pathway and remaining registration trials for RGN-259. Shortly following the ARISE-1 trial, the FDA approved ReGenTree's Phase 3 ARISE-2 dry eye, which enrolled approximately 600 patients.

The ARISE-2 study, which was sponsored by ReGenTree and managed by Ora, Inc., demonstrated a number of statistically significant improvements in both signs and symptoms of dry eye syndrome with 0.1% RGN-259 versus placebo, while showing excellent safety, comfort, and tolerability profiles. The ocular discomfort symptom showed a statistically significant reduction in the RGN-259-treated group at day 15 as compared to placebo ($p=0.0149$) in the change from baseline. For sign, RGN-259 also improved the dry eye patient's ability to withstand an exacerbated condition in a patient subgroup with both compromised corneal fluorescein staining and Schirmer's test at baseline. In this population, RGN-259 showed superiority over placebo in reducing corneal fluorescein staining in the change from baseline at days 15 and 29 ($p=0.0207$ and 0.0254, respectively). RGN-259 confirmed its global effects on dry eye syndrome and fast onset in multiple sign and symptom efficacies with no safety issues in the ARISE-1 and ARISE-2 studies as well as in the pooled data, although ARISE-2 was not successful in duplicating the results of ARISE-1 where the study population was limited and less diversified. ReGenTree and ORA, Inc. initiated the study with the first patient enrolled in the second quarter of 2019. The trial is expected to be completed in the Summer of 2020.

RGN-352

During 2009, we completed a Phase 1a and Phase 1b clinical trial evaluating the safety, tolerability and pharmacokinetics of the intravenous administration of RGN-352 in 60 healthy subjects (40 in each group, 20 of whom participated in both phases). Based on the results of these Phase 1 trials and extensive preclinical efficacy data published in peer-reviewed journals, in the second half of 2010, we began start-up activities for a Phase 2 study to evaluate RGN-352 (Tß4 injectable solution) in patients who had suffered an AMI. We had planned to begin enrolling patients in this clinical trial in the second quarter of 2011. However, in March 2011, we were notified by the FDA that the trial was placed on clinical hold as a result of our contract manufacturer's alleged failure to comply with the current Good Manufacturing Practices (cGMP) regulations. The manufacturer has since closed its manufacturing facility and filed for bankruptcy protection. The FDA prohibited us from using any of the active drug or placebo formulated by this manufacturer in human trials; consequently, we must have study drug (RGN-352 and RGN-352 placebo) manufactured by a new cGMP-compliant manufacturer in the event we seek to move forward with this trial. While we have identified a qualified manufacturer for RGN-352, we elected to postpone activities on this trial until the requisite funding or a partner is secured.

In addition to the potential application of RGN-352 for the treatment of cardiovascular disease, preclinical research published in the scientific journals Neuroscience and the Journal of Neurosurgery, among numerous others, indicates that RGN-352 may also prove useful for patients with multiple sclerosis, or MS, as well as patients suffering a stroke, traumatic brain injury, peripheral neuropathy, or spinal cord injury. In these preclinical studies, the administration of Tß4 resulted in regeneration of neuronal tissue by promoting remyelination of axons and stimulating oligodendrogenesis, resulting in improvement of neurological functional activity. In 2012, researchers studying Tß4 under a material transfer agreement (MTA) found that Tß4 had beneficial effects in animal models of peripheral neuropathy, one of the major complications of diabetes. This research was published in the journal of Neurobiology of Disease in 2012 and appears to corroborate previous findings using Tß4 for repair of central nervous system disorders. We are continuing to evaluate opportunities to develop RGN-352 in these medical fields, including government funding and private partnerships for a Phase 2a clinical trial to show proof-of-concept in each case while also talking with prospective strategic partners with the interest, capabilities and resources to further develop product candidate in these fields.

RGN-137

Clinical Development — Epidermolysis Bullosa (EB). Starting in 2005, we began conducting a Phase 2 clinical trial designed to assess the safety and effectiveness of RGN-137 for the treatment of patients with EB. EB is a genetic disease of approximately 10 gene mutations that results in fragile skin and other epithelial structures (e.g., cornea and GI tract) that can blister spontaneously or separate at the slightest trauma or friction, creating a wound that at times does not heal or heals poorly. In severe cases, recurrent blistering and tissue loss may be life threatening. EB has been designated as an "orphan" indication by the FDA's Office of Orphan Drugs. We closed the Phase 2 trial in late 2011 and we submitted the final report to the FDA in 2014. In February 2017, GtreeBNT, our licensee for RGN-137, received permission from the U.S. FDA to sponsor a Phase 3 clinical trial using RGN-137 to treat patients with EB. In December 2018 GtreeBNT initiated a small Phase 2 open trial in a limited number of patients with EB. Three patients have been enrolled to date. It was reported in August 2019, that the first patient had positively responded to RGN-137. It is hoped that 12 additional patients can be enrolled through 2020 now that all of the clinical sites have received IRB approval.

Clinical Development — Pressure Ulcers. In late 2005, we began conducting a Phase 2 clinical trial designed to assess the safety and effectiveness of RGN-137 for the treatment of patients with chronic pressure ulcers, commonly known as bedsores.

In January 2009, we reported final data from this trial. RGN-137 was well-tolerated at all three dose levels studied, with no dose-limiting adverse events, which achieved the primary objective of the study. A follow-on evaluation, reported at the 3rd International Symposium on the Thymosins in Health and Disease in March 2012, showed that for those pressure ulcer patients' wounds that healed, RGN-137 mid dose (0.02% Tβ4 gel product) accelerated wound closure with a median time to healing of 22 days as compared to 57 days for the placebo. Although those results were clinically significant, they were not statistically significant.

Clinical Development — Venous Stasis Ulcers. In mid-2006 we began conducting a Phase 2 clinical trial designed to assess the safety and effectiveness of RGN-137 for the treatment of patients with venous stasis ulcers. Venous stasis ulcers are a common type of chronic wound that develops on the ankle or lower leg in patients with chronic vascular disease. In these patients' blood flow in the lower extremities is impaired leading to venous hypertension, edema (swelling) and mild redness and scaling of the skin that gradually progresses to ulceration. In 2009, we reported final data from that trial. Those results were both clinically and statistically significant.

Our Strategy

We seek to maximize the value of our product candidates by advancing their clinical development and then identifying suitable partners for further development, regulatory approval, and marketing. We intend to engage in strategic partnerships with companies with clinical development and commercialization strengths in desired pharmaceutical therapeutic fields. We are actively seeking partners with suitable infrastructure, expertise and a long-term initiative in our medical fields of interest. To that end, we have entered the licensing and joint ventures discussed above. We continue to control our ophthalmic assets (RGN-259) in the EU, while awaiting results of U.S. clinical trials. We also retain the cardiovascular and neurovascular assets (RGN-352) in the U.S. and EU and other territories in Asia to create a worldwide portfolio that we believe will be more attractive to multi-national pharmaceutical companies. We previously licensed RGN-137 to GtreeBNT for dermal wound healing in the U.S. and in August 2017, the we amended the license to include Europe, Canada, South Korea, Australia and Japan.

Manufacturing

We use a major contract manufacturer to produce bulk Tß4, which is the active pharmaceutical ingredient (API) in our product candidates by an established and proven manufacturing process known as solid-phase peptide synthesis. While we do not currently have long-term supply agreements in place, we and ReGenTree intend to establish a long-term supply arrangement with at least one manufacturer once practicable. No assurance can be given, however, that future agreements by us or our partners will be negotiated on favorable terms, or at all. Contractors are selected on the basis of their supply capability, ability to produce a product in accordance with Current Good Manufacturing Practice, or cGMP, requirements of the FDA and ability to meet our established specifications and quality requirements. Given our recent licensing and joint venture deals, our partner in Korea and the U.S. are working closely with our current primary contract manufacturer on the cGMP validation process and consistency runs, among other things, to prepare for the manufacture of bulk Tß4 for use in future clinical trials and commercialization of our formulated product candidates. Through ReGenTree we are also identifying and qualifying other potential API manufacturers. We will have access to the data resulting from this endeavor should we need to use it for purposes outside the licensed territories.

We and our licensees also use a number of outside contract manufacturers to formulate bulk Tß4 into our product candidates, RGN-137, RGN-259 and RGN-352. We use separate manufacturers for each formulation of Tß4. All of these formulations may require modifications, along with additional studies, as we advance our clinical development programs through commercialization.

Competition

We are engaged in a business that is highly competitive, and our target medical indications are ones with significant unmet needs. Consequently, there are many enterprises, both domestic and foreign, pursuing therapies and products that could compete with ours. Most of these entities have financial and human resources that are substantially greater than ours, specifically with regard to the conduct of clinical research and development activities, clinical testing and in obtaining the regulatory approvals necessary to market pharmaceutical products. Brief descriptions of some of these competitive products follow:

RGN-259. Most specialty ophthalmic companies have a number of products on the market that could compete with RGN-259. There are numerous antibiotics to treat eye infections to promote corneal wound healing and many eye lubrication products that are soothing to the eye and help eye healing, many of which are sold without prescriptions. Companies also market steroids to treat certain conditions within our area of interest. Allergan, Inc. markets Restasis®, Ophthalmic Emulsion, an FDA-approved eye drop used to treat dry eye. Restasis, and other products, have been approved for marketing in certain other countries where we have licensed RGN-259. Novartis is marketing the recently FDA-approved product, Xiidra®. We believe RGN-259 is different from Restasis® and Xiidra® and any other product or product candidate available for dry eye in that it actively promotes repair using a multi-faceted approach of increasing cell migration and laminin-5 production, and decreasing inflammation and apoptosis, without any noted adverse effects.

In 2018, Dompé Farmaceutici S.p.A. announced FDA approval of Oxervate™ to treat patients with neurotrophic keratitis. Oxervate™ is manufactured using a recombinant form of human nerve growth factor. It is used six times per day for two months and monthly treatment costs can be as high as $46,760 for one eye according to *The Balance*, a lifestyle journal covering health care trends and costs. Patients have reported eye pain, corneal deposits, foreign body sensation and inflammation, among other side effects associated with Oxervate™. We believe that RGN-259 is different from Oxervate™ in that it is faster acting, shows no adverse effects, and would likely be far less expensive.

RGN-352. Currently, we do not believe there are any approved pharmaceutical products for regenerating cardiac tissue following a heart attack, nor for regeneration of nervous tissue or for the remyelination of axons of patients with multiple sclerosis or patients suffering from traumatic brain injury. However, many pharmaceutical companies and research organizations are developing products, pharmacologic and stem cell therapies and technologies that are intended to prevent cardiac damage, improve cardiac function, and regenerate cardiac muscle after a heart attack. There are also companies developing products that are purported to remyelinate neurons and provide functional improvement for patients suffering from multiple sclerosis, stroke, traumatic brain injury, and peripheral neuropathy. If we, or a partner, were to successfully develop RGN-352 for cardiovascular or central nervous system indications, such products would have to compete with other drugs or therapies currently being developed or marketed by large pharmaceutical companies for similar indications.

RGN-137. There are numerous companies developing new pharmaceutical products for wound healing and for EB, in particular. Products and therapies such as antibiotics, honey-based ointments, silver-based compounds and low frequency cavitational ultrasound are also used to treat certain types of dermal wounds. Moreover, dermal wound healing is a large and highly fragmented marketplace that includes numerous therapeutic products and medical devices for treating acute and chronic dermal wounds. Most recently, various other companies are attempting to develop genetic therapies to try to heal or prevent serious wound disorders.

Government Regulation

In the United States, the Federal Food, Drug, and Cosmetic Act, as amended, or FFDCA, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacturing, labeling, storing, recordkeeping, distribution, advertising and promotion of our product candidates. Regulation by governmental authorities in the United States and foreign countries will be a significant factor in the manufacturing and potential marketing of our product candidates and in our ongoing research and product development activities. Any product candidate we develop will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical studies, clinical trials and other approval procedures by the FDA and similar health authorities in foreign countries. The process of obtaining these approvals and subsequent compliance with appropriate federal and state statutes and regulations requires the expenditure of substantial resources.

Preclinical studies must ordinarily be conducted to evaluate an investigational new drug's potential safety by toxicology studies and potential efficacy by pharmacology studies. The results of these studies, among other things, are submitted to the FDA as part of an Investigational New Drug Application, or IND, which must be reviewed by the FDA before clinical trials can begin. Typically, clinical evaluation involves a three-stage process. Phase 1 clinical trials are conducted with a small number of healthy volunteers to determine the safety profile and the pattern of drug absorption, distribution, metabolism and excretion, and to assess the drug's effect on the patient. Phase 2, or therapeutic exploratory, trials are conducted with somewhat larger groups of patients, who are selected by relatively narrow criteria yielding a more homogenous population that is afflicted with the target disease, in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. Phase 2 trials should allow for the determination of the dose to be used in Phase 3 clinical trials. Phase 3, or therapeutic confirmatory, large scale, multi-center, comparative trials are conducted with patients afflicted with a target disease in order to provide enough data for the statistical proof of safety and efficacy required by the FDA and other regulatory authorities. The primary objective of Phase 3 clinical trials is to show that the drug confers therapeutic benefit that outweighs any safety risks. All clinical trials must be registered with a central public database, such as www.clinicaltrials.gov, and once completed, results of the clinical trials must be entered in the database.

The results of these preclinical studies and clinical trials, along with detailed information on manufacturing, are submitted to the FDA in the form of a New Drug Application, or NDA, for approval to commence commercial sales. The FDA's review of an NDA requires the payment of a user fee currently in excess of $1.8 million, which may be waived for the first NDA submitted by a qualifying small business. In responding to an NDA, the FDA may refuse to file the application if the FDA determines that the application does not satisfy its regulatory approval criteria, request additional information or grant marketing approval. Therefore, even if we complete Phase 3 clinical trials for our product candidates and submit an NDA to the FDA, there can be no assurance that the FDA will grant marketing approval, or if granted, that it will be granted on a timely basis. If the FDA does approve a product candidate, it may require, among other things, post-marketing testing, including potentially expensive Phase 4 trials, which monitor the safety of the drug. In addition, the FDA may in some circumstances impose risk evaluation and mitigation strategies that may be difficult and expensive to administer. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market.

Among the conditions for NDA approval is the requirement that the applicable clinical, pharmacovigilance, quality control and manufacturing procedures conform on an ongoing basis with current Good Clinical Practices, Good Laboratory Practices, current Good Manufacturing Practices, and computer information system validation standards. During the review of an NDA, the FDA will perform a pre-licensing inspection of select clinical sites, manufacturing facilities and the related quality control records to determine the applicant's compliance with these requirements. To assure compliance, applicants must continue to expend time, money and effort in the area of training, production and quality control. After approval of any product, manufacturers are subject to periodic inspections by the FDA. If a company fails to comply with FDA regulatory requirements, FDA may pursue a wide range of remedial actions, including seizure of products, corrective actions, warning letters and fines.

We have received orphan drug designation from the FDA for RGN-137 for the treatment of EB and RGN-259 for the treatment of neurotrophic keratitis or NK, (now to be developed by ReGenTree). The FDA may designate a product or products as having orphan drug status to treat a disease or condition that affects less than 200,000 individuals in the United States, or, if patients of a disease number more than 200,000, the sponsor can establish that it does not realistically anticipate its product sales will be sufficient to recover its costs. If a product candidate is designated as an orphan drug, then the sponsor may receive incentives to undertake the development and marketing of the product, including grants for clinical trials, as well as a waiver of the user fees for submission of an NDA application. For example, as described above, we received a grant from the FDA for our Phase 2 clinical trial of RGN-137 to treat patients with EB.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to marketing exclusivity for a period of seven years in the United States and ten years in the EU. There may be multiple designations of orphan drug status for a given drug and for different indications. Orphan drug designation does not guarantee that a product candidate will be approved by the FDA for marketing for the designation, and even if a sponsor of a product candidate for an indication for use with an orphan drug designation is the first to obtain FDA approval of an NDA for that designation and obtains marketing exclusivity, another sponsor's application for the same drug product may be approved by the FDA during the period of exclusivity if the FDA concludes that the competing product is clinically superior. In this instance, the orphan designation and marketing exclusivity originally granted would be lost in favor of the clinically superior product.

Intellectual Property

We hold worldwide patents and patent applications covering peptide compositions, uses and formulations related to dermal and ophthalmic indications and other organ and tissue repair activities. In 2001, we entered into a license agreement with the NIH under which we received an exclusive worldwide license from the NIH for all claims within the scope of the NIH's patent application, and any issued patents, covering the use of Tß4 as a tissue repair and regeneration factor. In 2007, patents were issued in Europe and the United States related to the original NIH patent application. These patents expired in July 2019. Corresponding patents have also been granted in Hong Kong, Australia and China and certain other territories. The issued European patent was opposed by a third party at the European Patent Office and, in December 2009, we argued the case before the Opposition Division of the European Patent Office in Munich, Germany and prevailed with certain amendments to the claims. In exchange for the exclusive license, we agreed to make certain minimum royalty and milestone payments to the NIH. This license agreement expired with the last of the issued patents. The expiration of the patents and license has no impact on our current programs.

We hold a U.S. patent relating to the use of Tß4 for the treatment of congestive heart failure. This patent was issued in January 2012. In 2006, we were issued a patent in China for the use of Tß4 to treat EB. We also hold two patents for the treatment of dry eye in the U.S. or through our in-license from Henry Ford Hospital System patents for certain neuro disorders, as well as peripheral neuropathy. Other patent applications for our various product candidates, if issued, will offer protection in the U.S. and certain other territories through 2033.

We, and our partners, have also filed additional U.S. and international patent applications covering various compositions, uses, formulations and other components of Tß4, as well as for novel peptides resulting from our research efforts, the latest of which were filed during 2015. There can be no assurance that these, or any other future patent applications under which we have rights, will result in the issuance of a patent or that any patent issued will not be subject to challenge or opposition. In the case of a claim of patent infringement by or against us, there can be no assurance that we will be able to afford the expense of any litigation that may be necessary to enforce our proprietary rights or that relevant patents will not expire prior to approval of any of our product candidates.

We continuously evaluate our patents and patent applications in certain territories to determine whether it is cost-effective to continue to maintain or prosecute them. In some cases, we have determined that the value or potential value of such patents and/or applications is not worth the continued effort or expense and have either ceased efforts to pursue specific patents or abandoned any that have short expiries or cover countries of minimal strategic interest to us or our partners. We will continue to evaluate our portfolio and take such actions from time to time as appropriate.

Material Agreements

National Institutes of Health

We are party to a license agreement with NIH under which we are obligated to pay an annual minimum royalty of $2,000. In 2013, we amended certain provisions of the exclusive license; we were permitted to credit amounts paid to prosecute or maintain the licensed patent rights during 2013 calendar year against the 2013 minimum annual royalty. Beginning in 2014, the minimum annual royalty was $2,000. Additionally, we are obligated to pay the NIH a percentage of sales of qualifying product candidates, if any. There have been no such sales to date. Through December 31, 2019, we have complied with all minimum royalty requirements, and no milestone payments have been required under the agreement. The patent expired in July 2019.

Lee's Pharmaceuticals

On July 15, 2012, we entered into a license agreement with Lee's Pharmaceutical for the license of Tß4 in any pharmaceutical formulation, including our RGN-259, RGN-352 and RGN-137 product candidates, in China, Hong Kong, Macau and Taiwan. The terms of the agreement include aggregate potential milestone payments of up to $3.6 million and royalties ranging from low double digit to high single digit royalties on commercial sales, if any. Under the agreement, Lee's is responsible for all developmental costs associated with each product candidate. We provided Tß4 to Lee's at no charge for a Phase 2 ophthalmic clinical trial and will provide Tß4 to Lee's for all other developmental and clinical work at a price equal to our cost.

Lee's originally filed an investigational new drug application IND with the Chinese FDA to conduct a Phase 2, randomized, double-masked, dose-response clinical trial with RGN-259 in China for dry-eye syndrome. Lee's subsequently informed us that it received notice from China's FDA (CFDA) declining its investigational new drug (IND) application for a Phase 2b dry eye clinical trial because the API (active pharmaceutical ingredient or Tß4) was manufactured outside of China. The API was manufactured in the U.S. and provided to Lee's by RegeneRx pursuant to a license agreement to develop RGN-259 ophthalmic eye drops in the licensed territory. However, in mid-2016, we were informed by Lee's that the CFDA modified its manufacturing regulations and will now allow Chinese companies to utilize API manufactured outside of China for Phase 1 and 2 clinical trials. In February 2019, the agreement was amended and assigned by Lee's to their affiliate, Zhaoke Ophthalmology Pharmaceutical Limited. There are no economic changes to the agreement. Recently, we have been in discussions with management of Zhaoke to further refine its development plan for RGN-259. We have not yet been informed of a projected starting date for Phase 2 trials but we believe Lee's is awaiting the outcome of the ARISE-3 DES trial prior to initiating clinical trials in China.

GtreeBNT

On March 7, 2014, we entered into license agreements with GtreeBNT Co., Ltd. The two licensing agreements are for the license of territorial rights to two of our Thymosin Beta 4-based products candidates, RGN-259 and RGN-137.

Under the agreement for RGN-259, our preservative-free eye drop product candidate, GtreeBNT will have the right to develop and commercialize RGN-259 in Asia (excluding Greater China). The rights will be exclusive in Korea, Japan, Australia, New Zealand, Brunei, Cambodia, East Timor, Indonesia, Laos, Malaysia, Mongolia, Myanmar (Burma), Philippines, Singapore, Thailand, Vietnam, and Kazakhstan, and semi-exclusive in India, Pakistan, Bangladesh, Bhutan, Maldives, Nepal, Sri Lanka, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan, collectively, the Territory (the "259 Territory" or Pan Asia). Under the agreement for RGN-259 we are eligible to receive aggregate potential milestone payments of up to $3.5 million. In addition, we are eligible to receive royalties of a low double-digit percentage of any commercial sales of the licensed product sold by GtreeBNT in the 259 Territory.

Under the license agreement for RGN-137, our topical dermal gel product candidate, GtreeBNT will have the exclusive right to develop and commercialize RGN-137 in the U.S. (the "137 Territory"). Under the agreement for RGN-137 we are eligible to receive aggregate potential milestone payments of up to $3.5 million. In addition, we are eligible to receive royalties of a low double-digit percentage of any commercial sales of our licensed product sold by GtreeBNT in the 137 Territory. Under an amendment to the agreement for RGN-137, for which we were compensated, the 137 Territory was expanded to include Europe, Canada, South Korea, Australia and Japan.

Both the license agreement for RGN-137 and the license agreement for RGN-259 contain diligence provisions that require the initiation of certain clinical trials within certain time periods that, if not met, would result in the loss of rights or exclusivity in certain countries. GtreeBNT will pay for all developmental costs associated with each product candidate. We will also have the right to exclusively license any improvements made by GtreeBNT to our products outside of the licensed territory on a royalty-free basis.

The two firms have created a joint development committee and continue to discuss and the development of the licensed products and share information relating thereto. Both companies will also share all non-clinical and clinical data and other information related to the development of the licensed product candidates.

ReGenTree - U.S. Joint Venture

On January 28, 2015, we entered into the Joint Venture Agreement with GtreeBNT, a shareholder in the Company and licensee in certain Pan Asian countries. The Joint Venture Agreement provides for the creation of the Joint Venture, ReGenTree, LLC ("ReGenTree"), jointly owned by the Company and GtreeBNT that will commercialize RGN-259 for treatment of dry eye and neurotrophic keratitis in the United States, as well as any other relevant ophthalmic indications.

GtreeBNT is solely responsible for funding all of the product development and commercialization efforts of ReGenTree. GtreeBNT made an initial contribution of $3 million in cash and received an initial equity stake of 51%. RegeneRx received and initial equity stake of 49% of ReGenTree. GtreeBNT's equity stake may increase (and RegeneRx's would proportionally decrease) upon ReGenTree achieving certain product development milestones (including receipt of a new drug application ("NDA") by the U.S. FDA). GtreeBNT has subsequently funded the initial Phase 2b/3 and the ongoing Phase 3 U.S. clinical trials for dry eye syndrome and neurotrophic keratitis, respectively.

Our initial ownership interest in ReGenTree was 49% and was reduced to 38.5% after filing of the final clinical study report with the FDA for the Phase 3 trial for Dry Eye Syndrome completed in 2017. Based on when, and if, ReGenTree achieves certain additional development milestones in the U.S. with RGN-259, our equity ownership may be incrementally reduced to between 38.5% and 25%, with 25% being the final equity ownership upon FDA approval of an NDA for Dry Eye Syndrome in the U.S. In addition to our equity ownership, RegeneRx retains a royalty on net sales that varies between single and low double digits, depending on whether commercial sales are made by ReGenTree or a licensee. In the event the ReGenTree entity is acquired or there is a change of control that occurs following achievement of an NDA, RegeneRx shall be entitled to a minimum of 40% of all proceeds paid or payable and will forgo any future royalties.

The Company is not required or otherwise obligated to provide financial support to ReGenTree.

ReGenTree is controlled by a Board of Directors consisting of three members, one of which must be from RegeneRx. Certain critical matters require unanimous board approval, including merger, consolidation, or sale of the JV, transfer or licensing of any intellectual property, incurring indebtedness, and entering into any material agreements, among others.

ReGenTree is responsible for executing all development and commercialization activities under the Joint Venture Agreement, which activities will be directed by a joint development committee comprised of representatives of the Company and GtreeBNT. The agreement has a term that extends to the later of the expiration of the last patent covered by the agreement or 25 years from the first commercial sale under the agreement. The agreement may be earlier terminated if the Joint Venture fails to meet certain commercialization milestones, or if either party breaches the Joint Venture Agreement and fails to cure such breach, or as a result of government action that limits the ability of the Joint Venture to commercialize the product, as a result of a challenge to a licensed patent, following termination of the license between the Company and certain agencies of the United States federal government, or upon the bankruptcy of either party.

Development Agreements

While we are not currently directly engaged in development activities, historically we have entered into agreements with outside service providers for the manufacture and development of Tß4, the formulation of Tß4 into our product candidates, the conduct of nonclinical safety, toxicology and efficacy studies in animal models, and the management and execution of clinical trials in humans. Terms of these agreements vary in that they can last from a few months to more than a year in duration. For additional information regarding our research and development expenses over the past two years, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Results of Operations” in this report.

Employees

We currently have three full time employees including our President and CEO and one part time financial, accounting and SEC compliance consultant. We also retain three independent contractors. We believe that we have good relations with our employees and contractors.

Corporate Information

We were incorporated in Delaware in 1982 under the name Alpha 1 Biomedicals, Inc. In 2000, we changed our corporate name to RegeneRx Biopharmaceuticals, Inc. Our principal executive office is located at 15245 Shady Grove Road, Suite 470, Rockville, Maryland 20850. Our telephone number is (301) 208-9191.

Available Information

Our corporate website is www.regenerx.com. Our electronic filings with the U.S. Securities and Exchange Commission, or SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after we have electronically filed such information with, or furnished such information to, the SEC.

Item 1A. Risk Factors

Set forth below and elsewhere in this report and in other documents we file with the SEC are risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. The descriptions below include any material changes to and supersede the description of the risk factors affecting our business previously disclosed in “Part II, Item 1A. Risk Factors” of the Annual Report.

Risks Related to Our Liquidity and Need for Financing

Before giving effect to any potential additional sales of our securities, we estimate that our existing capital will only be sufficient to fund our operations through the third quarter of 2020.

Even though we sold the 2019 Notes in February and have received proceeds of $1,300,000 and received approximately $480,000, including approximately $240,000 in January 2020, from the exercise of the warrants, these proceeds are only projected to fund our operations at the current level through the third quarter of 2020, therefore we will need to secure additional operating capital to continue operations substantially beyond the third quarter of 2020. We continuously monitor our cash use as well as the clinical timelines. We will need to secure additional operating capital in 2020 and are evaluating options including the licensing of additional rights to commercialize our clinical products as well as raising capital through the capital markets, either of which could cause a reduction in the trading price of our common stock.

We will need substantial additional capital for the continued development of product candidates through marketing approval and for our longer-term future operations.

We anticipate that substantial new capital resources will be required to continue our longer-term product development efforts, including any and all follow-on trials that will result from our current clinical programs beyond those currently contemplated, and to scale up manufacturing processes for our product candidates. However, the actual amount of funds that we will need will be determined by many factors, some of which are beyond our control. These factors include, without limitation:

- the scope of our, or our partners', clinical trials, which is significantly influenced by the quality of clinical data achieved as trials are completed and the requirements established by regulatory authorities;
- the speed with which we, or our partners, complete our clinical trials, which depends on our ability to attract and enroll qualifying patients and the quality of the work performed by our clinical investigators and contract research organizations chosen to conduct the studies;
- the time required to prosecute, enforce and defend our intellectual property rights, which depends on evolving legal regimes and infringement claims that may arise between us and third parties;
- the ability to manufacture at scales sufficient to supply commercial quantities of any of our product candidates that receive regulatory approval, which may require levels of effort not currently anticipated; and
- the successful commercialization of our product candidates, which will depend on our, or our partners', ability to either create or partner with an effective commercialization organization and which could be delayed or prevented by the emergence of equal or more effective therapies.

Emerging biotechnology companies like us may raise capital through corporate collaborations and by licensing intellectual property rights to other biotechnology or pharmaceutical enterprises. We intend to pursue this strategy, but there can be no assurance that we will be able to enter into additional license agreements with respect to our intellectual property or product development programs on commercially reasonable terms, if at all. There are substantial challenges and risks that will make it difficult to successfully implement any of these alternatives. If we are successful in raising additional capital through such a license or collaboration, we may have to give up valuable rights to our intellectual property. In addition, the business priorities of a strategic partner may change over time, which creates the possibility that the interests of the strategic partner in developing our technology may diminish and could have a potentially material negative impact on the value of our interest in the licensed intellectual property or product candidates.

Further, if we raise additional funds by selling shares of our common stock or securities convertible into our common stock the ownership interest of our existing stockholders may be significantly diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock and may involve significant fees, interest expense, restrictive covenants or the granting of security interests in our assets.

Our failure to successfully address our short-term capital needs and our long-term liquidity requirements would have a material negative impact on our business, including the possibility of surrendering our rights to some technologies or product opportunities, delaying our clinical trials or ceasing our operations.

We have incurred losses since inception and expect to incur significant losses in the foreseeable future and may never become profitable.

We have not commercialized any product candidates to date and incurred net operating losses every year since our inception in 1982. We believe these losses will continue for the foreseeable future, and may increase, as we pursue our product development efforts related to Tß4. As of December 31, 2019, our accumulated deficit totaled approximately $107 million.

As we expand our research and development efforts and seek to obtain regulatory approval of our product candidates to make them commercially viable, we anticipate substantial and increasing operating losses. Our ability to generate revenues and to become profitable will depend largely on our ability, alone or through the efforts of third-party licensees and collaborators, to efficiently and successfully complete the development of our product candidates, obtain necessary regulatory approvals for commercialization, scale-up commercial quantity manufacturing capabilities either internally or through third-party suppliers, and market our product candidates. There can be no assurance that we will achieve any of these objectives or that we will ever become profitable or be able to maintain profitability. Even if we do achieve profitability, we cannot predict the level of such profitability. If we continue to sustain losses over an extended period of time and are not otherwise able to raise necessary funds to continue our development efforts and maintain our operations, we may be forced to cease operations.

Our common stock is quoted on the over-the-counter market, which subjects us to the SEC's penny stock rules and may decrease the liquidity of our common stock.

Our common stock is traded over-the-counter on the OTC Bulletin Board. Over-the-counter markets are generally considered to be less efficient than, and not as broad as, a stock exchange. There may be a limited market for our stock now that it is quoted on the OTC Bulletin Board, trading in our stock may become more difficult and our share price could decrease. Specifically, you may not be able to resell your shares of common stock at or above the price you paid for such shares or at all.

In addition, our ability to raise additional capital may be impaired because of the less liquid nature of the over-the-counter markets. While we cannot guarantee that we would be able to complete an equity financing on acceptable terms, or at all, we believe that dilution from any equity financing while our shares are quoted on an over-the-counter market would likely be substantially greater than if we were to complete a financing while our common stock is traded on a national securities exchange. Further, we are unable to use short-form registration statements on Form S-3 for the registration of our securities, which could impair our ability to raise additional capital as needed.

Our common stock is also subject to penny stock rules, which impose additional sales practice requirements on broker-dealers who sell our common stock. The SEC generally defines "penny stock" as an equity security that has a market price of less than $5.00 per share, subject to certain exceptions. The ability of broker-dealers to sell our common stock and the ability of our stockholders to sell their shares in the secondary market will be limited and, as a result, the market liquidity for our common stock will likely be adversely affected. We cannot assure you that trading in our securities will not be subject to these or other regulations in the future.

Further, recently some discount and major brokerage firms have implemented new rules regarding the deposit of penny stock shares into new or existing accounts where such stocks do not meet minimum price and volume requirements. Such rules may make it difficult or even prevent stockholders from timely selling their shares through such brokerage firms unless the shares meet such minimum requirements.

The report of our independent registered public accounting firm contains explanatory language that substantial doubt exists about our ability to continue as a going concern.

The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2019, contains explanatory language that substantial doubt exists about our ability to continue as a going concern, without raising additional capital. As described in this report, we will need to secure additional operating capital to continue operations beyond the third quarter of 2020. Therefore, we are seeking sources of capital, but if we are unable to obtain sufficient financing to support and complete these activities, then we would, in all likelihood, experience severe liquidity problems and may have to curtail our operations. If we curtail our operations, we may be placed into bankruptcy or undergo liquidation, the result of which will adversely affect the value of our common shares.

Risks Related to Our Business and Operations

Public health threats could have an adverse effect on our clinical trials and financial results.

Public health threats could adversely affect our ongoing or planned business operations. In particular, the novel coronavirus (COVID-19) has resulted in quarantines, restrictions on travel and other business and economic disruptions. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the partners and other third parties with whom we 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 adversely impacted.

Our planned Phase 2 clinical trial of RGN-352 was placed on clinical hold by the FDA in March 2011 due to non-compliance of cGMP regulations by a contract manufacturer and we are unsure when, if ever, we will be able to resume this trial.

In the second half of 2010, we implemented the development plans for our Phase 2 clinical trial to evaluate RGN-352 in patients who have suffered an acute myocardial infarction, or AMI. We had planned to begin enrolling patients near the end of the first quarter of 2011. However, in March 2011, we were notified by the FDA that the trial was placed on clinical hold as a result of our contract manufacturer's alleged failure to comply with current Good Manufacturing Practice ("cGMP") regulations. The FDA has prohibited us from using any of the active drug or placebo manufactured by this manufacturer in human trials, which will require us to identify a cGMP-compliant manufacturer and to have new material produced in the event that we seek to resume this trial. We learned that the contract manufacturer has closed its manufacturing facility and has filed for bankruptcy protection. Significant preparatory time and procedures will be required before any new suitable manufacturer would be able to manufacture RGN-352 for the AMI trial. Since we are unable to estimate the length of time that the trial will be on clinical hold, we have elected to cease activities on this trial until the FDA clinical hold is resolved and the requisite funding might be secured. Consequently, there can be no assurance that we will be able to timely initiate trial activities or complete this trial, if at all. As of the date of this report, we have received no new information on that status of this trial.

All of our drug candidates are based on a single compound.

Our current primary business focus is the development of Tß4, and its analogues, derivatives and fragments, for the regeneration and accelerated repair of damaged tissue from non-healing dermal and corneal wounds, cardiac injury, central/peripheral nervous system diseases and other conditions, as well as an improvement in various functions, such as, but not limited to, cardiac and neurological. Unlike many pharmaceutical companies that have a number of unique chemical entities in development, we are dependent on a single molecule, formulated for different routes of administration and different clinical indications, for our potential commercial success. As a result, any common safety or efficacy concerns for Tß4-based products that cross formulations would have a much greater impact on our business prospects than if our product pipeline were more diversified.

We may never be able to commercialize our product candidates.

Although Tß4 has shown biological activity in *in vitro* studies and *in vivo* animal models and while we observed clinical activity and efficacious outcomes in our recent RGN-259 Phase 2a trial and earlier Phase 2 dermal trials, we cannot assure you that our product candidates will exhibit activity or importance in humans in large-scale trials. Our drug candidates are still in research and development, and we do not expect them to be commercially available for the foreseeable future, if at all. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These include the possibility that the potential products may:

- be found ineffective or cause harmful side effects during preclinical studies or clinical trials;
- fail to receive necessary regulatory approvals;
- be precluded from commercialization by proprietary rights of third parties;
- be difficult to manufacture on a large scale; or
- be uneconomical or otherwise fail to achieve market acceptance.

If any of these potential problems occurs, we may never successfully market Tß4-based products.

We are subject to intense government regulation, and we may not receive regulatory approvals for our drug candidates.

Our product candidates will require regulatory approvals prior to sale. In particular, therapeutic agents are subject to stringent approval processes, prior to commercial marketing, by the FDA and by comparable agencies in most foreign countries. The process of obtaining FDA and corresponding foreign approvals is costly and time-consuming, and we cannot assure you that such approvals will be granted. Also, the regulations we are subject to change frequently and such changes could cause delays in the development of our product candidates.

Three of our drug candidates are currently in the clinical development stage, and we cannot be certain that we, or our partners, will successfully complete the clinical trials necessary to receive regulatory product approvals. The regulatory approval process is lengthy, unpredictable and expensive. To obtain regulatory approvals in the United States, we or a partner must ultimately demonstrate to the satisfaction of the FDA that our product candidates are sufficiently safe and effective for their proposed administration to humans. Many factors, known and unknown, can adversely impact clinical trials and the ability to evaluate a product candidate’s safety and efficacy, including:

- the FDA or other health regulatory authorities, or institutional review boards, or IRBs, do not approve a clinical trial protocol or place a clinical trial on hold;
- suitable patients do not enroll in a clinical trial in sufficient numbers or at the expected rate, for reasons such as the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the perceptions of investigators and patients regarding safety, and the availability of other treatment options;
- clinical trial data is adversely affected by trial conduct or patient withdrawal prior to completion of the trial;
- there may be competition with ongoing clinical trials and scheduling conflicts with participating clinicians;
- patients experience serious adverse events, including adverse side effects of our drug candidates, for a variety of reasons that may or may not be related to our product candidates, including the advanced stage of their disease and other medical problems;
- patients in the placebo or untreated control group exhibit greater than expected improvements or fewer than expected adverse events;
- third-party clinical investigators do not perform the clinical trials on the anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- service providers, collaborators or co-sponsors do not adequately perform their obligations in relation to the clinical trial or cause the trial to be delayed or terminated;

- we are unable to obtain a sufficient supply of manufactured clinical trial materials;
- regulatory inspections of manufacturing facilities, which may, among other things, require us or a co-sponsor to undertake corrective action or suspend the clinical trials, such as the clinical hold with respect to our Phase 2 clinical trial of RGN-352;
- the interim results of the clinical trial are inconclusive or negative;
- the clinical trial, although approved and completed, generates data that is not considered by the FDA or others to be clinically relevant or sufficient to demonstrate safety and efficacy; and
- changes in governmental regulations or administrative actions affect the conduct of the clinical trial or the interpretation of its results.

There can be no assurance that clinical trials sponsored by our partners will in fact demonstrate, to the satisfaction of the FDA and others, that our product candidates are sufficiently safe or effective. The FDA or we may also restrict or suspend our clinical trials at any time if it is believed that subjects participating in the trials are being exposed to unacceptable health risks.

Clinical trials for product candidates such as ours are often conducted with patients who have more advanced forms of a particular condition or other unrelated conditions. For example, in clinical trials for our product candidate RGN-137, we have studied patients who are not only suffering from chronic epidermal wounds but who are also older and much more likely to have other serious adverse conditions. During the course of treatment with our product candidates, patients could die or suffer other adverse events for reasons that may or may not be related to the drug candidate being tested. Further, and as a consequence that all of our drug candidates are based on Tß4, crossover risk exists such that a patient in one trial may be adversely impacted by one drug candidate, and that adverse event may have implications for our other trials and other drug candidates. However, even if unrelated to our product candidates, such adverse events can nevertheless negatively impact our clinical trials, and our business prospects would suffer.

These factors, many of which may be outside of our control, may have a negative impact on our business by making it difficult to advance product candidates or by reducing or eliminating their potential or perceived value. As a consequence, we may need to perform more or larger clinical trials than planned. Further, if we are forced to contribute greater financial and clinical resources to a study, valuable resources will be diverted from other areas of our business. If we fail to complete or if we experience material delays in completing our clinical trials as currently planned, or we otherwise fail to commence or complete, or experience delays in, any of our other present or planned clinical trials, including as a result of the actions of third parties upon which we rely for these functions, our ability to conduct our business as currently planned could materially suffer.

We may not successfully establish and maintain development and testing relationships with third-party service providers and collaborators, which could adversely affect our ability to develop our product candidates.

We have only limited resources, experience with and capacity to conduct requisite testing and clinical trials of our drug candidates. As a result, we rely and expect to continue to rely on third-party service providers and collaborators, including corporate partners, licensors and contract research organizations, or CROs, to perform a number of activities relating to the development of our drug candidates, including the design and conduct of clinical trials, and potentially the obtaining of regulatory approvals. For example, we currently rely on several third-party contractors to manufacture and formulate Tß4 into the product candidates used in our clinical trials, develop assays to assess Tß4's effectiveness in complex biological systems, recruit clinical investigators and sites to participate in our trials, manage the clinical trial process and collect, evaluate and report clinical results.

We may not be able to maintain or expand our current arrangements with these third parties or maintain such relationships on favorable terms. Our agreements with these third parties may also contain provisions that restrict our ability to develop and test our product candidates or that give third parties rights to control aspects of our product development and clinical programs. In addition, conflicts may arise with our collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any conflicts arise with our existing or future collaborators, they may act in their self-interest, which may be adverse to our best interests. Any failure to maintain our collaborative agreements and any conflicts with our collaborators could delay or prevent us from developing our product candidates. We and our collaborators may fail to develop products covered by our present and future collaborations if, among other things:

- we or our partners do not achieve our objectives under our collaboration agreements;
- we or our partners are unable to obtain patent protection for the products or proprietary technologies we develop in our partnerships;
- we are unable to manage multiple simultaneous product development partnerships;
- our partners become competitors of ours or enter into agreements with our competitors;
- we or our partners encounter regulatory hurdles that prevent commercialization of our product candidates; or
- we develop products and processes or enter into additional partnerships that conflict with the business objectives of our other partners.

We also have less control over the timing and other aspects of our clinical trials than if we conducted the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol or applicable regulations. We, and our partners, also rely on clinical research organizations to perform much of our data management and analysis. They may not provide these services as required or in a timely manner. If any of these parties do not meet deadlines or follow proper procedures, including procedures required by law, the preclinical studies and clinical trials may take longer than expected, may be delayed or may be terminated, which would have a materially negative impact on our product development efforts. If we were forced to find a replacement entity to perform any of our preclinical studies or clinical trials, we may not be able to find a suitable entity on favorable terms or at all. Even if we were able to find a replacement, resulting delays in the tests or trials may result in significant additional expenditures and delays in obtaining regulatory approval for drug candidates, which could have a material adverse impact on our results of operations and business prospects.

GtreeBNT Co., Ltd. has limited drug development experience.

We are a party to several license agreements and a Joint Venture with GtreeBNT. Historically, GtreeBNT's business focus has been in the IT software industry in Korea with strong IP positions addressing specific software tools and apps such as optimized multimedia software for smart phones. GtreeBNT made a strategic decision in November 2013 to expand into the biopharmaceutical business through selected strategic alliances with biopharmaceutical companies in the U.S. and EU. The collaboration with RegeneRx is the first strategic investment in this initiative. While GtreeBNT has hired executives and staff with significant pharmaceutical experience, the company has no internal drug development experience. As a result, GtreeBNT may face more and different challenges in the development of these product candidates than would more established pharmaceutical companies.

GtreeBNT Co., Ltd. has limited financial resources.

GtreeBNT has informed us that they have limited financial resources. They have to continuously raise capital to fund research, development, clinical trials, and operations. Therefore, their ability to finance each of these areas is subject to its ability to secured adequate capital. While GtreeBNT has been able to finance each of these areas, to date, there is no assurance that they will be able to do so in the future. If GtreeBNT is unable to secure necessary financing to fund clinical trials or operations, it could have a material adverse impact on RGN-137 and RGN-259 and our ability to continue funding operations while these products are under development.

We are subject to intense competition from companies with greater resources and more mature products, which may result in our competitors developing or commercializing products before or more successfully than we do.

We are engaged in a business that is highly competitive. Research and development activities for the development of drugs to treat indications within our focus are being sponsored or conducted by private and public research institutions and by major pharmaceutical companies located in the United States and a number of foreign countries. Most of these companies and institutions have financial and human resources that are substantially greater than our own and they have extensive experience in conducting research and development activities and clinical trials and in obtaining the regulatory approvals necessary to market pharmaceutical products that we do not have. As a result, they may develop competing products more rapidly that are safer, more effective, or have fewer side effects, or are less expensive, or they may develop and commercialize products that render our product candidates non-competitive or obsolete.

With respect to our product candidate RGN-259, there are also numerous ophthalmic companies developing drugs for corneal wound healing and other front-of-the-eye diseases and injuries, including dry eye syndrome. Amniotic membranes have been successfully used to treat corneal wounds in certain cases, as have topical steroids and antibacterial agents. Most specialty ophthalmic companies have a number of products on the market that could compete with RGN-259. There are numerous antibiotics to treat eye infections to promote corneal wound healing and many eye lubrication products that are soothing to the eye and help eye healing, many of which are sold without prescriptions. Companies also market steroids to treat certain conditions within our area of interest. Allergan, Inc. markets Restasis™, Ophthalmic Emulsion, which was the only commercially available and FDA-approved eye drop to treat dry eye. Shire PLC recently received FDA approval to market Xiidra™ for the treatment of dry eye and has launched the product in the U.S. Restasis, and other products, have been approved for marketing in certain other countries where we have licensed RGN-259.

We have targeted our product candidate RGN-352 for cardiovascular and neurovascular indications. Most large pharmaceutical companies and many smaller biomedical companies are vigorously pursuing the development of therapeutics to treat patients after heart attacks or brain trauma and for other related indications.

With respect to our product candidate RGN-137 for wound healing, Johnson & Johnson has previously marketed Regranex™ for this purpose in patients with diabetic foot ulcers. Other companies, such as Novartis, are developing and marketing artificial skins, which we believe could also compete with RGN-137. Other companies are developing genetic therapies to treat wound healing of the skin and internal organs. Wound healing is a large and highly fragmented marketplace attracting many companies, large and small, to develop products for treating acute and chronic wounds, including, for example, honey-based ointments, hyperbaric oxygen therapy, and low frequency cavitational ultrasound.

We are also interested in developing potential cosmeceutical products, which are loosely defined as products that bridge the gap between cosmetics and pharmaceuticals, for example, by improving skin texture and reducing the appearance of aging. This industry is intensely competitive, with potential competitors ranging from large multinational companies to very small specialty companies. New cosmeceutical products often have a short product life and are frequently replaced with newer products developed to address the latest trends in appearance and fashion. We may not be able to adapt to changes in the industry as quickly as larger and more experienced cosmeceutical companies. Further, larger cosmetics companies have the financial and marketing resources to effectively compete with smaller companies like us in order to sell products aimed at larger markets.

Even if approved for marketing, our technologies and product candidates are unproven, and they may fail to gain market acceptance.

Our product candidates, all of which are based on the molecule Tß4, are new and unproven and there is no guarantee that health care providers or patients will be interested in our product candidates, even if they are approved for use. If any of our product candidates are approved by the FDA, our success will depend in part on our ability to demonstrate sufficient clinical benefits, reliability, safety, and cost effectiveness of our, or our partners', product candidates relative to other approaches, as well as on our ability to continue to develop our product candidates to respond to competitive and technological changes. If the market does not accept our product candidates, when and if we are able to commercialize them, then we may never become profitable. Factors that could delay, inhibit or prevent market acceptance of our product candidates may include:

- the timing and receipt of marketing approvals;
- the safety and efficacy of the products;
- the emergence of equivalent or superior products;
- the cost-effectiveness of the products; and
- ineffective marketing.

It is difficult to predict the future growth of our business, if any, and the size of the market for our product candidates because the markets are continually evolving. There can be no assurance that our product candidates will prove superior to products that may currently be available or may become available in the future or that our research and development activities will result in any commercially profitable products.

We have no marketing experience, sales force or distribution capabilities. If our product candidates are approved, and we are unable to recruit key personnel to perform these functions, we may not be able to commercialize them successfully.

Although we do not currently have any marketable products, our ability to produce revenues ultimately depends on our, or our partners', ability to sell our product candidates if and when they are approved by the FDA and other regulatory authorities. We currently have no experience in marketing or selling pharmaceutical products, and we do not have a marketing and sales staff or distribution capabilities. Developing a marketing and sales force is also time-consuming and could delay the launch of new products or expansion of existing product sales. In addition, we will compete with many companies that currently have extensive and well-funded marketing and sales operations. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, our ability to generate revenues will suffer.

If we enter markets outside the United States our business will be subject to political, economic, legal and social risks in those markets, which could adversely affect our business.

There are significant regulatory and legal barriers to entering markets outside the United States that must be overcome if we, or our partners, seek regulatory approval to market our product candidates in countries other than the United States. We would be subject to the burden of complying with a wide variety of national and local laws, including multiple and possibly overlapping and conflicting laws. We also may experience difficulties adapting to new cultures, business customs and legal systems. Any sales and operations outside the United States would be subject to political, economic and social uncertainties including, among others:

- changes and limits in import and export controls;
- increases in custom duties and tariffs;
- changes in currency exchange rates;
- economic and political instability;
- changes in government regulations and laws;
- absence in some jurisdictions of effective laws to protect our intellectual property rights; and
- currency transfer and other restrictions and regulations that may limit our ability to sell certain product candidates or repatriate profits to the United States.

Any changes related to these and other factors could adversely affect our business if and to the extent we enter markets outside the United States. Additionally, we have entered into license agreements with Lee's Pharmaceutical Limited and GtreeBNT Co, Ltd. for the development of certain of our product candidates in international markets. As a result, these development activities will be subject to compliance in all respects with local laws and regulations and may be subject to many of the risks described above.

Governmental and third-party payors may subject any product candidates we develop to sales and pharmaceutical pricing controls that could limit our product revenues and delay profitability.

The successful commercialization of our product candidates, if they are approved by the FDA, will likely depend on our ability to obtain reimbursement for the cost of the product and treatment. Government authorities, private health insurers and other organizations, such as health maintenance organizations, are increasingly seeking to lower the prices charged for medical products and services. Also, the trend toward managed health care in the United States, the growth of healthcare maintenance organizations, and recently enacted legislation reforming healthcare and proposals to reform government insurance programs could have a significant influence on the purchase of healthcare services and products, resulting in lower prices and reducing demand for our product candidates. The cost containment measures that healthcare providers are instituting, and any healthcare reform could reduce our ability to sell our product candidates and may have a material adverse effect on our operations. We cannot assure you that reimbursement in the United States or foreign countries will be available for any of our product candidates, and that any reimbursement granted will be maintained, or that limits on reimbursement available from third-party payors will not reduce the demand for, or the price of, our product candidates. The lack or inadequacy of third-party reimbursements for our product candidates would decrease the potential profitability of our operations. We cannot forecast what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect the legislation or regulation would have on our business.

We have no manufacturing or formulation capabilities and are dependent upon third-party suppliers to provide us with our product candidates. If these suppliers do not manufacture our product candidates in sufficient quantities, at acceptable quality levels and at acceptable cost, or if we are unable to identify suitable replacement suppliers if needed, our clinical development efforts could be delayed, prevented or impaired.

We do not own or operate manufacturing facilities and have little experience in manufacturing pharmaceutical products. We currently rely, and expect to continue to rely, primarily on peptide manufacturers to supply us with Tß4 for further formulation into our product candidates. We have historically engaged three separate smaller drug formulation contractors for the formulation of clinical grade product candidates, one for each of our three product candidates in clinical development, although, as described in this report, the contractor we engaged to formulate and vial RGN-352 has filed for bankruptcy and closed its manufacturing facility, and our clinical trial involving RGN-352 has been placed on clinical hold. We currently do not have an alternative source of supply for either Tß4 or the individual drug candidates. If these suppliers, together or individually, are not able to supply us with either Tß4 or individual product candidates on a timely basis, in sufficient quantities, at acceptable levels of quality and at a competitive price, or if we are unable to identify a replacement manufacturer to perform these functions on acceptable terms as needed, our development programs could be seriously jeopardized.

The clinical hold on our RGN-352 trial will require us to have new material manufactured by a cGMP-compliant manufacturer in the event that we seek to resume this trial. Significant preparatory time and procedures will be required before any new manufacturer would be able to manufacture RGN-352 for the AMI trial, due to the time required for revalidation of processes and assays related to such production that were already in place with the original manufacturer. Since we are unable to estimate the length of time that the trial will be on clinical hold, we have elected to cease activities on this trial until the FDA clinical hold is resolved and the requisite funding might be secured.

Other risks of relying solely on single suppliers for each of our product candidates include:

- the possibility that our other manufacturers, and any new manufacturer that we, or our partners, may identify for RGN-352, may not be able to ensure quality and compliance with regulations relating to the manufacture of pharmaceuticals;
- their manufacturing capacity may not be sufficient or available to produce the required quantities of our product candidates based on our planned clinical development schedule, if at all;
- they may not have access to the capital necessary to expand their manufacturing facilities in response to our needs;
- commissioning replacement suppliers would be difficult and time-consuming;
- individual suppliers may have used substantial proprietary know-how relating to the manufacture of our product candidates and, in the event we must find a replacement or supplemental supplier, our ability to transfer this know-how to the new supplier could be an expensive and/or time-consuming process;
- an individual supplier may experience events, such as a fire or natural disaster, that force it to stop or curtail production for an extended period;
- an individual supplier could encounter significant increases in labor, capital or other costs that would make it difficult for them to produce our products cost-effectively; or
- an individual supplier may not be able to obtain the raw materials or validated drug containers in sufficient quantities, at acceptable costs or in sufficient time to complete the manufacture, formulation and delivery of our product candidates.

Our suppliers may use hazardous and biological materials in their businesses. Any claims relating to improper handling, storage or disposal of these materials could be time-consuming and costly to us, and we are not insured against such claims.

Our product candidates and processes involve the controlled storage, use and disposal by our suppliers of certain hazardous and biological materials and waste products. We and our suppliers and other collaborators are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Even if we and these suppliers and collaborators comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and we do not carry insurance for this type of claim. We may also incur significant costs to comply with current or future environmental laws and regulations.

We face the risk of product liability claims, which could adversely affect our business and financial condition.

We, or our partners, may be subject to product liability claims as a result of our testing, manufacturing, and marketing of drugs. In addition, the use of our product candidates, when and if developed and sold, will expose us to the risk of product liability claims. Product liability may result from harm to patients using our product candidates, such as a complication that was either not communicated as a potential side effect or was more extreme than anticipated. We require all patients enrolled in our clinical trials to sign consents, which explain various risks involved with participating in the trial. However, patient consents provide only a limited level of protection, and it may be alleged that the consent did not address or did not adequately address a risk that the patient suffered. Additionally, we will generally be required to indemnify our clinical product manufacturers, clinical trial centers, medical professionals and other parties conducting related activities in connection with losses they may incur through their involvement in the clinical trials.

Our ability to reduce our liability exposure for human clinical trials and commercial sales, if any, of Tß4 is dependent in part on our ability to obtain sufficient product liability insurance or to collaborate with third parties that have adequate insurance. Although we intend to obtain and maintain product liability insurance coverage if we gain approval to market any of our product candidates, we cannot guarantee that product liability insurance will continue to be available to us on acceptable terms, or at all, or that its coverage will be sufficient to cover all claims against us. A product liability claim, even one without merit or for which we have substantial coverage, could result in significant legal defense costs, thereby potentially exposing us to expenses significantly in excess of our revenues, as well as harm to our reputation and distraction of our management.

If any of our key employees discontinue their services with us, our efforts to develop our business may be delayed.

We are highly dependent on the principal members of our management team. The loss of our chairman and Chief Scientific Officer, Allan Goldstein, or chief executive officer, J.J. Finkelstein could prevent or significantly delay the achievement of our goals. We cannot assure you that Dr. Goldstein or Mr. Finkelstein, or any other key employees or consultants, will not elect to terminate their employment or consulting arrangements. In addition, we do not maintain a key man life insurance policy with respect to any of our management personnel. In the future, we anticipate that we will also need to add additional management and other personnel. Competition for qualified personnel in our industry is intense, and our success will depend in part on our ability to attract and retain highly skilled personnel. We cannot assure you that our efforts to attract or retain such personnel will be successful.

Mauro Bove, a member of our Board is a consultant to Lee's Pharmaceuticals, a relationship which could give rise to a conflict of interest for Mr. Bove.

Mauro Bove is a member of our Board of Directors and currently provides consulting services to Lee's Pharmaceuticals Group in Hong Kong. There can be no assurance that we will ever receive any further payments from Lee's under the current agreement established between RegeneRx and Lee's. As a result of Mr. Bove's relationship with Lee's, Mr. Bove may have interests that are different from our other stockholders in connection with our agreement with Lee's and circumstances may arise that require the exercise of the Board's discretion with respect to Lee's that require the exclusion of Mr. Bove.

Risks Related To Our Intellectual Property

We may not be able to maintain broad patent protection for our product candidates, which could limit the commercial potential of our product candidates.

Our success will depend in part on our, or our partners' ability to obtain, defend and enforce patents, both in the United States and abroad. We have attempted to create a substantial intellectual property portfolio, submitting patent applications for various compositions of matter, methods of use and fragments and derivatives of Tß4. As described elsewhere in this report, we currently do not have adequate financial resources to fund our ongoing business activities beyond the third quarter of 2020 without additional funding. Thus, we continuously evaluate our issued patents and patent applications and may decide to limit their therapeutic and/or geographic coverage in an effort to enhance our ability to focus on certain medical conditions and countries within our financial constraints. As a result, we may not be able to protect our intellectual property rights in indications and/or territories that we otherwise would, and, therefore, our ability to commercialize Tß4, if at all, could be substantially limited, which could have a material adverse impact on our future results of operations.

Our patents may expire before any of our product candidates reach commercialization.

Our success will depend in part on our, or our partners' patents to provide market exclusivity for our product candidates. We have numerous patent and patent applications in the U.S. and abroad, however, some of our patents are reaching the end of their 20-year patent exclusivity and, therefore, may expire prior to developing any marketable products or expire shortly after product launch, which could negatively affect our commercial success.

If we, or our partners, are not able to maintain adequate patent protection for our product candidates, we may be unable to prevent our competitors from using our technology or technology that we license.

Our success will depend in substantial part on our, or our partners', abilities to obtain, defend and enforce patents, maintain trade secrets and operate without infringing upon the proprietary rights of others, both in the United States and abroad. While patents covering our use of Tß4 have issued in some countries, we cannot guarantee whether or when corresponding patents will be issued, or the scope of any patents that may be issued, in other countries. We have attempted to create a substantial intellectual property portfolio, submitting patent applications for various compositions of matter, methods of use and fragments and derivatives of Tß4. We have also in-licensed other intellectual property rights from third parties that could be subject to the same risks as our own patents. If any of these patent applications do not issue, or do not issue in certain countries, or are not enforceable, the ability to commercialize Tß4 in various medical indications could be substantially limited or eliminated.

In addition, the patent positions of the products being developed by us and our collaborators involve complex legal and factual uncertainties. As a result, we cannot assure you that any patent applications filed by us, or by others under which we have rights, will result in patents being issued in the United States or foreign countries. In addition, there can be no assurance that any patents will be issued from any pending or future patent applications of ours or our partners, that the scope of any patent protection will be sufficient to provide us with competitive advantages, that any patents obtained by us or our partners will be held valid if subsequently challenged or that others will not claim rights in or ownership of the patents and other proprietary rights we or our partners may hold. Unauthorized parties may try to copy aspects of our product candidates and technologies or obtain and use information we consider proprietary. Policing the unauthorized use of our proprietary rights is difficult. We cannot guarantee that no harm or threat will be made to our or our partners' intellectual property. In addition, changes in, or different interpretations of, patent laws in the United States and other countries may also adversely affect the scope of our patent protection and our competitive situation.

Due to the significant time lag between the filing of patent applications and the publication of such patents, we cannot be certain that our licensors were the first to file the patent applications we license or, even if they were the first to file, also were the first to invent, particularly with regards to patent rights in the United States. In addition, a number of pharmaceutical and biotechnology companies and research and academic institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to our product candidates. Some of these technologies, applications or patents may conflict with our or our licensors' technologies or patent applications. A conflict could limit the scope of the patents, if any, that we or our licensors may be able to obtain or result in denial of our or our licensors' patent applications. If patents that cover our activities are issued to other companies, we may not be able to develop or obtain alternative technology.

Additionally, there is certain subject matter that is patentable in the United States but not generally patentable outside of the United States. Differences in what constitutes patentable subject matter in various countries may limit the protection we can obtain outside of the United States. For example, methods of treating humans are not patentable in many countries outside of the United States. These and other issues may prevent us from obtaining patent protection outside of the United States, which would have a material adverse effect on our business, financial condition and results of operations.

Changes to U.S. patent laws could materially reduce any value our patent portfolio may have.

The value of our patents depends in part on their duration. A shorter period of patent protection could lessen the value of our rights under any patents that may be obtained and may decrease revenues derived from its patents. For example, the U.S. patent laws were previously amended to change the term of patent protection from 17 years following patent issuance to 20 years from the earliest effective filing date of the application. Because the time from filing to issuance of biotechnology applications may be more than three years depending on the subject matter, a 20-year patent term from the filing date may result in substantially shorter patent protection. Moreover, a divisional patent that is filed after a parent patent, if granted, would begin its term beginning when the parent patent was initially filed, thus having an impact on the divisional patent's practical patent life, Future changes to patent laws could shorten our period of patent exclusivity and may decrease the revenues that we might derive from the patents and the value of our patent portfolio.

We, or our partners, may not have adequate protection for our unpatented proprietary information, which could adversely affect our competitive position.

In addition to our patents, we, and our partners, also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. However, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. To protect our trade secrets, we may enter into confidentiality agreements with employees, consultants and potential collaborators. However, we may not have such agreements in place with all such parties and, where we do, these agreements may not provide meaningful protection of our trade secrets or adequate remedies in the event of unauthorized use or disclosure of such information. Also, our trade secrets or know-how may become known through other means or be independently discovered by our competitors. Any of these events could prevent us from developing or commercializing our product candidates.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets of former employers.

As is commonplace in the biotechnology industry, we employ now, and may hire in the future, individuals who were previously employed at other biotechnology or pharmaceutical companies, including competitors or potential competitors. Although there are no claims currently pending against us, we may be subject to claims that we or certain employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and would be a significant distraction to management.

Risks Related To Our Securities

Our common stock price is volatile, our stock is highly illiquid, and any investment in our securities could decline substantially in value.

For the period from January 1, 2019 through March 10, 2020 the closing price of our common stock has ranged from $0.09 to $0.35, with an average daily trading volume of approximately 50,000 shares. In light of our small size and limited resources, as well as the uncertainties and risks that can affect our business and industry, our stock price is expected to continue to be highly volatile and can be subject to substantial drops, with or even in the absence of news affecting our business. The following factors, in addition to the other risk factors described in this report, and the potentially low volume of trades in our common stock since it is not listed on a national securities exchange, may have a significant impact on the market price of our common stock, some of which are beyond our control:

- results of pre-clinical studies and clinical trials;
- commercial success of approved products;
- corporate partnerships;
- technological innovations by us or competitors;
- changes in laws and government regulations both in the U.S. and overseas;
- changes in key personnel at our company;
- developments concerning proprietary rights, including patents and litigation matters;
- public perception relating to the commercial value or safety of any of our product candidates;
- other issuances of our common stock, or securities convertible into or exercisable for our common stock, causing dilution;
- anticipated or unanticipated changes in our financial performance;
- general trends related to the biopharmaceutical and biotechnological industries; and
- general conditions in the stock market.

The stock market in general has recently experienced relatively large price and volume fluctuations. In particular, the market prices of securities of smaller biotechnology companies have experienced dramatic fluctuations that often have been unrelated or disproportionate to the operating results of these companies. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in its value. You should also be aware that price volatility may be worse if the trading volume of the common stock remains limited or declines.

Our principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

Our officers, directors and principal stockholders together control approximately 48% of our outstanding common stock. Included in this group are previous stockholders of Sigma-Tau and their affiliates, which now have consolidated their holding into Essetifin S.p.A. which holds outstanding shares representing approximately 26.2% of our outstanding common stock and GtreeBNT which owns approximately 14.7% of our outstanding common stock. These stockholders also hold options, warrants, convertible promissory notes and stock purchase rights that provide them with the right to acquire significantly more shares of common stock. Accordingly, if these stockholders acted together, they could control the outcome of all stockholder votes. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock, and therefore may not be in the best interest of our other stockholders.

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

The trading market for our common stock and other securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have research coverage by one securities and industry analysts, and from time to time other independent analysts. If securities or industry analysts do not commence or maintain coverage of us, the trading price for our common stock and other securities would be negatively affected. In the event one or more of the analysts who covers us downgrades our securities, the price of our securities would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our securities could decrease, which could cause the price of our common stock and other securities and their trading volume to decline.

The exercise of options and warrants, conversion of convertible promissory notes, and other issuances of shares of common stock or securities convertible into common stock will dilute your interest.

As of December 31, 2019, there were outstanding options to purchase an aggregate of 9,821,250 shares of our common stock under our 2010 and 2018 incentive equity plans at exercise prices ranging from $0.16 per share to $0.64 per share and outstanding warrants to purchase 10,420,594 shares of our common stock at a weighted average exercise price of $0.17 per share. In February 2019 we sold a series of convertible promissory notes that will initially be convertible at $0.12 into 10,833,333 shares and also issued warrants to purchase 8,125,000 shares with an exercise price of $0.18 per share. In March 2018 we entered into a warrant reprice and exercise and issuance agreement (the “Reprice Agreement”) with the holders of the warrants issued in June 2016. Under the terms of the Reprice Agreement, in consideration of the holders exercising in full all of the 2016 Offering warrants the exercise price per share of 5,147,059 warrants was reduced to $0.20 per share. As further consideration, we issued to the holders of the 2016 Offering warrants 3,860,294 new warrants with an exercise price of $0.2301 per share. Pursuant to the terms of the Reprice Agreement the exercise of the new warrants has been reduced to $0.125 as a result of the February 2019 convertible note sale. In addition to the notes, options and warrants described above, we had previously issued five series of convertible promissory notes of which one remained outstanding. In January 2014, we sold a series of convertible promissory notes, which notes totaled $55,000 and are initially convertible into 916,667 shares of common stock at a conversion price of $0.06 per share. The notes matured in January 2019 and, along with the accrued interest were converted into common stock. The exercise of options and warrants or note conversions at prices below the market price of our common stock could adversely affect the price of shares of our common stock. Additional dilution may result from the issuance of shares of our capital stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

Any issuance of our common stock that is not made solely to then-existing stockholders proportionate to their interests, such as in the case of a stock dividend or stock split, will result in dilution to each stockholder by reducing his, her or its percentage ownership of the total outstanding shares. Moreover, if we issue options or warrants to purchase our common stock in the future and those options or warrants are exercised or we issue restricted stock, stockholders may experience further dilution. Holders of shares of our common stock have no preemptive rights that entitle them to purchase their pro rata share of any offering of shares of any class or series.

Our certificate of incorporation and Delaware law contain provisions that could discourage or prevent a takeover or other change in control, even if such a transaction would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation provides our Board with the power to issue shares of preferred stock without stockholder approval. In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Subject to specified exceptions, this section provides that a corporation may not engage in any business combination with any interested stockholder, as defined in that statute, during the three-year period following the time that such stockholder becomes an interested stockholder. This provision could also have the effect of delaying or preventing a change of control of our company. The foregoing factors could reduce the price that investors or an acquirer might be willing to pay in the future for shares of our common stock.

We may become involved in securities class action litigation that could divert management's attention and harm our business and our insurance coverage may not be sufficient to cover all costs and damages.

The stock market has from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical and biotechnology companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. If we experience this sort of volatility, we may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could hurt our business, operating results and financial condition.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Securities.

Our common stock is quoted on the OTC Bulletin Board under the symbol "RGRX." Our common stock last traded at $0.19 on March 10, 2020.

The following table sets forth the high and low closing prices for our common stock, as reported by the OTC Bulletin Board, for the periods indicated. The quotations reported by the OTC Bulletin Board reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

	2019		2018	
	High	Low	High	Low
First Quarter	$ 0.35	$ 0.10	$ 0.29	$ 0.20
Second Quarter	$ 0.24	$ 0.17	$ 0.24	$ 0.19
Third Quarter	$ 0.18	$ 0.13	$ 0.22	$ 0.16
Fourth Quarter	$ 0.18	$ 0.13	$ 0.20	$ 0.09

We have never declared or paid a cash dividend on our common stock and since all of our funds are committed to clinical research, we do not anticipate that any cash dividends will be paid on our common stock in the foreseeable future.

In February 27, 2019 we sold a series of convertible promissory notes to accredited investors including Essetifin S.p.A., our largest stockholder (the "2019 Notes"). The sale of in the 2019 Notes resulted in gross proceeds to the Company of $1,300,000 over two closings. The first closing in the amount of $650,000 occurred in February 2019 and the second closing, also in the amount of $650,000, occurred on May 13, 2019, after the Company provided notice of the enrollment of the first patent in the ARISE-3 clinical trial in patients with dry eye syndrome ("DES") sponsored by ReGenTree. The 2019 Notes contain a $0.12 conversion price and are initially convertible into 10,833,333 shares of common stock. The purchasers also received a warrant exercisable at $0.18 to purchase additional 8,125,000 shares of common stock.

In January 2019, at note maturity, the holders of the January 2014 Notes elected to convert the note principal and accrued interest into shares of common stock. As a result, the Company issued 1,149,016 shares of common stock.

In September 2018, at note maturity, the holders of the September 2013 Notes elected to convert the note principal and accrued interest into shares of common stock. As a result, the Company issued 6,706,076 shares of common stock.

In July 2018, at note maturity, the holders of the July 2013 Notes elected to convert the note principal and accrued interest into shares of common stock. As a result, the Company issued 2,089,120 shares of common stock.

In March 2018, at note maturity, the holders of the March 2013 Notes elected to convert the note principal and accrued interest into shares of common stock. As a result, the Company issued 4,700,520 shares of common stock.

On March 2, 2018 we entered into a warrant reprice and exercise and issuance agreement with the holders of the warrants issued in June 2016. Under the terms of the Reprice Agreement, in consideration of the holders exercising in full all of the 2016 Offering warrants the exercise price per share of 5,147,059 warrants was reduced to $0.20 per share. As further consideration, we issued to the holders of the 2016 Offering warrants 3,860,294 new warrants with an exercise price of $0.2301 per share. Pursuant to the terms of the Reprice Agreement the exercise price of the new warrants will be reduced from $0.2301 to $0.125 as a result of the February 2019 note sale.

In October 2017, at note maturity, the holders of the 2012 Convertible Notes elected to convert the note principal and accrued interest into shares of common stock. The note holders also elected to exercise the warrants issued with the 2012 Convertible Notes. As a result, the Company issued 2,906,944 shares of common stock.

Item 6. Selected Financial Data.

Not Applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation.

You should read the following discussion and analysis together with our financial statements and the related notes included elsewhere in this annual report.

Business Overview

We are a biopharmaceutical company focused on the development of a novel therapeutic peptide, Thymosin beta 4, or Tß4, for tissue and organ protection, repair, and regeneration. We have formulated Tß4 into three distinct product candidates in clinical development:

· RGN-259, a preservative-free topical eye drop for regeneration of corneal tissues damaged by injury, disease or other pathology;

· RGN-352, an injectable formulation to treat cardiovascular diseases, central and peripheral nervous system diseases, and other medical indications that may be treated by systemic administration; and

· RGN-137, a topical gel for dermal wounds and reduction of scar tissue.

We are continuing strategic partnership discussions with biotechnology and pharmaceutical companies regarding the further clinical development of all of our product candidates.

Current Financial Circumstances

In February 2019, we sold a series of convertible promissory notes to management, the Company's Board of Directors and accredited investors including Essetifin S.p.A., our largest stockholder (the "2019 Notes"). The sale of the 2019 Notes resulted in gross proceeds to the Company of $1,300,000 over two closings. The first closing in the amount of $650,000 occurred in February 2019 and the second closing, also in the amount of $650,000, occurred on May 13, 2019 after the Company provided notice of the enrollment of the first patent in the ARISE-3 clinical trial in DES sponsored by ReGenTree. The 2019 Notes contain a $0.12 conversion price and the purchasers also received a warrant exercisable at $0.18 to purchase additional shares of common stock equal to 75% of the number of shares into which each note is initially convertible (the "2019 Warrants"). In addition, we received proceeds of $115,625 pursuant to the exercise of warrants held by Sabby Management as well as $125,000 for April 2019 warrant exercises. In January 2020, Sabby exercised their remaining warrants and the Company received proceeds of $241,912. At present, with the receipt of the sale proceeds from the closing on the 2019 Notes and proceeds from the March and April 2019 and January 2020 warrant exercises, we will have sufficient cash to fund planned operations through the third quarter of 2020.

Current Clinical Status

In January 2015, we entered into a Joint Venture Agreement with GtreeBNT whereby we created ReGenTree LLC ("ReGenTree" or "Joint Venture") jointly owned by us and GtreeBNT, which will commercialize RGN-259 for treatment of dry eye syndrome and neurotrophic keratitis, an orphan indication in the United States.

To date ReGenTree has sponsored a Phase 2/3 clinical trial ("ARISE-1") and Phase 3 clinical trials in patients with DES ("ARISE-2"). Currently, it is sponsoring a Phase 3 clinical trial in patients with neurotrophic keratitis ("NK") ("SEER-1"), and a Phase 3 trial in patients with DES (ARISE-3), both in the U.S. In May 2016, we reported the results of the 317-patient ARISE-1 trial and in October 2017, we reported the results of the ARISE-2 trial. The ARISE-2 study, which was sponsored by ReGenTree and managed by Ora, Inc. pursuant a recent contract between the parties, demonstrated a number of statistically significant improvements in both signs and symptoms of DES with 0.1% RGN-259 versus placebo, while showing excellent safety, comfort, and tolerability profiles. The ocular discomfort symptom showed a statistically significant reduction in the RGN-259-treated group at day 15 as compared to placebo (p=0.0149) in the change from baseline. For sign, RGN-259 also improved the dry eye patient's ability to withstand an exacerbated condition in a patient subgroup with both compromised corneal fluorescein staining and Schirmer's test at baseline. In this population, RGN-259 showed superiority over placebo in reducing corneal fluorescein staining in the change from baseline at days 15 and 29 (p=0.0207 and 0.0254, respectively). RGN-259 confirmed its global effects on dry eye syndrome and fast onset in multiple sign and symptom efficacies with no safety issues in the ARISE-1 and ARISE-2 studies as well as in the pooled data, although ARISE-2 was not successful in duplicating the results of ARISE-1 where the study population was limited and less diversified. ReGenTree is proceeding with its RGN-259 development plan as discussed with the FDA in April 2018. Most recently, ReGenTree reaffirmed that the manufacturing of the investigational product for ARISE-3 has been completed and the protocol for the study has been finalized. ReGenTree and Ora, Inc. have entered into a contract for management of ARISE-3. ReGenTree, LLC has initiated the study, the first patient was enrolled in the second quarter of 2019, and it is expected to be completed in the Summer of 2020.

The NK trial (SEER-1), a smaller study in an orphan population, last reported enrollment of 17 patients. ReGenTree previously disclosed that 7 of 17 patients had completely healed. To participate in the trial the patients were required to have a persistent epithelial defect (non-healing corneal wound). While these preliminary observations are encouraging, it should be noted that the patients and treating physicians remained masked while the trial was on-going, so it is not known whether the healed patients were in the RGN-259 group, placebo group, or distributed among both. We expect ReGenTree to report top line data should be available in the next few months.

GtreeBNT has developed the CMC (chemistry, manufacturing and controls) dossier required for Phase 3 clinical trials and commercialization in the U.S. and in Korea. This comprehensive and critical effort ensures that final drug product manufacturing, packaging, stability, purity, reproducibility, etc., meets regulatory guidelines and product specifications. The product of this activity is the current product formulation being utilized in the U.S. trials being conducted by ReGenTree and will also be utilized in the planned clinical activity to be conducted by GtreeBNT under the RGN-259 license agreement for Pan Asia.

In February 2017, our licensee for RGN-137, GtreeBNT, through its subsidiary, Lenus Therapeutics, LLC, received permission from the U.S. FDA to sponsor a Phase 3 clinical trial using RGN-137 to treat patients with epidermolysis bullosa (EB), a genetic disease that causes severe blistering of the skin and internal organs. In August 2017, the Company amended the agreement for RGN-137 held by GtreeBNT. Under the amendment the Territory was expanded to include Europe, Canada, South Korea, Australia and Japan. In December 2018, GtreeBNT initiated a small Phase 2 open trial in patients with EB to evaluate RGN-137 in such patients prior to sponsoring a larger Phase 3 trial. Three patients have been enrolled in the open clinical trial to date. It was reported in August 2019, that the first patient had positively responded to RGN-137. It is hoped that 12 additional patients can be enrolled through 2020 now that all the clinical sites have received IRB approval.

Financial Operations Overview

We have never generated product revenues, and we do not expect to generate product revenues until the FDA approves one of our product candidates, if ever, and we begin marketing and selling it. We anticipate incurring additional operating losses in the future as we continue to explore the potential clinical benefits of Tß4-based product candidates over multiple indications. To fund further development and clinical trials we have entered into a series of strategic partnerships under licensing and joint venture agreements (see Note 4 of our financial statements) where our partners are responsible for advancing development of our product candidates with multiple clinical trials.

In February 2019, we sold a series of convertible promissory notes to management, the Company's Board of Directors and accredited investors including Essetifin S.p.A., our largest stockholder (the "2019 Notes"). The sale of the 2019 Notes resulted in gross proceeds to the Company of $1,300,000 over two closings. The first closing in the amount of $650,000 occurred in February 2019 and the second closing, also in the amount of $650,000, occurred on May 13, 2019 after the Company provided notice of the enrollment of the first patent in the ARISE-3 clinical trial in DES sponsored by ReGenTree. In addition, we received proceeds of $115,625 pursuant to the exercise of warrants held by Sabby Management as well as $125,000 for April 2019 warrant exercises. In January 2020, Sabby exercised their remaining warrants and the Company received proceeds of $241,912. At present, with the receipt of the sale proceeds from the closing on the 2019 Notes and proceeds from the March and April 2019 and January 2020 warrant exercises, we will have sufficient cash to fund planned operations through the third quarter of 2020. Accordingly, we will continue to evaluate opportunities to raise additional capital and are in the process of exploring various alternatives, including, without limitation, a public or private placement of our securities, debt financing, corporate collaboration and licensing arrangements, government grants, or the sale of our company or certain of our intellectual property rights.

Most of our expenditures to date have been for research and development, or R&D, activities and general and administrative, or G&A, activities. R&D costs include all of the wholly-allocable costs associated with our various clinical programs passed through to us by our outsourced vendors. Those costs include manufacturing Tß4 and peptide fragments, formulation of Tß4 into our product candidates, stability studies for both Tß4, and the various formulations, preclinical toxicology, safety and pharmacokinetic studies, clinical trial management, medical oversight, laboratory evaluations, statistical data analysis, regulatory compliance, quality assurance and other related activities. R&D includes cash and non-cash compensation, payroll taxes, travel and other miscellaneous costs of our internal R&D personnel, three persons in total, who are dedicated on a part-time hourly basis to R&D efforts. R&D also includes a proration of our common infrastructure costs for office space and communications. We expense our R&D costs as they are incurred.

R&D expenditures are subject to the risks and uncertainties associated with clinical trials and the FDA review and approval process. As a result, these expenses could exceed our expectations, possibly materially. We are uncertain as to what we will incur in future research and development costs for our clinical studies, as these amounts are subject to, management's continuing assessment of the economics of each individual research and development project and the internal competition for project funding.

G&A costs include outside professional fees for legal, business development, audit and accounting services. G&A also includes cash and non-cash compensation, travel and other miscellaneous costs of our internal G&A personnel, two in total, who are wholly dedicated to G&A efforts. G&A also includes a proration of our common infrastructure costs for office space and communications. Our G&A expenses also include costs to maintain our intellectual property portfolio. Historically we have expanded our patent prosecution activities, and in some cases, we have filed patent applications for non-critical strategic purposes intended to prevent others from filing similar patent claims. We continue to closely monitor our patent applications in the United States, Europe and other countries with the advice of outside legal counsel to determine if they will continue to provide strategic benefits. In cases where we believe the benefit has been realized or it becomes unnecessary due to the issuance of other patents, or for other reasons that will not affect the strength of our intellectual property portfolio, we have and will continue to abandon these patent applications in order to reduce our costs of continued prosecution or maintenance.

Critical Accounting Policies

We prepare our financial statements in conformity with accounting principles generally accepted in the United States. Such accounting principles require that our management make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Our actual results could differ materially from those estimates. The items in our financial statements that have required us to make significant estimates and judgments are as follows:

Revenue Recognition

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 our customers) in an amount that reflects the consideration to which it expects to be entitled to in exchange for those goods or services. Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed, and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. We recognize revenue using the relative performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

The Company’s contracts with customers may at times include multiple promises to transfer products and services. Contracts with multiple promises are analyzed to determine whether the promises, which may include a license together with performance obligations such as providing a clinical supply of product and steering committee services, are distinct and should be accounted for as separate performance obligations or whether they must be accounted for as a single performance obligation. The Company accounts for individual performance obligations separately if they are distinct. Determining whether products and services are considered distinct performance obligations may require significant judgment. If we cannot reasonably estimate when our performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance.

Whenever the Company determines that an arrangement should be accounted for as a combined performance obligation, we must determine the period over which the performance obligation will be performed and when revenue will be recognized. Revenue is recognized using either a relative performance or straight-line method. We recognize revenue using the relative performance method provided that the we can reasonably estimate the level of effort required to complete our performance obligation under an arrangement and such performance obligation is provided on a best-efforts basis. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If the Company cannot reasonably estimate the level of effort required to complete our performance obligation under an arrangement, the performance obligation is provided on a best-efforts basis and we can reasonably estimate when the performance obligation ceases or the remaining obligations become inconsequential and perfunctory, then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

If the Company cannot reasonably estimate when our performance obligation either ceases or becomes inconsequential and perfunctory, revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance.

At the inception of each arrangement that includes development milestone payments, the Company evaluates the probability of reaching the milestones and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur in the future, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore revenue recognized is constrained as management is unable to assert that a reversal of revenue would not be possible. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as unearned revenue in our accompanying balance sheets.

Contract assets are generated when contractual billing schedules differ from revenue recognition timing. Contract assets represent a conditional right to consideration for satisfied performance obligations that becomes a billed receivable when the conditions are satisfied. There were no contract assets as of December 31, 2019.

Contract liabilities result from arrangements where we have received payment in advance of performance under the contract. Changes in contract liabilities are generally due to either receipt of additional advance payments or our performance under the contract.

We have the following amounts recorded for contract liabilities:

	December 31	
	2019	2018
Unearned revenue	$ 2,178,086	$ 2,254,848

The contract liabilities amounts disclosed above as of December 31, 2019 and 2018, are primarily related to revenue being recognized on a straight-line basis over periods ranging from 23 to 30 years, which, in management’s judgment, is the best measure of progress towards satisfying the performance obligations and represents the Company’s best estimate of the period of the obligation.

Variable Interest Entities

We have determined that the Joint Venture is a “variable interest entity”, since the total equity investment at risk is not sufficient to permit the Joint Venture to finance its activities without additional subordinated financial support. Further, because of GtreeBNT’s majority equity stake in the Joint Venture, voting control, control of the board of directors, and substantive management rights, and given that we do not have the power to direct the Joint Venture’s activities that most significantly impact its economic performance, we have determined that it is not the primary beneficiary of the Joint Venture and therefore is not required to consolidate the Joint Venture. We report our equity stake in the Joint Venture using the equity method of accounting because, while it does not control the Joint Venture, we can exert significant influence over the Joint Ventures activities by virtue of our board representation.

Because we are not obligated to fund the Joint Venture, and have not provided any financial support, and have no commitment to provide financial support in the future to the Joint Venture, the carrying value of our investment in the Joint Venture is zero at both December 31, 2019 and 2018. As a result, we are not recognizing our share of the Joint Venture's operating losses and will not recognize any such losses until the Joint Venture produces net income (as opposed to net losses) and at that point we will reduce our share of the Joint Venture's net income by our share of previously suspended net losses. As of December 31, 2019, because we have not provided any financial support, we have no financial exposure as a result of its variable interest in the Joint Venture.

Convertible Notes with Detachable Warrants.

In accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 470-20, *Debt with Conversion and Other Options*, the proceeds received from convertible notes are allocated to the instruments based on the relative fair values of the convertible notes without the warrants and of the warrants themselves at the time of issuance. The portion of the proceeds allocated to the warrants is recognized as additional paid-in capital and a debt discount. The debt discount related to warrants is accreted into interest expense through maturity of the notes.

Share-based payment

We account for share-based compensation based on the estimated grant date fair value of the award using the Black-Scholes option-pricing model. The estimated grant date fair value is recognized over the requisite service period.

Determining the appropriate fair value model and calculating the fair value of share-based payment awards require the input of highly subjective assumptions, including the expected life of the share-based payment awards and stock price volatility. Since our historical data is limited, the expected life was determined in accordance with SEC Staff Accounting Bulletin No. 107 guidance for "plain vanilla" options. Since our historical trading volume is relatively low, we estimated the expected volatility based on monthly closing prices for a period consistent with the expected life of the option.

The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. See Notes 2 and 8 to the Financial Statements for a further discussion on stock-based compensation and the relative ranges of our historical, underlying assumptions.

Results of Operations

Comparison of years ended December 31, 2019 and 2018

Revenues. For the year ended December 31, 2019, we recorded revenue in the amount of approximately $77,000 versus $70,000 recorded for the year ended December 31, 2018. The 2019 revenue reflects the amortization over 30 years of the payments we received under the original joint venture license agreement and the payment we received for the expansion of the territorial rights to include Canada in April 2016. The payments received under the 2017 RGN-137 license amendment were amortized for revenue over 23 years. The 2019 increase reflects license amendment fees being amortized for the full year.

Expenses — Research and development. For the year ended December 31, 2019, our R&D expenditures decreased by $16,000, or 20%, to $65,000, from approximately $81,000 in 2018. The limited R&D expenditures reflects the shift of our internal R&D efforts as our partners assume full responsibility for clinical development. The decrease in 2019 results from lower stock option expense versus 2018. We expect our R&D expenses will remain at low levels unless we decide to reinitiate internal R&D efforts for our unpartnered programs.

Expenses — General and administrative. For the year ended December 31, 2019, our G&A expenses decreased by approximately $38,000, or 3%, to $1,274,000 from $1,312,000 in 2018. Decreases are reflected in 2019 expenses for salaries (decrease of $50,000), professional fees (decrease of $51,000) and non-income based tax expense (decrease of $29,000). These decreases were partially offset by increases in insurance (increase of $53,000), sponsorship (increase of $5,000), travel (increase of $6,000), investor relations (increase of $2,000), stock option expense (increase of $10,000), facility and related (increase of $14,000), and license fees (increase of $2,000). We believe that our G&A expenses will remain at current levels as we wait for data from the upcoming clinical trials being conducted by our partners. If we enter into additional partnerships or other business transactions, including financings, we will incur additional legal and transaction related expenses.

Net Loss. Our statement of operations reflects a net loss of $1,404,247 for the year ended December 31, 2019 versus net loss of $1,993,553 for the year ended December 31, 2018. The 2018 net loss reflects an inducement expense of $582,904 related to the new warrant component of the March 2018 warrant reprice and exercise agreement. Losses from operations decreased in 2019 versus 2018, $1,261,881 and $1,323,369, respectively.

Liquidity and Capital Resources

We have not commercialized any of our product candidates to date and have incurred significant losses since inception. In addition, we have primarily financed our operations through the equity or issuance of debt including the sale of a series of convertible promissory notes through private placements with accredited investors and the March and August 2014 private placements of common stock with GtreeBNT as well as our entry into the ReGenTree joint venture in early 2015. The report of our independent registered public accounting firm regarding our financial statements for the year ended December 31, 2019 contains an explanatory paragraph regarding our ability to continue as a going concern based upon our history of operating losses and dependence on future financing in order to meet our planned operating activities.

Our statement of operations reflects a net loss of $1,404,247 for the year ended December 31, 2019. We had cash and cash equivalents of $639,916 at December 31, 2019. In February 2019 we sold the 2019 Notes. The sale of the 2019 Notes resulted in gross proceeds to the Company of $1,300,000. In addition, we received proceeds of $115,625 pursuant to the exercise of warrants held by Sabby Management as well as $125,000 for April 2019 warrant exercises. In January 2020, Sabby exercised their remaining warrants and the Company received proceeds of $241,912. At present, with the receipt of the sale proceeds from the closing on the 2019 Notes and proceeds from the March and April 2019 and January 2020 warrant exercises, we will have sufficient cash to fund planned operations through the third quarter of 2020.

We may also receive funds from grants, new partnerships or the raising of additional capital if the market climate warrants. Additionally, we intend to continue to pursue additional partnering activities, particularly for RGN-352, our injectable systemic product candidate for cardiac and central nervous system indications. This estimate also does not include receipt of any funds from grants, new partnerships or the raising of additional capital if the market climate warrants. A sale of common stock and warrants, a convertible instrument or additional partnering of licensed rights are possible sources of operating capital in the future. Additionally, we intend to continue to pursue additional partnering activities, particularly for RGN-352, our injectable systemic product candidate for cardiac and central nervous system indications.

Net Cash Used in Operating Activities. Net cash used in operating activities was $1,138,000 and $888,000 for the years ended December 31, 2019 and 2018, respectively. In 2018, our statement of cash flows reflects a net inflow of $130,333 related to payments received under license agreements.

Net Cash Used in Investing Activities. We did not use any cash for investing activities in 2019 or 2018.

Net Cash Provided by Financing Activities. Net cash provided by financing activities totaled $1,541,000 and $944,000 for the years ended December 31, 2019 and 2018, respectively. In 2019, the cash provided by financing activities consisted of the proceeds from the sale of the 2019 Notes of $1,300,000 and $241,000 from the exercise of warrants, while in 2018, the cash provided by financing activities consisted of the proceeds from the exercise of warrants in March 2018.

Future Funding Requirements

The expenditures that will be necessary to execute our business plan are subject to numerous uncertainties that may adversely affect our liquidity and capital resources. Currently, RegeneRx has active partnerships in four major territories: the U.S., Europe, China and Pan Asia. Our partners have been moving forward and making progress in each territory. In each case, the cost of development is being borne by our partners with no financial obligation for RegeneRx. Patient accrual, treatment, and follow-up for ophthalmic trials are, in general, relatively fast, as opposed to most other clinical efforts, ARISE-3, ReGenTree's Phase 3 trial, was initiated and the first patient was enrolled in the second quarter of 2019 and enrollment is expected to be completed in the Summer of 2020. Top line data from the U.S. Phase 3 NK study SEER-1 is expected in the first half of 2020.

We still have significant clinical assets to develop, primarily RGN-352 (injectable formulation of Tß4 for cardiac and CNS disorders) in the U.S., Pan Asia, and Europe, and RGN-259 in the EU. Our goal is to wait until the results are obtained from the current ophthalmic clinical trials before moving into the EU with RGN-259. If successful, this should allow us to obtain a higher value for the clinical asset at that time. However, we intend to continue to develop RGN-352, either by obtaining grants to fund a Phase 2a clinical trial in the cardiovascular or central nervous system fields or finding a suitable partner with the resources and capabilities to develop it as we have with RGN-259.

In addition, the length of time required for clinical trials varies substantially according to the type, complexity, novelty and intended use of a product candidate. Some of the factors that could impact our liquidity and capital needs include, but are not limited to:

- the progress of our clinical trials;
- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our preclinical development activities;

- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;
- the costs related to development and manufacture of preclinical, clinical and validation lots for regulatory purposes and commercialization of drug supply associated with our product candidates;
- our ability to enter into corporate collaborations and the terms and success of these collaborations;
- the costs and timing of regulatory approvals; and
- the costs of establishing manufacturing, sales and distribution capabilities.

Moreover, the duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial protocol, including, among others, the following:

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that seems appropriate in view of the results;
- the number of clinical sites included in the trials; and
- the length of time required to enroll suitable patient subjects.

Also, we test our product candidates in numerous preclinical studies to identify indications for which they may be efficacious. We may conduct multiple clinical trials to cover a variety of indications for each product candidate. As we obtain results from trials, we may elect to discontinue clinical trials for certain product candidates or for certain indications in order to focus our resources on more promising product candidates or indications.

Our proprietary product candidates have not yet achieved FDA regulatory approval, which is required before we can market them as therapeutic products. In order to proceed to subsequent clinical trial stages and to ultimately achieve regulatory approval, the FDA must conclude that our clinical data establish safety and efficacy. Historically, the results from preclinical studies and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

Sources of Liquidity

We have not commercialized any of our product candidates to date and have primarily financed our operations through the issuance of common stock and common stock warrants in private and public financings. In June of 2016, we raised $1,520,000 by selling 5,147,059 shares of common stock and warrants to purchase 5,147,059 shares of common stock to Sabby. On March 2, 2018, we entered into a warrant reprice and exercise and issuance agreement with Sabby, which, in consideration of the holders exercising in full all of the 2016 Offering warrants the exercise price per share of the warrants was reduced to $0.20 per share. In addition, and as further consideration, we issued to the holders of the 2016 Offering warrants 3,860,294 new warrants with an exercise price of $0.2301 per share. Pursuant to the terms of the Reprice Agreement the exercise price of the new warrants will be reduced from $0.2301 to $0.125 as a result of the sale of the 2019 Notes. We received gross proceeds of approximately $1,000,000 pursuant the exercise and issued 5,147,059 of common stock. Most recently, in February 2019, we sold a series of convertible promissory notes to accredited investors including Essetifin S.p.A., our largest shareholder. The sale of the notes resulted in gross proceeds to the Company of $1,300,000 over two closings. The first closing in the amount of $650,000 occurred in February 2019 and the second closing, also in the amount of $650,000, occurred on May 13, 2019 after the Company provided notice of the enrollment of the first patient in the ARISE-3 clinical trial in DES sponsored by ReGenTree. The notes contain a $0.12 conversion price and are initially convertible into 10,833,333 chares off common stock. The purchasers also received a warrant exercisable at $0.18 to purchase additional 8,125,000 shares of common stock. In addition, we received proceeds of $115,625 pursuant to the exercise of warrants held by Sabby Management as well as $125,000 for April 2019 warrant exercises. In January 2020, Sabby exercised their remaining and the Company received proceeds of $241,912. At present, with the receipt of the sale proceeds from the closing on the 2019 Notes and proceeds from the March and April 2019 and January 2020 warrant exercises, we will have sufficient cash to fund planned operations through the third quarter of 2020.

We continuously monitor our cash use as well as the clinical timelines. We continue to evaluate options including the licensing of additional rights to commercialize our clinical products as well as raising capital through the capital markets.

We have various strategic agreements and license agreements with: GtreeBNT, ReGenTree and Lee’s. These license agreements provide for the opportunity for us to receive milestone payments upon specified commercial events and royalty payments in connection with any commercial sales of the licensed products in the respective territories. However, there are no assurances that we will be able to attain any such milestones or generate any such royalty payments under the agreements.

Licensing Agreements

As noted above, we have entered into two strategic agreements with GtreeBNT. GtreeBNT licensed the development and commercialization rights for RGN-259, in Asia (excluding China, Hong Kong, Macau and Taiwan) while also licensing the development and commercialization rights for RGN-137 in the U.S. In August 2017, the Company amended the license agreement for RGN-137 held by GtreeBNT. Under the amendment the Territory was expanded to include Europe, Canada, South Korea, Australia and Japan. In January 2015, we entered into a joint venture and licensing agreement with GtreeBNT that will commercialize RGN-259 for treatment of dry eye and neurotrophic keratitis in the United States, as well as any other indications within the field of ophthalmology. The license agreements provide for the opportunity for us to receive milestone payments upon specified commercial events and royalty payments in connection with any commercial sales of the licensed products in the respective territories. However, there are no assurances that we will be able to attain any such milestones or generate any such royalty payments under the agreements.

We also have entered into a license agreement with Lee's Pharmaceuticals that provides for the opportunity for us to receive milestone payments upon specified events and royalty payments in connection with any commercial sales of Tß4-based products in China, Hong Kong, Macau and Taiwan (Greater China). However, there are no assurances that we will be able to attain any such milestones or generate any such royalty payments under the agreement. In February 2019, the agreement was amended and assigned by Lee's to their affiliate, Zhaoke Ophthalmology Pharmaceutical Limited. There were no economic changes to the agreement.

Government Grants

We have pursued, and may continue to pursue, government funding for both RGN-259 and RGN-352. We are not currently receiving funding under a Government Grant.

Other Financing Sources

Other potential sources of outside capital include entering into additional strategic business relationships, additional issuances of equity securities or debt financing or other similar financial instruments. If we raise additional capital through a strategic business relationship, we may have to give up valuable rights to our intellectual property. If we raise funds by selling additional shares of our common stock or securities convertible into our common stock, the ownership interest of our existing stockholders may be significantly diluted. In addition, if additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock and may involve significant fees, interest expense, restrictive covenants and the granting of security interests in our assets.

Our failure to successfully address liquidity requirements could have a materially negative impact on our business, including the possibility of surrendering our rights to some technologies or product opportunities, delaying our clinical trials, or ceasing operations. There can be no assurance that we will be able to obtain additional capital in sufficient amounts, on acceptable terms, or at all.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as such term is defined in Item 303(a)(4) of Regulation S-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

The financial statements required by this item are included beginning on page F-1 of this report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and timely reported as provided in SEC rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer who currently serves as both our principal executive officer and our principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. We periodically review the design and effectiveness of our disclosure controls and procedures, including compliance with various laws and regulations that apply to our operations. We make modifications to improve the design and effectiveness of our disclosure controls and procedures and may take other corrective action if our reviews identify a need for such modifications or actions. In designing and evaluating the disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and we apply judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

We have carried out an evaluation, under the supervision and the participation of our management, including our Chief Executive Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act), as of December 31, 2019 the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer, in his capacity as principal executive officer and principal financial officer, concluded that our disclosure controls and procedures were effective as of December 31, 2019.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. A 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 assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; 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 our financial statements.

Because of its inherent limitations, including the possibility of human error and the circumvention or overriding of controls, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect all misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Further, because of changes in conditions, effectiveness of internal control over financial reporting may vary over time.

A significant deficiency is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for oversight of the company's financial reporting. A material weakness is a deficiency, or combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

Under the supervision and with the participation of our management, including our Chief Executive Officer in his capacity as principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework set forth in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2019.

This Annual Report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to the rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this Annual Report.

Changes in Internal Control over Financial Reporting

There were no changes to the Company's Internal Controls over Financial Reporting in the year ended December 31, 2019.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth as of March 15, 2020, the name, age and position of each person who serves as an executive officer or director of our company. There are no family relationships among any of our executive officers or directors, with the exception that Mr. Finkelstein is the first cousin of Dr. Goldstein's wife.

We seek to assemble a board that, as a whole, possesses the appropriate balance of professional and industry knowledge, financial expertise and high-level management experience necessary to oversee and direct our business. To that end, our board intends to maintain membership of directors who complement and strengthen the skills of other members and who also exhibit integrity, collegiality, sound business judgment and other qualities that we view as critical to effective functioning of the board. The brief biographies below include information, as of the date of this report, regarding the specific and particular experience, qualifications, attributes or skills of each director or nominee that led the board to believe that the director should serve on the board.

Name	Age	Position
Executive Officers:		
Mr. J.J. Finkelstein	68	President, Chief Executive Officer and Director
Directors:		
Dr. Allan L. Goldstein	82	Founder, Chairman of the Board and Chief Scientific Officer
Mr. R. Don Elsey	66	Director
Mr. Joseph C. McNay	86	Director
Mr. Mauro Bove	65	Director
Dr. Alessandro Noseda	61	Director

Mr. Finkelstein has served as our President and Chief Executive Officer and a member of our Board of Directors since 2002. Mr. Finkelstein also served as our Chief Executive Officer from 1984 to 1989 and as the Vice Chairman of our Board of Directors from 1989 to 1991. Mr. Finkelstein has worked as an executive officer and consultant in the bioscience industry for the past 38 years, including serving from 1989 to 1996 as chief executive officer of Cryomedical Sciences, Inc., a publicly-traded medical device company. Mr. Finkelstein has significant experience in developing early-stage companies. He has been responsible for the regulatory approval and marketing of several medical devices in the U.S. and abroad. Mr. Finkelstein has previously served on the executive committee of the Board of Directors of the Technology Council of Maryland and MdBio, Inc. and formerly chaired the MdBio Foundation for six years, all of which are non-profit entities that support bioscience development and education in the State of Maryland. Mr. Finkelstein received a business degree in finance from the University of Texas. The Board believes that Mr. Finkelstein's history and long tenure as our Chief Executive Officer positions him to contribute to the Board his extensive knowledge of our company and to provide Board continuity. In addition, the Board believes that his experience at prior companies has provided him with operational and industry expertise, as well as leadership skills that are important to the Board.

Dr. Goldstein has served as the Chairman of our Board of Directors and our Chief Scientific Officer since he founded our company in 1982. Dr. Goldstein is Emeritus Professor & former Chairman of the Department of Biochemistry and Molecular Medicine at the George Washington University School of Medicine and Health Sciences. Dr. Goldstein is a recognized expert in the field of immunology and protein chemistry, having authored over 435 scientific articles in professional journals. He is also the inventor on over 25 issued and/or pending patents in biochemistry, immunology, cardiology, cancer and wound healing. Dr. Goldstein discovered several important compounds, including Tß1, which is marketed worldwide, and Tß4, which is the basis for RegeneRx's clinical program. Dr. Goldstein served on the Board of Trustees of the Sabin Vaccine Institute from 2000 to 2012 and on the Board of Directors of the Richard B. and Lynne V. Cheney Cardiovascular Institute from 2006 to 2012. Dr. Goldstein has also done pioneering work in the area of medical education, developing distance learning programs for the internet entitled "Frontiers in Medicine," a medical education series that Dr. Goldstein developed. The Board believes that Dr. Goldstein's scientific expertise, industry background and prior experience as our founder all position him to make an effective contribution to the medical and scientific understanding of the Board, which the committee believes to be particularly important as we continue our Tß4 development efforts.

Mr. Elsey has served as a member of our Board of Directors since September 2010. Currently Mr. Elsey serves as CFO of Lyra Therapeutics, a private company pioneering a new therapeutic approach to treat debilitating ear, nose and throat diseases. Previously Mr. Elsey served as CFO of Senseonics, Inc., from February 2015 to February 2019, a medical device company focused on continuous glucose monitoring. From May 2014 until February 2015 Mr. Elsey served as chief financial officer of Regado Biosciences, a public, late-stage clinical development biopharmaceutical company. From December 2012 to February 2014 Mr. Elsey served as chief financial officer of LifeCell, Inc., a privately held regenerative medicine company. From June 2005 to December 2012, he served in numerous finance capacities, most recently as senior vice president and chief financial officer, at Emergent BioSolutions Inc., a publicly held biopharmaceutical company. He served as the director of finance and administration at IGEN International, Inc., a publicly held biotechnology company, and its successor BioVeris Corporation, from April 2000 to June 2005. Prior to joining IGEN, Mr. Elsey served as director of finance at Applera, a genomics and sequencing company, and in several finance positions at International Business Machines, Inc. He received an M.B.A. in finance and a B.A. in economics from Michigan State University. Mr. Elsey is a certified management accountant. The Board believes that Mr. Elsey's experience as chief financial officer of a public company is particularly valuable to our business in that it positions him to contribute to our board's and audit committee's understanding of financial matters.

Mr. McNay has served as a member of our Board of Directors since 2002. He is currently Chairman, Chief Investment Officer and Managing Principal of Essex Investment Management Company, LLC, positions he has held since 1976 when he founded Essex. He has direct portfolio management responsibilities for a variety of funds and on behalf of private clients. He is also a member of the firm's Management Board. Prior to founding Essex, Mr. McNay was Executive Vice President and Director of Endowment Management & Research Corp. from 1967. Prior to that, Mr. McNay was Vice President and Senior Portfolio Manager at the Massachusetts Company. Currently he is serving as Trustee of the Dana Farber Cancer Institute, member of the Children's Hospital Investment Committee. Mr. McNay served a Trustee for Brigham and Women's Physicians Organization from 2000 – 2018. He received his A.B. degree from Yale University and his M.B.A. degree in finance from the Wharton School of the University of Pennsylvania. The Board believes that Mr. McNay's extensive financial experience is valuable to our business and also positions him to contribute to the audit committee's understanding of financial matters.

Mr. Bove has served as a member of our Board of Directors since 2004 and has more than 30 years of business and management experience within the pharmaceutical industry. Mr. Bove is currently based in Hong Kong and in Europe, serving as a consultant to emerging pharmaceutical companies worldwide. Previously, Mr. Bove led for more than 20 years the Corporate & Business Development of Sigma-Tau Finanziaria S.p.A., formerly the holding company of Sigma-Tau Group, a leading international pharmaceutical company (Sigma-Tau Finanziaria S.p.A. - now Essetifin S.p.A. - and its affiliates are collectively our largest stockholder). Mr. Bove, who resigned this role with Sigma-Tau on March 31, 2014, has also held a number of senior positions in business, licensing and corporate development within Sigma-Tau Group. Mr. Bove obtained his law degree at the University of Parma, Italy, in 1980. In 1985, he attended the Academy of American and International Laws at the International and Comparative Law Center, Dallas, Texas. The Board believes that Mr. Bove's extensive business and management experience within the pharmaceutical industry allows him to recognize and advise the Board with respect to recent industry developments.

Dr. Noseda is the Chief Scientific Officer (CSO) of Leadiant Biosciences S.p.A. and provides scientific and medical know-how to coordinate and manage the scientific and development programs at a global level as well as to evaluate new opportunities for the Leadiant Group. Since September 2018 he is also Chief Medical Officer of Leadiant Biosciences, Inc. After graduating as a Medical Doctor in 1984 at the University of Milan and following a Post Doctorate at Bowman Gray School of medicine (USA), he joined the pharma industry in 1988 where he held different managerial positions within the R&D and Marketing organizations of multinational companies. He has acquired a significant experience in R&D (through the whole development process, from research to interaction with Health Authorities for MA submission or HTA assessment) and strategic/business operations. He joined sigma-tau in 1998 as Director of Scientific Office and Strategic Alliances within the Corporate R&D organization. In this position he managed key R&D projects and contributed to the finalization of important partnerships (e.g. with Novartis, Debiopharm etc.) and to the advancement of product development (from research to product registration). He has been part of the management Team and Board of Directors of biotech companies of the sigma-tau Group, as Thule Therapeutics, Metheresis Translational Research and Rostaquo. He has also been Chief Executive Officer of Leadiant Biosciences SA (formerly sigma-tau Research Switzerland) from 2007 to 2017, a position which he held in parallel with his former positions in sigma-tau (1988-2014) and later in Leadiant where he acted as Chief Medical Officer (2014-2017) before becoming the CSO. Under his management this company developed and advanced a proprietary technology and he guided the Company through the process to obtain the authorization by the Swiss Health Authorities to import and release medicinal products, as well as the Orpha Drug Designations and registration of new products (e.g. Chenodeoxycholic Acid or CDCA). He worked in several therapeutic (and diagnostic) areas, but mostly in high unmet medical need specialty areas as cancer, immune-oncology and rare diseases.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of our company. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations of our directors and officers that no other reports were required, during the fiscal year ended December 31, 2019, all Section 16(a) filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with.

Corporate Code of Conduct and Ethics

We have adopted a corporate code of conduct and ethics that applies to all of our employees, officers and directors, as well as a separate code of ethics that applies specifically to our principal executive officer and principal financial officer. The corporate code of conduct and ethics and the code of ethics for our principal executive and financial officers are available on our corporate website at www.regenerx.com. If we make any substantive amendments to the corporate code of conduct and ethics or the code of ethics for our principal executive and financial officers or grant any waivers from a provision of these codes to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

Audit Committee and Audit Committee Financial Expert

We have a separately designated standing audit committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. The members of the audit committee are Messrs. McNay and Elsey. Mr. McNay serves as chairman of the audit committee.

Our board of directors periodically reviews the independence of our audit committee members and has determined that all current members of our audit committee are independent under NYSE Amex listing standards. Although our common stock is no longer listed on the NYSE Amex exchange, we have determined the independence of our audit committee members using the NYSE Amex definitions of independence.

Our board of directors has also determined that each of Mr. McNay and Mr. Elsey qualifies as an audit committee financial expert, as defined in applicable SEC rules.

Item 11. Executive Compensation.

Summary Compensation Table

The following table shows, for the fiscal years ended December 31, 2019 and 2018, compensation awarded to or paid to, or earned by, our chief executive officer who was our only named executive officers for fiscal 2019. For purposes of this report, we sometimes refer to our chief executive officer as our named executive officer.

Name and Principal Position	Year	Salary(1) ($)	Bonus ($)	Option Awards(2) ($)	All Other Compensation(3) ($)	Total ($)
J.J. Finkelstein, President and	2019	81,528	--	103,523	3,360	188,411
Chief Executive Officer	2018	102,399	--	38,809	3,360	144,568

(1) Mr. Finkelstein reduced his 2019 salary to $80,000 and he had previously reduced his 2018 salary from $150,000 to $125,000 in March 2018. Additionally, he forwent his October, November and December 2018 salary due to the limited cash held by RegeneRx.

(2) The 2019 & 2018 amounts reflect the aggregate total grant date fair values (computed in accordance with FASB ASC Topic 718 or ASC Topic 505).

(3) The 2019 & 2018 amounts reflect payment of life insurance premiums for Mr. Finkelstein in the amount of $3,360

Employment Agreements; Potential Payments Upon Termination or Change in Control

Employment Agreement with Mr. Finkelstein

We entered into an employment agreement with Mr. Finkelstein on April 16, 2014 for him to serve as our president and chief executive officer. Mr. Finkelstein's employment agreement has an initial three-year term, which is automatically renewed for additional one-year periods unless either we or Mr. Finkelstein elect not to renew it. Mr. Finkelstein's annual base salary was $125,000, which was increased to $150,000 on January 1, 2015 and subsequently reduced back to $125,000 in March 2018. Mr. Finkelstein's salary may not be adjusted downward without his written consent, except in a circumstance which is part of a general reduction or other concessionary arrangement affecting all employees or affecting senior executive officers. Effective January 1, 2019, Mr. Finkelstein suggested and consented that his salary be reduced to $80,000 annually. Mr. Finkelstein is also eligible to receive an annual bonus in an amount established by the Board and is entitled to participate in and receive all standard employee benefits and to participate in all of our applicable incentive plans, including stock option, stock, bonus, savings and retirement plans. We also provide him with $1 million in life insurance.

Mr. Finkelstein is eligible to receive options to purchase common stock under our equity incentive plans. The decision to grant any such options and the terms of such options are within the discretion of our Board or the compensation committee thereof. All vested options are exercisable for a period of time following any termination of Mr. Finkelstein's employment as may be set forth in the applicable benefit plan or in any option agreement between Mr. Finkelstein and us.

In the event that Mr. Finkelstein's employment is terminated by us without "cause" or by Mr. Finkelstein for "good reason," each as defined in his employment agreement, subject to Mr. Finkelstein's entering into and not revoking a release of claims in a form acceptable to us, Mr. Finkelstein will be entitled to receive (i) a lump sum payment in an amount equal to one-half of his then annual base salary if within the first anniversary date of this Agreement; or (ii) a lump sum payment in an amount equal to three-fourths of his then annual base salary if within the first anniversary date and second anniversary date of this Agreement; or (iii) a lump sum payment in an amount equal to his then annual base salary if any time after the second anniversary date of this Agreement, less all federal and state withholdings. In the event of a "change in control," as defined in his employment agreement and Mr. Finkelstein is involuntarily terminated within 12 months after a change in control event or within 12 months after a change in control event he resigns his employment for "good reason", then the Company shall (i) pay Mr. Finkelstein, in a lump sum cash payment, an amount equal to his annual base salary in effect on the date of his termination from employment, less any applicable federal and state taxes and withholdings. In addition, in each instance Mr. Finkelstein would also be eligible to receive (i) any earned bonus and accrued vacation pay, and (ii) to the extent that he is eligible for and participates in a Company sponsored health insurance plan the Company shall pay or reimburse Executive for the amount of any insurance premiums for a twelve-month period, but these payments shall be limited to the amount of the premiums being paid by the Company for Executive's coverage or the amount being reimbursed for insurance premiums immediately prior to the date of his termination from employment.

In addition, if Mr. Finkelstein's employment is terminated without "cause," or if there is a "change in control" event, in each case as defined in either the applicable benefit plan or in Mr. Finkelstein's employment agreement, then the unvested portion of Mr. Finkelstein's outstanding options would accelerate in full.

Outstanding Equity Awards at December 31, 2019

The following table shows certain information regarding outstanding equity awards at December 31, 2019 for the named executive officer, all of which were stock options granted under our Amended and Restated 2000 Stock Option and Incentive Plan, our 2010 Equity Incentive Plan or our 2018 Equity Incentive Plan.

Name	Number of Shares Underlying Unexercised Options (#) Exercisable	Number of Shares Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Note
Mr. Finkelstein	162,500	487,500	0.21	5/15/2029	(1)
	200,000	—	0.64	3/17/2023	
	125,000	125,000	0.21	7/16/2028	(1)
	500,000	—	0.21	3/25/2021	
	500,000	—	0.36	6/30/2022	
	112,500	37,500	0.28	9/1/2027	(1)

(1) These options vest in equal installments upon grant and on the first three anniversaries of the grant date. In each case these options were granted ten years prior to the listed expiration dates.

Post-Employment Compensation

We do not maintain any plans providing for payment or other benefits at, following, or in connection with retirement other than a 401(k) plan which was available to all employees through 2011. The Company did not make any plan contributions in 2019 or 2018. In addition, we do not maintain any non-qualified deferred compensation plans.

Director Compensation

The following table sets forth certain information for the fiscal year ended December 31, 2019 with respect to the compensation of our directors. Mr. Finkelstein's compensation is disclosed in the Summary Compensation Table above, and he does not receive any additional compensation for his service as a director. Dr. Goldstein is an employee of our company and his compensation as an employee is set forth in the table below. He does not receive any additional compensation for his service as a director.

The Company had in effect a non-employee director compensation policy which was suspended in November 2011 by our Board of Directors elected to help the company preserve capital and consistent with this, certain fees accrued in 2011 were forfeited and no retainer or meeting fees were paid to non-employee directors in 2019 or 2018.

In 2019 each independent director was granted options to purchase either 200,000 or 250,000 shares of common stock at an exercise price of $0.21 per share, which vests in four segments pursuant to each director's continued service. In 2018 each independent director was granted options to purchase 200,000 shares of common stock with an exercise price per share of $0.21. These option grants vests in four segments pursuant to each director's continued service. These option grants were the only compensation received by non-employee directors in 2019 and 2018.

We also reimburse directors for expenses incurred in attending meetings of the board and other events attended on our behalf and at our request.

Director Compensation for Fiscal 2019

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Allan Goldstein, Ph.D.	--	65,362	90,000(2)	155,362
R. Don Elsey	--	39,855	--	39,855
Alessandro Noseda	--	31,844	--	31,844
Joseph McNay	--	39,855	--	39,855
Mauro Bove	--	31,844	--	31,844

(1) Total Options held by each Board member as of December 31, 2019, are as follows:

Allan Goldstein, Ph.D.	1,706,942
R. Don Elsey	795,000
Alessandro Noseda	200,000
Joseph McNay	803,024
Mauro Bove	832,155

(2) In addition to being Chairman of our Board of Directors, Dr. Goldstein also serves as our Chief Science Officer. In this capacity, Dr. Goldstein received cash compensation of $90,000 in 2019. In 2019 Dr. Goldstein was also granted options to purchase 410,000 shares of common stock.

We entered into an employment agreement with Dr. Goldstein on April 16, 2014 for him to serve as our Chief Science Officer. Dr. Goldstein's employment agreement had an initial one-year term, which has been and will be automatically renewed for additional one-year periods unless either we or Mr. Goldstein elect not to renew it. Dr. Goldstein's annual base salary was $75,000 and was increased to $90,000 on January 1, 2015. Dr. Goldstein's salary may not be adjusted downward without his written consent, except in a circumstance which is part of a general reduction or other concessionary arrangement affecting all employees or affecting senior executive officers. Dr. Goldstein is also eligible to receive an annual bonus in an amount established by the Board and is entitled to participate in and receive all standard employee benefits and to participate in all of our applicable incentive plans, including stock option, stock, bonus, savings and retirement plans.

Dr. Goldstein is eligible to receive options to purchase common stock under our equity incentive plans. The decision to grant any such options and the terms of such options are within the discretion of our Board or the compensation committee thereof. All vested options are exercisable for a period of time following any termination of Dr. Goldstein's employment as may be set forth in the applicable benefit plan or in any option agreement between Dr. Goldstein and us.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information regarding the ownership of our common stock as of March 15, 2020 by (i) each director; (ii) each named executive officer; (iii) all currently serving executive officers and directors as a group; and (iv) all those known by us to be beneficial owners of more than five percent of our common stock. The address for all directors and executive officers is c/o RegeneRx Biopharmaceuticals, Inc., 15245 Shady Grove Road, Suite 470, Rockville, MD 20850.

	Beneficial Ownership[1]	
Beneficial Owner	**Number of Shares**	**Percent of Total**
5% Stockholders:		
Entities affiliated previously affiliated with Essetifin S.p.A., Via Sudafrica, 20, Rome, Italy 00144	49,572,413[2]	33.5%
GtreeBNT Co., Ltd. 22nd FL, Parkview Tower, 248 Jungjail-ro, Bundang-gu, Seongnam-si, Gyeonggi-do 463-863, Republic of Korea	19,583,333[3]	14.7%
Named Executive Officers and Directors:		
J.J. Finkelstein	3,602,574[4]	2.7%
Allan L. Goldstein	2,825,710[5]	2.1%
Joseph C. McNay	7,564,955[6]	5.6%
Mauro Bove	839,583[7]	*
R. Don Elsey	853,623[8]	*
Alessandro Noseda	50,000[9]	*
All directors and executive officers as a group (6 persons)	**15,736,445[10]**	11.3%

* Less than one percent.

(1) This table is based upon information supplied by officers, directors and principal stockholders. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 133,441,788 shares of common stock outstanding on March 15, 2020, adjusted as required by rules promulgated by the Securities and Exchange Commission (the "SEC").

(2) Consists of 34,989,080 shares of common stock held of record held by Essetifin S.p.A. (f/k/a Sigma-Tau Finanziaria, S.p.A.) ("Essetifin"), 8,333,333 shares of common stock issuable upon conversion of a convertible promissory note and 6,250,000 upon the exercise of warrants. In each case exercisable within 60 days of March 15, 2020. Paolo Cavazza and members of his family directly and indirectly own 38% of Essetifin. The beneficial ownership of Essetifin and its affiliates is derived from the Schedule 13D/A filed by Essetifin on March 14, 2018.

(3) Consists of 19,583,333 shares of common stock held of record by GtreeBNT which were acquired in two equity purchases in March 2014 and August 2014. The beneficial ownership of GtreeBNT is derived from its Schedule 13D/A filed on April 1, 2015.

(4) Consists of 1,637,991 shares of common stock held of record by Mr. Finkelstein, 208,333 shares of common stock issuable upon conversion of convertible promissory notes, 156,250 shares of common stock issuable upon exercise of warrants and 1,600,000 shares of common stock issuable upon exercise of options, in each case exercisable within 60 days of March 15, 2020.

(5) Consists of 1,512,793 shares of common stock held of record by Dr. Goldstein, 41,667 shares of common stock issuable upon conversion of convertible promissory notes, 31,250 shares of common stock issuable upon exercise of warrants and 1,240,000 shares of common stock issuable upon exercise of options, in each case exercisable within 60 days of March 15, 2020.

(6) Consists of 6,524,122 shares of common stock held of record by Mr. McNay, 208,333 shares of common stock issuable upon conversion of convertible promissory notes, 156,250 shares of common stock issuable upon exercise of warrants and 676,250 shares of common stock issuable upon exercise of options, in each case exercisable within 60 days of March 15, 2020.

(7) Consists of 83,333 shares of common stock issuable upon conversion of convertible promissory notes, 62,500 shares of common stock issuable upon exercise of warrants and 693,750 shares of common stock issuable upon exercise of options, in each case exercisable within 60 days of March 15, 2020.

(8) Consists of 104,456 shares of common stock held of record, 41,667 shares of common stock issuable upon conversion of convertible promissory notes, 31,250 shares of common stock issuable upon exercise of warrants and 676,250 shares of common stock issuable upon exercise of options, in each case exercisable within 60 days of March 15, 2020.

(9) Consists of 50,000 shares of common stock issuable upon exercise of options within 60 days of March 15, 2020.

(10) Consists of 9,779,362 shares of common stock held of record, 583,333 shares of common stock issuable upon conversion of convertible promissory notes, 437,500 shares of common stock issuable upon exercise of warrants and 4,936,250 shares of common stock issuable upon exercise of options, in each case exercisable within 60 days of March 15, 2020.

Equity Compensation Plan Information

The following table provides information as of December 31, 2019 about the securities authorized for issuance to our employees, directors and other eligible participants under our equity compensation plans, consisting of the 2010 Equity Incentive Plan and the 2018 Equity Incentive Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants 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	9,821,250	$ 0.28	3,610,130
Equity compensation plans not approved by security holders	—	—	—
Total	9,821,250	$ 0.28	3,610,130

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Related Party Transactions

Described below are transactions and series of similar transactions that have occurred during fiscal 2019 to which we were a party or are a party in which:

- the amounts involved exceeded or will exceed $120,000; and
- a director, executive officer, beneficial owner of more than five percent of any class of our voting securities or any member of their immediate family had or will have a direct or indirect material interest.

2019 Convertible Notes

In February 2019, we sold a series of convertible promissory notes to management, the Company's Board of Directors and accredited investors including Essetifin S.p.A., our largest stockholder (the "2019 Notes"). The sale of the 2019 Notes resulted in gross proceeds to the Company of $1,300,000 over two closings The first closing in the amount of $650,000 occurred in February 2019 and the second closing, also in the amount of $650,000, occurred on May 13, 2019 after the Company provided notice of the enrollment of the first patent in the ARISE-3 clinical trial in DES sponsored by ReGenTree. The 2019 Notes will mature on March 1, 2024. The 2019 Notes bear interest at a rate of five percent (5%) per annum and are convertible into shares of our common stock at a conversion price of twelve cents ($0.12) per share (subject to adjustment as described in the 2019 Notes) at any time prior to repayment, at the election of the investors. In the aggregate, the 2019 Notes issued in both closings are convertible into up to 10,833,333 shares of our common stock excluding interest.

At any time prior to maturity of the 2019 Notes, with the consent of the holders of a majority in interest of the 2019 Notes, we can prepay the outstanding principal amount of the 2019 Notes plus unpaid accrued interest without penalty. The outstanding principal and all accrued interest on the 2019 Notes will accelerate and automatically become immediately due and payable upon the occurrence of certain events of default.

In connection with the issuance of the 2019 Notes we also issued warrants to each investor. The warrants are exercisable for an aggregate of 8,125,000 shares of common stock with an exercise price of eighteen cents ($0.18) per share for a period of five years (the "2019 Warrants").

The affiliated investors and the principal amount of their respective 2019 Notes purchase are as set forth below:

Investor	Note Principal
Essetifin S.p.A.	$ 1,000,000
Joseph C. McNay	$ 25,000
J.J. Finkelstein	$ 25,000
Mauro Bove	$ 10,000
Allan L. Goldstein	$ 5,000
R. Don Elsey	$ 5,000

Essetifin S.p.A., our largest stockholder, is currently the holder of all of our securities previously held by Sigma-Tau and its affiliates. The other listed investors are members of our Board of Directors including Mr. Finkelstein, who serves as our CEO, and Dr. Goldstein who serves as our Chief Scientific Advisor and Chairman of our Board of Directors.

GtreeBNT

In August 2017, the Company and GtreeBNT reached an agreement to expand the territorial definition of the RGN-137 license agreement in Japan in exchange for a series of payments, two of which were received in 2017 with the remaining two were received in 2018. Under the amendment the Territory was expanded to include Europe, Canada, South Korea, Australia and Japan.

U.S. Joint Venture

On January 28, 2015, we announced that we had entered into a Joint Venture Agreement with GtreeBNT a shareholder of the Company. ReGenTree, LLC was created under the Agreement and is jointly owned by us and GtreeBNT. ReGenTree intends to commercialize RGN-259 for treatment of dry eye and neurotrophic keratitis, an orphan indication in the United States. GtreeBNT will be responsible for funding all product development and commercialization efforts and holds a majority interest in ReGenTree that varies depending on development milestones achieved and eventual commercialization path, if successful. In conjunction with the Joint Venture Agreement, we also entered into a royalty-bearing license with ReGenTree pursuant to which we granted to ReGenTree the right to develop and exclusively commercialize RGN-259 in the United States. We received a total of $1 million in two tranches under the terms of the agreement. The first tranche of $500,000 was received in March 2015 and a second in the amount of $500,000, was received in September 2015. On April 6, 2016, we received $250,000 from ReGenTree and executed an amendment to the license agreement on April 28, 2016. Under the amendment, the territorial rights were expanded to include Canada.

Our initial ownership interest in ReGenTree was 49% and has been reduced to 38.5% after filing of the final clinical study report with the FDA for the Phase 3 trial for Dry Eye Syndrome completed in 2017. Based on when, and if, ReGenTree achieves certain additional development milestones in the U.S. with RGN-259, our equity ownership may be incrementally reduced to between 38.5% and 25%, with 25% being the final equity ownership upon FDA approval of an NDA for Dry Eye Syndrome in the U.S. In addition to our equity ownership, RegeneRx retains a royalty on net sales that varies between single and low double digits, depending on whether commercial sales are made by ReGenTree or a licensee. In the event ReGenTree is acquired, or a change of control occurs following achievement of an NDA, RegeneRx shall be entitled to a minimum of 40% of all proceeds paid or payable and will forgo any future royalties.

In September 2015, ReGenTree began a Phase 2/3 clinical trial in patients with dry eye syndrome ("DES") and a Phase 3 clinical trial in patients with neurotrophic keratitis ("NK"), both in the U.S. In May 2016, we reported the results of the 317-patient Phase 2/3 trial (ARISE-1). The FDA approved ReGenTree's Phase 3 protocol for DES in late summer 2016 and we initiated a second Phase 3 trial (ARISE-2) that was completed in approximately 600 patients, the results of which were reported in October 2017. ReGenTree initiated a third Phase 3 trial (ARISE-3), and the first patient was enrolled in the second quarter of 2019 and enrollment is expected to be completed in the summer of 2020.

The NK trial (SEER-1), a smaller study in an orphan population, has enrolled seventeen patients. ReGenTree had previously disclosed that 7 of the 17 patients enrolled in SEER-1 had completely healed. To participate in the trial the patients were required to have a persistent epithelial defect (non-healing corneal wound). While these preliminary observations are encouraging, it should be noted that the patients and treating physicians remain masked while the trial is on-going, so it is not known whether the healed patients are in the RGN-259 group, placebo group, or distributed among both. We expect ReGenTree will report top line data in the next few months.

Director Independence

Under NYSE Amex listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board. Although our common stock is no longer listed on the NYSE Amex exchange, we have determined the independence of our directors using the NYSE Amex definitions of independence. Our board consults with counsel to ensure that its determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of the NYSE Amex, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his family members, and our company, our senior management and our independent auditors, our board has determined that the following three directors are independent directors within the meaning of the applicable NYSE Amex listing standards: Mr. Elsey, Mr. Bove and Mr. McNay. In making this determination, the board found that none of these directors had a material or other disqualifying relationship with us. Mr. Finkelstein, our President and Chief Executive Officer, and Dr. Goldstein our Chief Scientific Officer, are not independent by virtue of their employment with us.

In determining the independence of Mr. Bove, the board of directors considered the significant ownership of our common stock by Essetifin S.p.A. and our license agreement with Lee's Pharmaceuticals. The board of directors does not believe that any of the transactions with Lee's or Essetifin and its affiliates described in this report has interfered or would reasonably be expected to interfere with Mr. Bove's exercise of independent judgment in carrying out his responsibilities as a director of our company.

Item 14. Principal Accounting Fees and Services.

The following table represents aggregate fees billed to us for the fiscal years ended December 31, 2019 and 2018 by our independent registered public accounting firm CohnReznick LLP. All such fees described below were approved by the audit committee.

	2019	2018
Audit fees	$ 90,000	$ 73,000
Tax fees [(1)]	15,000	23,000
Total fees	$ 105,000	$ 96,000

(1) Tax fees include the preparation of our corporate federal and state income tax returns.

Our audit committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services, and tax services up to specified amounts. Pre-approval may also be given as part of the audit committee's approval of the scope of the engagement of the independent registered public accounting firm or on an individual explicit case-by-case basis before the independent registered public accounting firm is engaged to provide each service. On a periodic basis, the independent registered public accounting firm reports to the audit committee on the status of actual costs for approved services against the approved amounts.

The audit committee has determined that the rendering of the services other than audit services by CohnReznick LLP is compatible with maintaining that firm's independence.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

See Exhibit Index to Form 10-K following the signature page hereto, which is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of 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.

RegeneRx Biopharmaceuticals, Inc.
(Registrant)

Date: March 20, 2020

By: /s/ J.J. Finkelstein
J.J. Finkelstein
President and Chief Executive Officer

POWER OF ATTORNEY

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

In addition, each of the following persons hereby constitutes and appoints J.J. Finkelstein as his true and lawful attorney-in-fact and agent, with the full power of substitution, for him and in his name, to sign any and all amendments to this report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Name	Title	Date
/s/ Allan L. Goldstein Allan L. Goldstein	Chairman of the Board, Chief Scientific Officer, and Director	March 20, 2020
/s/ J.J. Finkelstein J.J. Finkelstein	President, Chief Executive Officer, and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	March 20, 2020
/s/ R. Don Elsey R. Don Elsey	Director	March 20, 2020
/s/ Joseph C. McNay Joseph C. McNay	Director	March 20, 2020
/s/ Mauro Bove Mauro Bove	Director	March 20, 2020
/s/ Alessandro Noseda Alessandro Noseda	Director	March 20, 2020

RegeneRx Biopharmaceuticals, Inc.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
RegeneRx Biopharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of RegeneRx Biopharmaceuticals, Inc. (the "Company") as of December 31, 2019 and 2018, and the related statements of operations, changes in stockholders' deficit and cash flows for the years then ended and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above 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 the years then ended in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred losses from operations since inception and will need additional capital to fund future operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 the 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 audit to obtain reasonable assurance about whether the 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 purposes 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 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 amounts and disclosures in the 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company's auditor since 2012.

Tysons, Virginia
March 20, 2020

RegeneRx Biopharmaceuticals, Inc.
Balance Sheets

	December 31, 2019	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 639,916	$ 237,261
Prepaid expenses and other current assets	41,639	36,609
Total current assets	681,555	273,870
Property and equipment, net of accumulated depreciation of $99,339 and $97,921	-	1,418
Operating lease right-of-use asset	24,453	-
Other assets	5,752	5,752
Total assets	$ 711,760	$ 281,040
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 43,678	$ 92,433
Unearned revenue	76,761	76,761
Accrued expenses	95,020	91,058
Convertible promisory notes, net	-	54,754
Current portion of operating lease liability	27,014	-
Total current liabilities	242,473	315,006
Long-term liabilities		
Unearned revenue	2,101,325	2,178,087
Convertible promisory notes, net	708,070	-
Total liabilities	3,051,868	2,493,093
Commitments and contingencies		
Stockholders' deficit		
Preferred stock, $.001 par value per share, 1,000,000 shares authorized; no shares issued	-	-
Common stock, par value $.001 per share, 200,000,000 shares authorized, 131,506,494 and 128,432,478 issued and outstanding	131,507	128,433
Additional paid-in capital	104,896,975	103,541,291
Accumulated deficit	(107,368,590)	(105,881,777)
Total stockholders' deficit	(2,340,108)	(2,212,053)
Total liabilities and stockholders' deficit	$ 711,760	$ 281,040

The accompanying notes are an integral part of these financial statements.

RegeneRx Biopharmaceuticals, Inc.
Statements of Operations

	Years ended December 31,	
	2019	2018
Revenues	$ 76,762	$ 69,667
Operating expenses		
Research and development	65,107	81,043
General and administrative	1,273,536	1,311,993
Total operating expenses	1,338,643	1,393,036
Loss from operations	(1,261,881)	(1,323,369)
Other income (expense)		
Interest income	11,044	-
Inducement expense	-	(582,904)
Interest expense	(153,410)	(87,280)
Total other expense	(142,366)	(670,184)
Loss before income taxes	(1,404,247)	(1,993,553)
Provision for income taxes	-	-
Net loss	(1,404,247)	(1,993,553)
Deemed dividend related to warrants down round provision	(82,566)	-
Net loss attributable to common stockholders	$ (1,486,813)	$ (1,993,553)
Basic net loss per common share	$ (0.01)	$ (0.02)
Diluted net loss per common share	$ (0.01)	$ (0.02)
Weighted average number of common shares outstanding - basic	130,970,754	120,716,329
Weighted average number of common shares outstanding - diluted	130,970,754	120,716,329

The accompanying notes are an integral part of these financial statements.

RegeneRx Biopharmaceuticals, Inc.
Statements of Changes in Stockholders' Deficit
Years ended December 31, 2019 and 2018

	Common stock		Additional	Accumulated	Total stockholders'
	Shares	Amount	paid-in capital	deficit	deficit
Balance, December 31, 2017	109,789,703	$ 109,790	$ 100,333,144	$ (104,559,226)	$ (4,116,292)
Issuance of common stock - note conversions	13,495,716	13,496	796,247	-	809,743
Issuance of common stock - warrant exercises	5,147,059	5,147	1,024,265	-	1,029,412
Inducement expense related to warrant reprice	-	-	582,904	-	582,904
Offering expense related to warrant reprice	-	-	(85,565)	-	(85,565)
Culmulative effect adjustment from adoption of ASU 2017-11	-	-	614,167	671,002	1,285,169
Share-based compensation expense	-	-	276,129	-	276,129
Net loss	-	-	-	(1,993,553)	(1,993,553)
Balance, December 31, 2018	128,432,478	128,433	103,541,291	(105,881,777)	(2,212,053)
Issuance of common stock - note conversions	1,149,016	1,149	67,792	-	68,941
Issuance of common stock - warrant exercises	1,925,000	1,925	238,700	-	240,625
Warrants issued with debt	-	-	348,443	-	348,443
Debt discount related to beneficial conversion feature	-	-	348,443	-	348,443
Deemed dividend related to warrant reprice	-	-	82,566	(82,566)	-
Share-based compensation expense	-	-	269,740	-	269,740
Net loss	-	-	-	(1,404,247)	(1,404,247)
Balance, December 31, 2019	131,506,494	$ 131,507	$ 104,896,975	$ (107,368,590)	$ (2,340,108)

The accompanying notes are an integral part of these financial statements.

RegeneRx Biopharmaceuticals, Inc.
Statements of Cash Flows

	Years ended December 31,	
	2019	2018
Operating activities:		
Net loss	$ (1,404,247)	$ (1,993,553)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,418	2,753
Non-cash share-based compensation	269,740	276,129
Non-cash interest expense	105,202	65,899
Inducement expense	-	582,904
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,030)	(1,167)
Accounts payable	(48,755)	25,972
Accrued expenses	23,496	22,436
Operating lease liability	(3,032)	-
Unearned revenue	(76,762)	130,333
Net cash used in operating activities	(1,137,970)	(888,294)
Financing activities:		
Payment of offering costs	-	(85,565)
Proceeds from the sale of convertible notes	1,300,000	-
Proceeds from the exercise of stock warrants	240,625	1,029,412
Net cash provided by financing activities	1,540,625	943,847
Net increase in cash and cash equivalents	402,655	55,553
Cash and cash equivalents at beginning of year	237,261	181,708
Cash and cash equivalents at end of year	$ 639,916	$ 237,261
Supplemental Disclosure of Non-Cash Operating and Financing Activities		
Conversion of promissory notes to common stock	$ 55,000	$ 646,000
Conversion of accrued interest to common stock	$ 13,941	$ 163,743
Fair value of warrants issued to placement agent	$ -	$ 15,545
Culmulative effect adjustment from adoption of ASU 2017-11	$ -	$ 1,285,169
Establishment of right-of-use asset	$ 59,822	$ -
Establishment of operating lease liability	$ 65,415	$ -
Issuance of warrants in conjunction with issuance of convertible notes	$ 348,443	$ -
Beneficial conversion feaure on issuance of convertible notes	$ 348,443	$ -

The accompanying notes are an integral part of these financial statements.

1. ORGANIZATION AND BUSINESS

Organization and Nature of Operations.

RegeneRx Biopharmaceuticals, Inc. ("RegeneRx", the "Company", "We", "Us", "Our"), a Delaware corporation, was incorporated in 1982. We are focused on the discovery and development of novel molecules to accelerate tissue and organ repair. Our operations are confined to one business segment: the development and marketing of product candidates based on Thymosin Beta 4 ("Tß4"), an amino acid peptide.

Management Plans to Address Operating Conditions.

Our strategy is aimed at being capital efficient while leveraging our portfolio of clinical assets by seeking strategic relationships with organizations with clinical development capabilities including development capital. Currently, we have active partnerships in four major territories: North America, Europe, China and Pan Asia. In each case, the cost of development is being borne by our partners with no financial obligation for RegeneRx. We still have significant clinical assets to develop, primarily RGN-352 (injectable formulation of Tß4 for cardiac and CNS disorders) in the U.S., Pan Asia, and Europe, and RGN-259 in the EU. Our goal is to wait until satisfactory results are obtained from the current ophthalmic clinical program in the U.S. before moving into the EU. However, we intend to continue to develop RGN-352, our injectable systemic product candidate for cardiac and central nervous system indications, either by obtaining grants to fund a Phase 2a clinical trial in the cardiovascular or central nervous system fields or finding a suitable partner with the resources and capabilities to develop it as we have with RGN-259.

Since inception, and through December 31, 2019, we have an accumulated deficit of $107 million and we had cash and cash equivalents of $639,916 as of December 31, 2019. We anticipate incurring additional operating losses in the future as we continue to explore the potential clinical benefits of Tß4-based product candidates over multiple indications. We have entered into a series of strategic partnerships under licensing and joint venture agreements where our partners are responsible for advancing development of our product candidates by sponsoring multiple clinical trials. In February 2019, we sold a series of convertible promissory notes to management, the Company's Board of Directors and accredited investors including Essetifin S.p.A., our largest stockholder (the "2019 Notes"). The sale of the 2019 Notes resulted in gross proceeds to the Company of $1,300,000 over two closings. The first closing in the amount of $650,000 occurred in February 2019 and the second closing, also in the amount of $650,000, occurred on May 13, 2019 after the Company provided notice of the enrollment of the first patient in the ARISE-3 clinical trial in DES sponsored by ReGenTree. The 2019 Notes contain a $0.12 conversion price and the purchasers also received a warrant exercisable at $0.18 to purchase additional shares of common stock equal to 75% of the number of shares into which each note is initially convertible (the "2019 Warrants"). In addition, we received proceeds of $115,625 pursuant to the exercise of warrants held by Sabby Management as well as $125,000 for April 2019 warrant exercises. In January 2020, Sabby exercised their remaining warrants and the Company received proceeds of $241,912. At present, with the receipt of the proceeds the January 2020 warrant exercises, we will have sufficient cash to fund planned operations through the third quarter of 2020.

While we successfully secured additional operating capital to continue operations through the third quarter of 2020, we will need substantial additional funds in order to significantly advance development of our unlicensed programs. Accordingly, we will continue to evaluate opportunities to raise additional capital and are in the process of exploring various alternatives, including, without limitation, a public or private placement of our securities, debt financing, corporate collaboration and licensing arrangements, or the sale of our Company or certain of our intellectual property rights.

These factors raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern. This basis of accounting contemplates the recovery of our assets and the satisfaction of our liabilities in the normal course of business.

Although we intend to continue to seek additional financing or additional strategic partners, we may not be able to complete a financing or corporate transaction, either on favorable terms or at all. If we are unable to complete a financing or strategic transaction, we may not be able to continue as a going concern after our funds have been exhausted, and we could be required to significantly curtail or cease operations, file for bankruptcy or liquidate and dissolve. There can be no assurance that we will be able to obtain any sources of funding. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we be forced to take any such actions.

In addition to our current operational requirements, we continually refine our operating strategy and evaluate alternative clinical uses of Tß4. However, substantial additional resources will be needed before we will be able to achieve sustained profitability. Consequently, we continually evaluate alternative sources of financing such as the sharing of development costs through strategic collaboration agreements. There can be no assurance that our financing efforts will be successful and, if we are not able to obtain sufficient levels of financing, we would delay certain clinical and/or research activities and our financial condition would be materially and adversely affected. Even if we are able to obtain sufficient funding, other factors including competition, dependence on third parties, uncertainty regarding patents, protection of proprietary rights, manufacturing of peptides, and technology obsolescence could have a significant impact on us and our operations.

To achieve profitability, we, and/or a partner, must successfully conduct pre-clinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture and market those pharmaceuticals we wish to commercialize. The time required to reach profitability is highly uncertain, and there can be no assurance that we will be able to achieve sustained profitability, if at all.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make certain estimates and assumptions that affect the reported earnings, financial position and various disclosures. Critical accounting policies involved in applying our accounting policies are those that require management to make assumptions about matters that are highly uncertain at the time the accounting estimate was made and those for which different estimates reasonably could have been used for the current period. Critical accounting estimates are also those which are reasonably likely to change from period to period and would have a material impact on the presentation of our financial condition, changes in financial condition or results of operations. Our most critical accounting estimates relate to accounting policies for revenue recognition, discount rate used to calculate the present value of the future lease payments and share-based arrangements. Management bases its estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances. Actual results could differ from these estimates.

Cash and Cash Equivalents. Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less when acquired and are stated at cost that approximates their fair market value.

Concentration of Credit Risk. Financial instruments which potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. We limit our exposure to credit loss by placing our cash and cash equivalents with high quality financial institutions and, in accordance with our investment policy, in securities that are rated investment grade.

Property and Equipment. Property and equipment consist of office furniture and equipment and is stated at cost and depreciated over the estimated useful lives of the assets (generally two to five years) using the straight-line method. Expenditures for maintenance and repairs which do not significantly prolong the useful lives of the assets are charged to expense as incurred. Depreciation expense was $1,418 and $2,753 for the years ended December 31, 2019 and 2018, respectively.

Impairment of Long-lived Assets. When we record long-lived assets, our policy is to regularly perform reviews to determine if and when the carrying value of our long-lived assets becomes impaired. During the years ended December 31, 2019 and 2018, no impairment losses were recorded.

Convertible Notes with Detachable Warrants. In accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 470-20, *Debt with Conversion and Other Options*, the proceeds received from convertible notes are allocated to the instruments based on the relative fair values of the convertible notes without the warrants and of the warrants themselves at the time of issuance. The portion of the proceeds allocated to the warrants is recognized as additional paid-in capital and a debt discount. The debt discount related to warrants is accreted into interest expense through maturity of the notes.

Derivative Financial Instruments. Derivative financial instruments consist of financial instruments or other contracts that contain a notional amount and one or more underlying variables (e.g. interest rate, security price or other variable), which require no initial net investment and permit net settlement. Derivative financial instruments may be free-standing or embedded in other financial instruments. Further, derivative financial instruments are initially, and subsequently, measured at fair value and recorded as liabilities or, in rare instances, assets.

The Company does not use derivative financial instruments to hedge exposures to cash-flow, market or foreign-currency risks. However, the Company has issued financial instruments including warrants that are either (i) not afforded equity classification, (ii) embody risks not clearly and closely related to host contracts, or (iii) may be net-cash settled by the counterparty. In certain instances, these instruments are required to be carried as derivative liabilities, at fair value, in the Company's financial statements.

The Company estimates the fair values of its derivative financials instrument using the Black-Scholes option pricing model because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk-free rates) necessary to fair value these instruments. Estimating fair values of derivative financial instruments requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the trading market price of the Company's common stock, which has a high historical volatility. Since derivative financial instruments are initially and subsequently carried at fair values, the Company's operating results reflect the volatility in these estimate and assumption changes in each reporting period.

On January 1, 2018, the Company adopted guidance for instruments with down round provisions. As a result, qualifying instruments as of December 31, 2017 of approximately $1.3 million were reclassified as equity as of January 1, 2018.

Revenue Recognition.

On January 1, 2018, we adopted guidance for revenue recognition for contracts, using the modified retrospective method. The implementation of the guidance had no material impact on the measurement or recognition of revenue from customer contracts of prior periods.

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 our customers) in an amount that reflects the consideration to which it expects to be entitled to in exchange for those goods or services. Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed, and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. We recognize revenue using the relative performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

The Company's contracts with customers may at times include multiple promises to transfer products and services. Contracts with multiple promises are analyzed to determine whether the promises, which may include a license together with performance obligations such as providing a clinical supply of product and steering committee services, are distinct and should be accounted for as separate performance obligations or whether they must be accounted for as a single performance obligation. The Company accounts for individual performance obligations separately if they are distinct. Determining whether products and services are considered distinct performance obligations may require significant judgment. If we cannot reasonably estimate when our performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance.

Whenever the Company determines that an arrangement should be accounted for as a combined performance obligation, we must determine the period over which the performance obligation will be performed and when revenue will be recognized. Revenue is recognized using either a relative performance or straight-line method. We recognize revenue using the relative performance method provided that the we can reasonably estimate the level of effort required to complete our performance obligation under an arrangement and such performance obligation is provided on a best-efforts basis. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If the Company cannot reasonably estimate the level of effort required to complete our performance obligation under an arrangement, the performance obligation is provided on a best-efforts basis and we can reasonably estimate when the performance obligation ceases or the remaining obligations become inconsequential and perfunctory, then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

At the inception of each arrangement that includes development milestone payments, the Company evaluates the probability of reaching the milestones and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur in the future, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore revenue recognized is constrained as management is unable to assert that a reversal of revenue would not be possible. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as unearned revenue in our accompanying balance sheets.

Contract assets are generated when contractual billing schedules differ from revenue recognition timing. Contract assets represent a conditional right to consideration for satisfied performance obligations that becomes a billed receivable when the conditions are satisfied. There were no contract assets as of December 31, 2019 and 2018.

Contract liabilities result from arrangements where we have received payment in advance of performance under the contract. Changes in contract liabilities are generally due to either receipt of additional advance payments or our performance under the contract.

We have the following amounts recorded for contract liabilities:

	December 31	
	2019	2018
Unearned revenue	$2,178,086	$2,254,848

The contract liabilities amount disclosed above are primarily related to revenue being recognized on a straight-line basis over periods ranging from 23 to 30 years, which, in management's judgment, is the best measure of progress towards satisfying the performance obligations and represents the Company's best estimate of the period of the obligation.

Revenue recognized from contract liabilities during the years ended December 31, 2019 and 2018, totaled $76,761 and $69,667, respectively. Revenue is expected to be recognized in the future from contract liabilities as the related performance obligations are satisfied.

Variable Interest Entities. On January 28, 2015, the Company entered into a Joint Venture Agreement with GtreeBNT, a shareholder in the Company. The Joint Venture Agreement provides for the operation of the joint venture, jointly owned by the Company and GtreeBNT, which is commercializing RGN-259 for the treatment of dry eye and neurotrophic keratitis in the U.S. and Canada. The Company has determined that the Joint Venture is a "variable interest entity", since the total equity investment at risk is not sufficient to permit the Joint Venture to finance its activities without additional subordinated financial support. Further, because of GtreeBNT's majority equity stake in the Joint Venture, voting control, control of the board of directors, and substantive management rights, and given that the Company does not have the power to direct the Joint Venture's activities that most significantly impact its economic performance, the Company determined that it is not the primary beneficiary of the Joint Venture and therefore is not required to consolidate the Joint Venture. The Company reports its equity stake in the Joint Venture using the equity method of accounting because, while it does not control the Joint Venture, the Company can exert significant influence over the Joint Ventures activities by virtue of its board representation.

Because the Company is not obligated to fund the Joint Venture and has not provided any financial support and has no commitment to provide financial support in the future to the Joint Venture, the carrying value of its investment in the Joint Venture is zero at both December 31, 2019 and 2018. As a result, the Company is not recognizing its share (38.5%) of the Joint Venture's operating losses and will not recognize any such losses until the Joint Venture produces net income (as opposed to net losses) and at that point the Company will reduce its share of the Joint Venture's net income by its share of previously suspended net losses. As of December 31, 2019, because it has not provided any financial support, the Company has no financial exposure as a result of its variable interest in the Joint Venture.

Research and Development. R&D expenditures are expensed as incurred and are subject to the risks and uncertainties associated with clinical trials and the FDA review and approval process. As a result, these expenses could exceed our expectations, possibly materially. We are uncertain as to what we will incur in future research and development costs for our clinical studies, as these amounts are subject to, management's continuing assessment of the economics of each individual research and development project and the internal competition for project funding.

Patent Costs. Costs related to filing and pursuing patent applications are recognized as general and administrative expenses as incurred since recoverability of such expenditures is uncertain.

Income Taxes. Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Tax Cuts and Jobs Act, which was enacted on December 22, 2017, included a number of changes to existing U.S. tax laws, most notably the reduction of the U.S. corporate income tax rate from 35% to 21%, beginning in 2018. We remeasured our deferred tax assets and deferred tax liabilities as of December 31, 2017 to reflect the reduction in the enacted U.S. corporate income tax rate.

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making that assessment. We recorded a full valuation allowance against all estimated net deferred tax assets at December 31, 2019 and 2018.

We recognize the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. Our policy for recording interest and penalties associated with audits is that penalties and interest expense are recorded in provision for income taxes in our statements of operations.

We have significant net operating loss carryforwards to potentially reduce future federal and state taxable income, and research and experimentation tax credit carryforwards available to potentially offset future federal and state income taxes. Use of our net operating loss and research and experimentation credit carryforwards may be limited due to changes in our ownership as defined within Section 382 of the Internal Revenue Code.

Net Loss Per Common Share. Basic net loss per common share for 2019 and 2018 is based on the weighted-average number of shares of common stock outstanding during the years. Diluted loss per share is based on the weighted average number of shares of common stock outstanding during each year in which a loss is incurred; potentially dilutive shares are excluded because the effect is antidilutive. In years where there is net income, diluted income per share is based on the weighted average number of shares of common stock outstanding plus dilutive securities with a purchase or conversion price below the per share price of our common stock on the last day of the year. The potentially dilutive securities include 31,075,178 shares and 14,182,086 shares in 2019 and 2018, respectively, reserved for the conversion of convertible debt or exercise of outstanding options and warrants.

Share-Based Compensation. We measure share-based compensation expense based on the grant date fair value of the awards which is then recognized over the period which service is required to be provided. We estimate the grant date fair value using the Black-Scholes option-pricing model (“Black-Scholes”). We recognized $269,740 and $276,129 in share-based compensation expense for the years ended December 31, 2019 and 2018, respectively.

Fair Value of Financial Instruments. The carrying amounts of our financial instruments, as reflected in the accompanying balance sheets, approximate fair value. Financial instruments consist of cash and cash equivalents, accounts payable, and convertible debt and accrued interest. Because the convertible debt with an interest rate of 5% is with related parties, it was not practicable to estimate the effect of subjective risk factors, which might influence the value of the debt. The most significant of these risk factors include the lack of collateralization.

Recently Adopted Accounting Pronouncements.

In June 2018, the FASB issued Accounting Standards Update (“ASU”) 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.* This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. The Company adopted ASU 2018-07 in the first quarter of 2019 and the adoption of this ASU did not have a material impact on its financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (“ASC 842”), which amends the existing accounting standards for leases. The new standard requires lessees to record an ROU asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases), whereas under prior accounting standards, the Company’s lease portfolio consists of an operating lease and was not recognized on its balance sheets. The new standard also requires expanded disclosures regarding leasing arrangements. The new standard was effective for the Company beginning January 1, 2019. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides an alternative modified transition method. Under this method, the cumulative-effect adjustment to the opening balance of retained earnings is recognized on the date of adoption with prior periods not restated. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We adopted this guidance effective January 1, 2019, using the following practical expedients:

- We did not reassess if any expired or existing contracts are, or contain, leases.

- We did not reassess the classification of any expired or existing leases.

Additionally, we made ongoing accounting policy elections whereby we (i) do not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12 months or less) and (ii) combine lease and non-lease elements of our operating leases.

Upon adoption of the new guidance on January 1, 2019, we recorded a ROU asset of approximately $60,000 (net of existing deferred rent liability) and recognized a lease liability of approximately $65,000, with no resulting cumulative effect adjustment to accumulated deficit.

Accounting Standard Not Yet Adopted

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. The amendment clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation and disclosure requirements. The amendment also adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606. Lastly, the amendment requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. For public business entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company is currently evaluating these clarifications but does not expect it will have any material impact.

The Company has evaluated all other issued and unadopted ASUs and believes the adoption of these standards will not have a material impact on its results of operations, financial position or cash flows.

3. FAIR VALUE MEASUREMENTS

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 — Quoted prices in active markets for identical assets and liabilities.

- Level 2 — Observable inputs other than quoted prices in active markets for identical assets and liabilities.

- Level 3 — Unobservable inputs.

As of December 31, 2019 and 2018, our only qualifying assets that required measurement under the foregoing fair value hierarchy were funds held in our Company bank accounts included in Cash and Cash Equivalents valued at $639,916 and $237,261, respectively, using Level 1 inputs.

4. LICENSES, INTELLECTUAL PROPERTY, AND RELATED PARTY TRANSACTIONS

We have filed numerous additional patent applications covering various compositions, uses, formulations and other components of T-4, as well as to novel peptides resulting from our research efforts. Some of these patents have been issued, while many patent applications are still pending.

We have also entered into an agreement with a university under the terms of which we have received an exclusive license to technology and intellectual property. The agreement, which is generally cancelable by us, provided for the payment of a license issue fee and/or minimum annual payments. The initial license fee of $25,000 was paid in 2010 and no minimum fees were due for the year ended December 31, 2011. Beginning in 2012, minimum annual maintenance fees are $5,000 annually which was paid in 2012 but has not been paid since. In addition, the agreements provide for payments upon the achievement of certain milestones in product development. The agreement also requires us to fund certain costs associated with the filing and prosecution of patent applications. In February 2013, this agreement was amended to include additional technology and intellectual property. The expanded license does not require payment of an initial license fee or additional annual maintenance fees but will be subject to payments upon the achievement of certain milestones for a product developed under the amended license of the additional technology and intellectual property.

All license fees are included in Research and Development in the accompanying statements of operations.

In 2012, we entered into a license agreement (the "Agreement") with Lee's Pharmaceutical (HK) Limited ("Lee's"), headquartered in Hong Kong, for the license of Thymosin Beta 4 in any pharmaceutical form, including our RGN-259, RGN-352 and RGN-137 product candidates, in China, Hong Kong, Macau and Taiwan. Under the agreement, we are eligible to receive milestone payments and royalties, ranging from low double digit to high single digit percentages of any commercial sales of the licensed products. Lee's will pay for all developmental costs associated with each product candidate. We will provide Tß4 to Lee's at no charge for a Phase 2 ophthalmic clinical trial and will provide Tß4 to Lee's for all other developmental and clinical work at a price equal to our cost. We will also have the right to exclusively license any improvements made by Lee's to RegeneRx's products outside of the licensed territory. Lee's paid us $200,000 upon signing of a term sheet in March 2012, and Lee's paid us an additional $200,000 upon signing of the definitive license agreement. The Company is accounting for the license agreement as a revenue arrangement. Since participation in the joint development committee is required it was deemed to be a material promise. Management has concluded that the participation in the joint development committee is not distinct from other promised goods and services. The Company assessed the license agreement in accordance with ASC 606. The Company evaluated the promised goods and services under the agreement and determined that there was one combined performance obligation representing a series of distinct goods and services including the license to research, develop and commercialize Tß4 in any pharmaceutical form and participation in the joint development committee. To date, management has not been able to reasonably measure the outcome of the performance obligation, but still expects to recover the costs incurred in satisfying the performance obligation. Accordingly, the Company has deferred all revenue until such time that it can reasonably measure the outcome of the performance obligation or until the performance obligation becomes onerous. As of December 31, 2019 and 2018, we have unearned revenue totaling $400,000 pursuant to this agreement. Revenue will be recognized for future royalty payments as they are earned. In February 2019, the license agreement was amended and assigned by Lee's to their affiliate, Zhaoke Ophthalmology Pharmaceutical Limited. There are no economic changes to the agreement.

On March 7, 2014, we entered into license agreements with GtreeBNT Co., Ltd. The two Licensing Agreements are for the license of territorial rights to two of our Thymosin Beta 4-based products candidates, RGN-259 and RGN-137.

Under the license agreement for RGN-259, our preservative-free eye drop product candidate, GtreeBNT will have the right to develop and commercialize RGN-259 in Asia (excluding China, Hong Kong, Taiwan, and Macau). The rights will be exclusive in Korea, Japan, Australia, New Zealand, Brunei, Cambodia, East Timor, Indonesia, Laos, Malaysia, Mongolia, Myanmar (Burma), Philippines, Singapore, Thailand, Vietnam, and Kazakhstan, and semi-exclusive in India, Pakistan, Bangladesh, Bhutan, Maldives, Nepal, Sri Lanka, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan, collectively, the Territory (the "259 Territory"). Under the 259 license agreement we are eligible to receive aggregate potential milestone payments of up to $3.5 million. In addition, we are eligible to receive royalties of a low double-digit percentage of any commercial sales of the licensed product sold by GtreeBNT in the 259 Territory.

Under the license agreement for RGN-137, our topical dermal gel product candidate, GtreeBNT will have the exclusive right to develop and commercialize RGN-137 in the U.S. (the "137 Territory"). Under the 137 agreement we are eligible to receive aggregate potential milestone payments of up to $3.5 million. In addition, we are eligible to receive royalties of a low double-digit percentage of any commercial sales of the Company's licensed product sold by GtreeBNT in the 137 Territory. In August 2017, we amended the license agreement for RGN-137 held by GtreeBNT. Under the amendment, the 137 Territory was expanded to include Europe, Canada, South Korea, Australia and Japan. Under the agreement, the Company received a series of non-refundable payments and is entitled to receive royalties on the future sales of products. The Company is accounting for the license agreement as a revenue arrangement. Since participation in the joint development committee is required it was deemed to be a material promise. Management has concluded that the participation in the joint development committee is not distinct from other promised goods and services. The Company assessed the license agreement in accordance with ASC 606. The Company evaluated the promised goods and services under the agreement and determined that there was one combined performance obligation representing a series of distinct goods and services including the license to research, develop and commercialize RGN-137 and participation in the joint development committee. Revenue is being recognized on a straight-line basis over a period of 23 years, which, in management's judgment, is the best measure of progress towards satisfying the performance obligation and represents the Company's best estimate of the period of the obligation. As of December 31, 2019 and 2018, we have unearned revenue totaling $718,480 and $753,623, respectively, pursuant to this agreement. Revenue will be recognized for future royalty payments as they are earned.

Each license agreement contains diligence provisions that require the initiation of certain clinical trials within certain time periods that, if not met, would result in the loss of rights or exclusivity in certain countries. GtreeBNT will pay for all developmental costs associated with each product candidate. We have the right to exclusively license any improvements made by GtreeBNT to our products outside of the licensed territory on a royalty free basis. The two firms have created a joint development committee and continue to discuss the development of the licensed products and share information relating thereto. Both companies will also share all non-clinical and clinical data and other information related to development of the licensed product candidates.

On January 28, 2015, the Company entered into the Joint Venture Agreement with GtreeBNT, a shareholder in the Company. The Joint Venture Agreement provides for the creation of the Joint Venture, jointly owned by the Company and GtreeBNT, which is commercializing RGN-259 for treatment of dry eye and neurotrophic keratitis in the U.S. and Canada.

GtreeBNT is solely responsible for funding all the product development and commercialization efforts of the Joint Venture. GtreeBNT made an initial contribution of $3 million in cash and received an initial equity stake of 51%. RegeneRx's ownership interest in ReGenTree was reduced to 38.5% when the Clinical Study Report was filed for the Phase 2/3 dry eye clinical trial. Based on when, and if, certain additional development milestones are achieved in the U.S. with RGN-259, our equity ownership may be incrementally reduced to between 38.5% and 25%, with 25% being the final equity ownership upon approval of an NDA for DES in the U.S. In addition to our equity ownership, RegeneRx retains a royalty on net sales that varies between single and low double digits, depending on whether commercial sales are made by ReGenTree or a licensee. In the event ReGenTree is acquired or there is a change of control that occurs following achievement of an NDA, RegeneRx shall be entitled to a minimum of 40% of all proceeds paid or payable and will forgo any future royalties. The Company is not required or otherwise obligated to provide financial support to the Joint Venture.

The Joint Venture is responsible for executing all development and commercialization activities under the license agreement, which activities will be directed by a joint development committee comprised of representatives of the Company and GtreeBNT. The license agreement has a term that extends to the later of the expiration of the last patent covered by the agreement or 25 years from the first commercial sale under the agreement. The license agreement may be earlier terminated if the Joint Venture fails to meet certain commercialization milestones, if either party breaches the license agreement and fails to cure such breach, as a result of government action that limits the ability of the Joint Venture to commercialize the product, as a result of a challenge to a licensed patent, following termination of the license between the Company and certain agencies of the United States federal government, or upon the bankruptcy of either party.

Under the license agreement, the Company received $1.0 million in up-front payments and is entitled to receive royalties on the Joint Venture's future sales of products. On April 6, 2016, we received $250,000 from ReGenTree and executed an amendment to the license agreement on April 28, 2016. Under the amendment the territorial rights were expanded to include Canada. The Company is accounting for the license agreement with the Joint Venture as a revenue arrangement. Since participation in the joint development committee is required it was deemed to be a material promise. Management has concluded that the participation in the joint development committee is not distinct from other promised goods and services. The Company assessed the license agreements in accordance with ASC 606. The Company evaluated the promised goods and services under the license agreements and determined that there was one combined performance obligation representing a series of distinct goods and services including the license to research, develop and commercialize RGN-259 and participation in the joint development committee. Revenue is being recognized on a straight-line basis over a period of 30 years, which, in management's judgment, is the best measure of progress towards satisfying the performance obligation and represents the Company's best estimate of the period of the obligation. As of December 31, 2019 and 2018, we have unearned revenue totaling $1,059,246 and $1,101,225, respectively, pursuant to this agreement. Revenue will be recognized for future royalty payments as they are earned.

5. COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

Prepaid expenses and other current assets are comprised of the following:

	December 31,	
	2019	2018
Prepaid insurance	$ 27,453	$ 7,604
Other	14,186	29,005
	$ 41,639	$ 36,609

Accrued expenses are comprised of the following:

	December 31,	
	2019	2018
Accrued professional fees	$ 8,479	$ 9,480
Accrued other	23,000	32,459
Accrued compensation	15,565	35,411
Accrued interest - convertible debt	47,976	13,708
	$ 95,020	$ 91,058

6. EMPLOYEE BENEFIT PLANS

In 2019 and 2018, the Company provided health and dental insurance to an employee under a group plan. No retirement plan was in place for 2019 or 2018.

7. CONVERTIBLE NOTES

2013 Convertible Notes

On March 29, 2013, we completed a private placement of convertible notes (the “March 2013 Notes”) raising an aggregate of $225,000 in gross proceeds. The March 2013 Notes bore interest at a rate of five percent (5%) per annum, matured sixty (60) months after their date of issuance and were convertible into shares of our common stock at a conversion price of six cents ($0.06) per share (subject to adjustment as described in the March 2013 Notes) at any time prior to repayment, at the election of the investors. In the aggregate, the March 2013 Notes were initially convertible into up to 3,750,000 shares of our common stock.

At any time prior to maturity of the March 2013 Notes, with the consent of the holders of a majority in interest of the March 2013 Notes, we could prepay the outstanding principal amount of the March 2013 Notes plus unpaid accrued interest without penalty. Upon the commission of any act of bankruptcy by the Company, the execution by the Company of a general assignment for the benefit of creditors, the filing by or against the Company of a petition in bankruptcy or any petition for relief under the Federal bankruptcy act or the continuation of such petition without dismissal for a period of ninety (90) days or more, or the appointment of a receiver or trustee to take possession of the property or assets of the Company, the outstanding principal and all accrued interest on the March 2013 Notes would accelerate and automatically become immediately due and payable.

The investors in the offering included two members of the Board of Directors, Dr. Goldstein and Joseph C. McNay, an outside director. The principal amounts of their respective March 2013 Notes are as set forth below:

Investor	Note Principal
Joseph C. McNay	$ 50,000
Allan L. Goldstein	$ 25,000

The Company evaluated the terms of the March 2013 Notes which contained a down round provision under which the conversion price could be decreased as a result of future equity offerings, as defined in the March 2013 Notes. The adjustment would reduce the conversion price of the March 2013 Notes to be equivalent to that of the newly issued stock or stock-related instruments. As a result, the Company concluded that the conversion feature represented an embedded conversion feature for accounting purposes and should be recognized as a derivative liability, requiring a mark-to-market adjustment at the end of each reporting period until the related March 2013 Notes have been settled prior to the adoption of ASU 2017-11. The bifurcated liability of $225,000 was recorded on the date of issuance which resulted in a residual debt value of $0. The discount related to the embedded feature was accreted as an addition to the debt through the maturity of the notes. The March 2013 Notes matured, and the holders elected to convert the note balances of $225,000 and accrued interest of approximately $57,000 into common stock in March 2018.

On July 5, 2013, we completed a private placement of convertible notes (the “July 2013 Notes”) raising an aggregate of $100,000 in gross proceeds. The July 2013 Notes bore interest at a rate of five percent (5%) per annum, matured sixty (60) months after their date of issuance and were convertible into shares of our common stock at a conversion price of six cents ($0.06) per share (subject to adjustment as described in the July 2013 Notes) at any time prior to repayment, at the election of the investors. In the aggregate, the July 2013 Notes were initially convertible into up to 1,666,667 shares of our common stock.

At any time prior to maturity of the July 2013 Notes, with the consent of the holders of a majority in interest of the July 2013 Notes, we could prepay the outstanding principal amount of the July 2013 Notes plus unpaid accrued interest without penalty. Upon the commission of any act of bankruptcy by the Company, the execution by the Company of a general assignment for the benefit of creditors, the filing by or against the Company of a petition in bankruptcy or any petition for relief under the federal bankruptcy act or the continuation of such petition without dismissal for a period of ninety (90) days or more, or the appointment of a receiver or trustee to take possession of the property or assets of the Company, the outstanding principal and all accrued interest on the July 2013 Notes would accelerate and automatically become immediately due and payable.

The investors in the offering included three current and one former member of Board of Directors, Mr. Finkelstein, Dr. Goldstein, Mr. McNay and L. Thompson Bowles, previously an outside director. The principal amounts of their respective July 2013 Notes are as set forth below:

Investor	Note Principal
Joseph C. McNay	$ 50,000
Allan L. Goldstein	$ 10,000
J.J. Finkelstein	$ 5,000
L. Thompson Bowles	$ 5,000

The Company evaluated the terms of the July 2013 Notes which contained a down round provision under which the conversion price could be decreased as a result of future equity offerings, as defined in the July 2013 Notes. The adjustment would reduce the conversion price of the July 2013 Notes to be equivalent to that of the newly issued stock or stock-related instruments. As a result, the Company concluded that the conversion feature represented an embedded conversion feature for accounting purposes and should be recognized as a derivative liability, requiring a mark-to-market adjustment at the end of each reporting period until the related July 2013 Notes have been settled prior to the adoption of ASU 2017-11. The bifurcated liability of $66,667 was recorded on the date of issuance which resulted in a residual debt value of $33,333. The discount related to the embedded feature was accreted back to debt through the maturity of the notes. The July 2013 Notes matured, and the holders elected to convert the note balances of $100,000 and accrued interest of approximately $25,000 into common stock in July 2018.

On September 11, 2013, we completed a private placement of convertible notes raising an aggregate of $321,000 in gross proceeds (the “September 2013 Notes”). The September 2013 Notes bore interest at a rate of five percent (5%) per annum, matured sixty (60) months after their date of issuance and were convertible into shares of our common stock at a conversion price of six cents ($0.06) per share (subject to adjustment as described in the September 2013 Notes) at any time prior to repayment, at the election of the investor. In the aggregate, the September 2013 Notes were initially convertible into up to 5,350,000 shares of our common stock.

At any time prior to maturity of the September 2013 Notes, with the consent of the holders of a majority in interest of the September 2013 Notes, we could prepay the outstanding principal amount of the September 2013 Notes plus unpaid accrued interest without penalty. Upon the commission of any act of bankruptcy by the Company, the execution by the Company of a general assignment for the benefit of creditors, the filing by or against the Company of a petition in bankruptcy or any petition for relief under the federal bankruptcy act or the continuation of such petition without dismissal for a period of ninety (90) days or more, or the appointment of a receiver or trustee to take possession of the property or assets of the Company, the outstanding principal and all accrued interest on the September 2013 Notes would accelerate and automatically become immediately due and payable.

The investors in the offering included an affiliate and three current and one former member of the Board of Directors. The principal amounts of their respective September 2013 Notes are as set forth below:

Investor	Note Principal
SINAF S.A.	$ 150,000
Joseph C. McNay	$ 100,000
Allan L. Goldstein	$ 11,000
L. Thompson Bowles	$ 5,000
R. Don Elsey	$ 5,000

The Company evaluated the terms of the September 2013 Notes which contained a down round provision under which the conversion price could be decreased as a result of future equity offerings, as defined in the September 2013 Notes. The adjustment would reduce the conversion price of the September 2013 Notes to be equivalent to that of the newly issued stock or stock-related instruments. As a result, the Company concluded that the conversion feature represented an embedded conversion feature for accounting purposes and should be recognized as a derivative liability, requiring a mark-to-market adjustment at the end of each reporting period until the related September 2013 Notes have been settled prior to the adoption of ASU 2017-11. The bifurcated liability of $267,500 was recorded on the date of issuance which resulted in a residual debt value of $53,500. The discount related to the embedded feature was accreted back to debt through the maturity of the notes. The September 2013 Notes matured, and the holders elected to convert the note balances of $321,000 and accrued interest of approximately $81,000 into common stock in September 2018.

2014 Convertible Notes

On January 7, 2014, we completed a private placement of convertible notes raising an aggregate of $55,000 in gross proceeds (the “January 2014 Notes”). The January 2014 Notes bore interest at a rate of 5% per annum, mature sixty (60) months after their date of issuance and were convertible into shares of our common stock at a conversion price of six cents ($0.06) per share (subject to adjustment as described in the January 2014 Notes) at any time prior to repayment, at the election of the investor. In the aggregate, the January 2014 Notes were initially convertible into up to 916,667 shares of our common stock.

At any time prior to maturity of the January 2014 Notes, with the consent of the holders of a majority in interest of the January 2014 Notes, we could prepay the outstanding principal amount of the January 2014 Notes plus unpaid accrued interest without penalty. Upon the commission of any act of bankruptcy by the Company, the execution by the Company of a general assignment for the benefit of creditors, the filing by or against the Company of a petition in bankruptcy or any petition for relief under the federal bankruptcy act or the continuation of such petition without dismissal for a period of 90 days or more, or the appointment of a receiver or trustee to take possession of the property or assets of the Company, the outstanding principal and all accrued interest on the January 2014 Notes would accelerate and automatically become immediately due and payable.

The investors in the offering included two current and one former member of the Board of Directors. The principal amounts of their respective January 2014 Notes were as set forth below:

Investor	Note Principal
Joseph C. McNay	$ 25,000
Allan L. Goldstein	$ 10,000
L. Thompson Bowles	$ 5,000

The Company evaluated the terms of the January 2014 Notes which contain a down round provision under which the conversion price could be decreased as a result of future equity offerings, as defined in the January 2014 Notes. The adjustment would reduce the conversion price of the January 2014 Notes to be equivalent to that of the newly issued stock or stock-related instruments. As a result, the Company concluded that the conversion feature represented an embedded conversion feature for accounting purposes and should be recognized as a derivative liability, requiring a mark-to-market adjustment at the end of each reporting period until the related January 2014 Notes have been settled prior to the adoption of ASU 2017-11. The bifurcated liability of $55,000 was recorded on the date of issuance which resulted in a residual debt value of $0. The discount related to the embedded feature is being accreted back to debt through the maturity of the notes. The January 2014 Notes matured, and the holders elected to convert the note balances of $55,000 and accrued interest of approximately $14,000 into common stock in January 2019.

2019 Convertible Notes

In February 2019, we sold a series of convertible promissory notes to management, the Company's Board of Directors and accredited investors including Essetifin S.p.A., our largest stockholder. The sale of the notes resulted in gross proceeds to the Company of $1,300,000 over two closings (the "2019 Notes"). The first closing in the amount of $650,000 occurred in February 2019 and the second closing, also in the amount of $650,000, occurred on May 13, 2019 after the Company provided notice of the enrollment of the first patient in the ARISE-3 clinical trial in DES sponsored by ReGenTree. The 2019 Notes will mature on March 1, 2024. The 2019 Notes bear interest at a rate of five percent (5%) per annum and are convertible into shares of our common stock at a conversion price of twelve cents ($0.12) per share (subject to adjustment as described in the 2019 Notes) at any time prior to repayment, at the election of the investors. In the aggregate, the 2019 Notes issued in both closings are convertible into up to 10,833,333 shares of our common stock excluding interest.

At any time prior to maturity of the 2019 Notes, with the consent of the holders of a majority in interest of the 2019 Notes, we can prepay the outstanding principal amount of the 2019 Notes plus unpaid accrued interest without penalty. The outstanding principal and all accrued interest on the 2019 Notes will accelerate and automatically become immediately due and payable upon the occurrence of certain events of default.

In connection with the issuance of the 2019 Notes we also issued warrants to each investor. The warrants are exercisable for an aggregate of 8,125,000 shares of common stock with an exercise price of eighteen cents ($0.18) per share for a period of five years (the "2019 Warrants"). The relative fair value of the 2019 Warrants issued was $348,443 calculated using the Black-Scholes-Merton valuation model value of $0.06 with an expected and contractual life of five years, an assumed volatility of 67.86%, and a risk-free interest rate of 2.49%. The 2019 Warrants are classified in equity.

The Company allocated $348,443 of the gross proceeds to the warrants, on a relative fair value basis. In addition, because the effective conversion price of the 2019 Notes was less than the fair value of the underlying common stock on the issuance date, we allocated the intrinsic value of that feature to additional paid in capital. The debt discount created by the 2019 Warrants and beneficial conversion feature is amortized over the term of the 2019 Notes as additional interest expense using the effective interest method.

The affiliated investors and the principal amount of their respective 2019 Notes purchase are as set forth below:

Investor	Note Principal
Essetifin S.p.A.	$ 1,000,000
Joseph C. McNay	$ 25,000
J.J. Finkelstein	$ 25,000
Mauro Bove	$ 10,000
Allan L. Goldstein	$ 5,000
R. Don Elsey	$ 5,000

Essetifin S.p.A., our largest stockholder, is currently the holder of all of our securities previously held by Sigma-Tau and its affiliates. The other listed investors are members of our Board of Directors including Mr. Finkelstein, who serves as our CEO, and Dr. Goldstein who serves as our Chief Scientific Advisor and Chairman of our Board of Directors.

The Company recorded interest expense and discount accretion as set forth below:

	For the years ended	
	December 31, 2019	December 31, 2018
March 2013 Notes	$ -	$ 14,192
July 2013 Notes	-	9,677
September 2013 Notes	-	49,661
January 2014 Notes	479	13,750
2019 Notes	152,931	-
Total interest expense	$ 153,410	$ 87,280

8. STOCKHOLDERS' EQUITY

Common Stock. In January 2019, the January 2014 Notes matured, and the holders elected to convert the note balances and accrued interest into common stock. As a result, we issued 1,149,016 shares of common stock. In March, July and September of 2018, the March 2013, July 2013 and September 2013 Notes matured, and the holders elected to convert the note balances and accrued interest into common stock. As a result, we issued 4,700,520, 2,089,120 and 6,706,076 shares of common stock, respectively (see Note 7).

On March 2, 2018, we entered into the Reprice Agreement with Sabby Healthcare Master Fund, Ltd., and Sabby Volatility Warrant Master Fund, Ltd. (collectively, "Sabby"). In connection with that certain securities purchase agreement between the Company and Sabby dated June 27, 2016 (the "Purchase Agreement") we also issued to Sabby warrants to purchase 5,147,059 shares of common stock (the "Warrant Shares") at an exercise price of $0.51 per share (the "Sabby Warrants"). Under the terms of the Reprice Agreement, in consideration of Sabby exercising in full all of the Sabby Warrants (the "Warrant Exercise"), the exercise price per share of the Sabby Warrants was reduced to $0.20 per share. We received gross proceeds of approximately $1,029,000 from the warrant reprice transaction. In addition, and as further consideration, we issued to Sabby warrants to purchase up to 3,860,294 shares of common stock at an exercise price of $0.2301 per share, the closing bid price for the Company's Common Stock on February 28, 2018 (the "March Warrants").

The exercise price under the March Warrants is subject to a limited anti-dilution provision, such that in the event the Company makes an issuance of common stock (subject to customary exceptions) at a price per share less than the applicable exercise price of the March Warrants, the exercise price of the March Warrants will be reduced to the price per share applicable to such new issuance but will not adjust to an exercise price below $0.125. As a result of the issuance of the 2019 Notes and Warrants, the exercise price of the March Warrants was adjusted to $0.125 per share. The estimated fair value of the effect of the exercise price adjustment of $82,566 is reflected as a dividend to Sabby for the year end December 31, 2019.

Subsequent to the reduction of the exercise price of the March Warrants to $0.125 in 2019, Sabby exercised warrants for 925,000 shares of common stock and the Company received exercise proceeds of $115,625. Sabby exercised additional warrants on April 23, 2019 for 1,000,000 shares of common stock and the Company received exercise proceeds of $125,000.

The Reprice Agreement was accounted for as an inducement and consequently, we recognized a non-operating expense of $582,904 equal to the fair value of the New Warrants calculated using a customized Monte Carlo simulation. The repricing of the Warrant Shares did not result in any incremental fair value and consequently did not result in any additional expense.

In conjunction with the Reprice Agreement we incurred $101,110 of expenses comprised of: (i) 102,947 warrants valued at $15,545 issued to an outside third party as a fee for the transaction and (ii) $85,565 of expenses for professional fees. Such expenses were netted against the proceeds from the transaction. The warrants contained the same terms and conditions as the New Warrants and were valued using the Black-Scholes model.

Registration Rights Agreements. In connection with the sale of certain equity instruments, we have entered into Registration Rights Agreements. Generally, these Agreements required us to file registration statements with the Securities and Exchange Commission to register common shares to permit re-sale of common shares previously sold under an exemption from registration or to register common shares that may be issued on exercise of outstanding warrants.

The Registration Rights Agreements usually require us to pay penalties for any failure or time delay in filing or maintaining the effectiveness of the required registration statements. These penalties are usually expressed as a fixed percentage, per month, of the original amount we received on issuance of the common shares, options or warrants. While to date we have not incurred any penalties under these agreements, if a penalty is determined to be probable, we would recognize the amount as a contingent liability and not as a derivative instrument.

Share-Based Compensation. We recognized $269,740 and $276,129 in stock-based compensation expense for the years ended December 31, 2019 and 2018, respectively. We expect to recognize the compensation cost related to non-vested options as of December 31, 2019 of $368,000 over the weighted average remaining recognition period of 1.2 years.

Stock Option and Incentive Plans. On June 13, 2018, at our Annual Meeting of Stockholders, our stockholders approved the 2018 Equity Incentive Plan (the "2018 Plan"). The terms of the 2018 Plan provide for the discretionary grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, other stock awards and performance cash awards to our employees, directors and consultants. The total number of shares of our common stock reserved for issuance under the 2018 Plan was initially 5,000,000 shares of common stock with additional shares being available for grant under the plan annually in an amount equal to 2% of the then outstanding shares of common stock on July 1 of each calendar year. Pursuant to this plan provision, on July 1, 2019, 2,630,130 additional shares of common stock became available for grant under the 2018 Plan.

We have previously adopted two equity incentive plans, known as the 2000 Equity Incentive Plan, or the 2000 Plan, and the 2010 Equity Incentive Plan, or the 2010 Plan. Both the 2000 Plan and the 2010 Plan have a term of ten years, with the 2000 Plan already expired and the 2010 Plan was scheduled to expire in July 2020. No further awards may be granted under the 2010 Plan with the approval of the 2018 Plan. All outstanding option awards granted under the 2010 Plan will continue to be subject to the terms and conditions as set forth in the agreements evidencing such option awards and the terms of the 2010 Plan. Shares remaining available for issuance under the shares reserved under the 2010 Plan will not be subject to future awards under the 2018 Plan, and shares subject to outstanding awards under the 2010 Plan that are terminated or forfeited in the future will not be subject to future awards under the 2018 Plan. All outstanding option awards granted under the 2000 Plan have expired.

The following summarizes share-based compensation expense for the years ended December 31, 2019 and 2018, which was allocated as follows:

	December 31,	
	2019	**2018**
Research and development	$ 63,207	$ 79,143
General and administrative	206,533	196,986
	$ 269,740	$ 276,129

The following summarizes stock option activity for the years ended December 31, 2019 and 2018:

		Options Outstanding		
	Shares available for grants	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2017	109,179	8,058,788	$ 0.14 - 0.64	$ 0.29
2018 Plan approved	5,000,000	-	-	-
Grants	(1,605,000)	1,605,000	0.21	0.21
Expirations	618,963	(618,963)	0.16 - 0.22	0.19
December 31, 2018	4,123,142	9,044,825	0.14 - 0.64	0.28
2018 Plan additons	2,630,130	-	-	-
Grants	(2,415,000)	2,415,000	0.21	0.21
Expirations	-	(1,638,575)	0.14 - 0.57	0.21
2010 Plan Expiration	(728,142)	-	-	-
December 31, 2019	3,610,130	9,821,250	$ 0.16 - 0.64	$ 0.28
Vested and expected to vest at December 31, 2019		9,690,671		
Exercisable at December 31, 2019		6,957,500		

The following summarizes information about stock options outstanding at December 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Options Outstanding, December 31, 2018	9,044,825	$ 0.28		
Granted	2,415,000	$ 0.21		
Exercised	-	$ -		
Forfeited	(1,638,575)	$ 0.21		
Options Outstanding, December 31, 2019	9,821,250	$ 0.28	5.5 years	$ -
Vested and unvested but expected to vest, December 31, 2019	9,690,671	$ 0.28	5.5 years	$ -
Exercisable at December 31, 2019	6,957,500	$ 0.30	4.0 years	$ -

Determining the Fair Value of Options. We use the Black-Scholes valuation model to estimate the fair value of options granted. Black-Scholes considers a number of factors, including the market price and volatility of our common stock. We used the following forward-looking range of assumptions to value each stock option granted to employees, directors and consultants during the years ended December 31, 2019 and 2018:

	2019	2018
Dividend yield	0.0%	0.0%
Risk-free rate of return	2.15%	2.76%
Expected life in years	5.88	5.88
Volatility	93.59%	88.57%
Forfeiture rate	2.6%	2.6%

Our dividend yield assumption is based on the fact that we have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. Our risk-free interest rate assumption is based on yields of U.S. Treasury notes in effect at the date of grant. Our expected life represents the period of time that options granted are expected to be outstanding and is calculated in accordance with the Securities and Exchange Commission ("SEC") guidance provided in the SEC's Staff Accounting Bulletin ("SAB") 107 and SAB 110, using a "simplified" method. The Company has used the simplified method and will continue to use the simplified method as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate an expected term. Our volatility assumption is based on reviews of the historical volatility of our common stock. Using Black-Scholes and these factors, the weighted average fair value of stock options granted to employees and directors was $0.21 and $0.21 for the years ended December 31, 2019 and 2018, respectively. We do not record tax-related effects on stock-based compensation given our historical and anticipated operating experience and offsetting changes in our valuation allowance which fully reserves against potential deferred tax assets.

The following table summarizes our warrant activity for 2019 and 2018:

	Warrants Outstanding		
	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2017	5,404,412	$ 0.37 - 0.51	$ 0.50
Issuances	3,963,241	0.23	0.23
Exercises	(5,147,059)	0.20	0.20
December 31, 2018	4,220,594	0.23 - 0.37	0.24
Issuances	8,125,000	0.18	0.18
Exercises	(1,925,000)	0.125	0.125
December 31, 2019	10,420,594	$ 0.125 - 0.37	$ 0.17

9. INCOME TAXES

The Company's provision for income taxes consists of the following for the years ended December 31, 2019 and 2018:

	2019	**2018**
Current income tax provision (benefit):		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Total	-	-
Deferred income tax provision (benefit):		
Federal	(162,000)	(345,000)
State	(51,000)	(107,000)
Foreign	-	-
Total	(213,000)	(452,000)
Change in valuation allowance	213,000	452,000
Total provision (benefit) for income taxes	$ -	$ -

Significant components of the Company's deferred tax assets at December 31, 2019 and 2018 and related valuation allowances are presented below:

	Year ended December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 13,721,000	$ 13,499,000
Research and experimentation credit carryforwards	2,268,000	2,268,000
Charitable contribution carryforwards	6,000	4,000
Accrued expenses, deferred revenue and other	591,000	632,000
Share-based compensation	774,000	743,000
	17,360,000	17,146,000
Less - valuation allowance	(17,360,000)	(17,146,000)
Net deferred tax assets	$ -	$ -

At December 31, 2019, we had net operating loss carryforwards for income tax purposes of approximately $49.9 million, which are available to offset future federal and state taxable income, if any, and, research and experimental tax credit carryforwards of approximately $2.3 million. Approximately $47.9 million of the net operating loss carryforwards, generated prior to 2018, expires in increments through 2037, while carryforwards generated in 2018 or later do not expire.

Section 382 of the Internal Revenue Code imposes substantial restrictions on the utilization of net operating losses and tax credits in the event of a corporation's ownership change. During 2009, the Company completed a preliminary study to compute any limits on the net operating losses and credit carryforwards for purposes of Section 382. It was determined that the Company experienced a cumulative change in ownership, as defined by the regulations, in 2002. This change in ownership triggers an annual limitation on the Company's ability to utilize certain U.S. federal and state net operating loss carryforwards and research tax credit carryforwards, resulting in the potential loss of approximately $9.8 million of net operating loss carryforwards and $0.2 million in research credit carryforwards. The Company has reduced the deferred tax assets associated with these carryforwards in its balance sheets. The Company believes that the future use of net operating losses and tax credits presented above may be further reduced as a result of additional ownership changes subsequent to 2009.

The provision for income taxes on earnings subject to income taxes differs from the statutory federal rate for the years ended December 31, 2019 and 2018, due to the following:

	2019	2018
US Federal statutory rate	21.00%	21.00%
State income tax, net of Federal benefit	6.52%	6.52%
Share-based compensation	-3.10%	-0.05%
Permanent differences and other	-9.26%	-1.74%
Change in tax rates	0.00%	-3.07%
Change in valuation allowance	-15.16%	-22.66%
	0.00%	0.00%

As discussed in Note 2, we recognize the effect of income tax positions only if those positions are more likely than not of being sustained. At December 31, 2019 and 2018, we had no gross unrecognized tax benefits. We do not expect any significant changes in unrecognized tax benefits over the next 12 months. In addition, we did not recognize any interest or penalties related to uncertain tax positions at December 31, 2019 and 2018.

The 2009 through 2019 tax years generally remain subject to examination by federal and most state tax authorities. In addition, we would remain open to examination for earlier years if we were to utilize net operating losses or tax credit carryforwards that originated prior to 2012.

10. LEASES

In February 2017, we amended our office lease agreement and the term was extended through July 2020. During the extended term, our rental payments will average approximately $4,000 per month. Pursuant to the adoption of ASC 842, our facility lease is our only existing lease as of December 31, 2019 and is classified as an operating lease. Our facility lease does not have a renewal option although we believe we will be able to extend or renew the lease if desired. The discount rate used in the calculation of our lease liability is approximately 20%, which is based on our estimate of the rate of interest that we would have to pay to borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment as the lease does not provide an implicit rate.

The following table summarizes the Company's recognition of its operating lease as of December 31, 2019:

Assets	
Operating lease right-of-use asset	$ 24,453
Total lease assets	$ 24,453
Liabilities	
Current portion of operating lease liability	$ 27,014
Total lease liabilities	$ 27,014

Rent expense, consisting of minimum operating lease payments and variable lease payments for pass through items such as common area maintenance and real estate taxes for the year ended December 31, 2019, is recorded in general and administrative and consisted of the following:

Operating lease cost	$ 48,101
Variable lease costs	4,381
Total lease costs	$ 52,482

Rent expense for the year ended December 31, 2018 was $51,568.

A maturity analysis of our operating lease minimum lease payments follows:

2020	$ 28,850
Total	28,850
Discount factor	(1,836)
Total lease liabilty	$ 27,014

11. COMMITMENTS

Employment Continuity Agreements. We have entered into employment contracts with our executive officers which provide for severance if the executive is dismissed without cause or under certain circumstances after a change of control in our ownership. At December 31, 2019, these obligations, if triggered, could amount to a maximum of approximately $170,000.

EXHIBIT INDEX

Exhibit No.	Description of Exhibit	Reference*
3.1	Restated Certificate of Incorporation	Exhibit 3.1 to Registration Statement on Form S-1 (File No. 333-166146) (filed April 16, 2010)
3.2	Certificate of Amendment to Restated Certificate of Incorporation	Exhibit 3.2 to Registration Statement on Form S-1 (File No. 333-166146) (filed April 16, 2010)
3.3	Certificate of Amendment to Restated Certificate of Incorporation	Exhibit 3.3 to Registration Statement on Form S-1 (File No. 333-166146) (filed April 16, 2010)
3.4	Certificate of Amendment of Restated Certificate of Incorporation	Exhibit 3.4 to Registration Statement on Form S-8 (File No. 333-168252) (filed July 21, 2010)
3.5	Certificate of Designation of Series A Participating Cumulative Preferred Stock	Exhibit 3.4 to Registration Statement on Form S-1 (File No. 333-166146) (filed April 16, 2010)
3.6	Amended and Restated Bylaws	Exhibit 3.4 to Quarterly Report on Form 10-Q (File No. 001-15070) for the quarter ended June 30, 2006 (filed August 14, 2006)
3.7	Amendment to Amended and Restated Bylaws	Exhibit 3.6 to Registration Statement on Form S-8 (File No. 333-152250) (filed July 10, 2008)
4.1	Specimen Common Stock Certificate	Exhibit 4.1 to Registration Statement on Form S-1 (File No. 333-166146) (filed April 16, 2010)
4.2	Specimen Rights Certificate	Exhibit 4.2 to Registration Statement on Form S-1 (File No. 333-166146) (filed April 16, 2010)
4.3	Rights Agreement, dated April 29, 1994, between the Company and American Stock Transfer & Trust Company, as Rights Agent	Exhibit 4.3 to Registration Statement on Form S-1 (File No. 333-166146) (filed April 16, 2010)
4.4	Amendment No. 1 to Rights Agreement, dated March 4, 2004, between the Company and American Stock Transfer & Trust Company, as Rights Agent	Exhibit 4.4 to Registration Statement on Form S-1 (File No. 333-166146) (filed April 16, 2010)
4.5	Warrant Agreement, dated May 21, 2010, between the Company and American Stock Transfer & Trust Company, as Warrant Agent	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed May 21, 2010)
4.6	Form of Warrant Certificate	Exhibit 4.6 to Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-166146) (filed May 17, 2010)
10.1^	Amended and Restated 2000 Stock Option and Incentive Plan, as amended	Annex A to the Company's Proxy Statement on Schedule 14A (File No. 001-15070) (filed May 9, 2008)
10.2^	2010 Equity Incentive Plan	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed July 20, 2010)
10.3	Form of Stock Option Grant Notice and Stock Option Agreement under the 2010 Equity Incentive Plan	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed July 20, 2010)

10.4	Patent License Agreement — Exclusive, dated January 24, 2001, between the Company and the U.S. Public Health Service	Exhibit B to Exhibit 10.1 to Amendment No. 1 to Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 (File No. 001-15070) (filed January 16, 2013)
10.5	Thymosin Beta 4 License and Supply Agreement, dated January 21, 2004, between the Company and Defiante Farmaceutica S.A.	Exhibit 10.10 to Registration Statement on Form SB-2 (File No. 333-113417) (filed March 9, 2004)**
10.6	Lease, by and between the Company and The Realty Associates Fund V, L.P., dated December 10, 2009	Exhibit 10.25 to Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-15070) (filed March 31, 2010)
10.7	Form of Warrant to Purchase Common Stock dated April 30, 2009	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed April 16, 2009)
10.8	Form of Common Stock Purchase Warrant, dated October 5, 2009	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed September 30, 2009)
10.9	Form of Warrant, dated October 15, 2009	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed October 5, 2009)
10.10	Representative's Warrant to Purchase Common Stock, dated May 21, 2010	Exhibit 4.3 to Current Report on Form 8-K (File No. 001-15070) (filed May 21, 2010)
10.11	Registration Rights Agreement, dated January 4, 2011	Exhibit 10.3 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.12	Warrant to Purchase Common Stock, dated January 7, 2011, issued to Lincoln Park Capital	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.13	Form of Warrant to Purchase Common Stock, dated January 7, 2011, issued to the Sigma-Tau Purchasers	Exhibit 4.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.14^	Amended and Restated Change in Control Agreement between the Company and J.J. Finkelstein, dated July 2, 2012	Exhibit 10.8 to Current Report on Form 10-Q (File No. 001-15070) (filed August 14, 2012)
10.15^	Amended and Restated Change in Control Agreement between the Company and Allan L. Goldstein, dated July 2, 2012	Exhibit 10.12 to Current Report on Form 10-Q (File No. 001-15070) (filed August 14, 2012)
10.16	Form of Convertible Promissory Note	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed October 24, 2012)
10.17	Form of Warrant	Exhibit 4.2 to Current Report on Form 8-K (File No. 001-15070) (filed October 24, 2012)
10.18	Convertible Note and Warrant Purchase Agreement	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed October 24, 2012)
10.19	License Agreement with Lee's Pharmaceutical (HK) Limited	Exhibit 10.1 to Amendment No. 1 to Form 10-Q (File No. 001-15070) for the quarter ended September 30, 2012 (filed January 16, 2013)**
10.20	Form of Convertible Promissory Note	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed April 2, 2013)

10.21	Convertible Note Purchase Agreement	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed April 2, 2013)
10.22	Form of Convertible Promissory Note	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed July 11, 2013)
10.23	Convertible Note Purchase Agreement	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed July 11, 2013)
10.24^	Letter Agreement between the Company and J.J. Finkelstein, dated July 5, 2013	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed July 11, 2013)
10.25^	Letter Agreement between the Company and Allan L. Goldstein, dated July 5, 2013	Exhibit 10.4 to Current Report on Form 8-K (File No. 001-15070) (filed July 11, 2013)
10.26	Form of Convertible Promissory Note	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed September 19, 2013)
10.27	Convertible Note Purchase Agreement	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed September 19, 2013)
10.28	Form of Convertible Promissory Note	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed January 9, 2014)
10.29	Convertible Note Purchase Agreement	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed January 9, 2014)
10.30^	Letter Agreement between the Company and J.J. Finkelstein, dated January 7, 2014	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 9, 2014)
10.31	Letter Agreement between the Company and Allan L. Goldstein, dated January 7, 2014	Exhibit 10.3 to Quarterly Report on Form10-Q (File No. 001-15070) (filed January 9, 2014)
10.32	Securities Purchase Agreement	Exhibit 10.5 to Quarterly Report on Form10-Q (File No. 001-15070) (filed May 15, 2014)
10.33	License Agreement RGN-259 dated March 7, 2014 with GtreeBNT (formerly Digital Aria)	Exhibit 10.6 to Quarterly Report on Form10-Q (File No. 001-15070) (filed May 15, 2014)**
10.34	License Agreement RGN-137 dated March 7, 2014 with GtreeBNT (formerly Digital Aria)	Exhibit 10.7 to Quarterly Report on Form10-Q (File No. 001-15070) (filed May 15, 2014)**
10.35^	Executive Employment Agreement between the Company and J.J. Finkelstein dated April 16, 2014	Exhibit 10.1 to Quarterly Report on Form10-Q (File No. 001-15070) (filed August 14, 2014)
10.36^	Executive Employment Agreement between the Company and Allan L. Goldstein dated April 16, 2014	Exhibit 10.2 to Quarterly Report on Form10-Q (File No. 001-15070) (filed August 14, 2014)
10.37^	Executive Employment Agreement between the Company and Dane Saglio dated April 16, 2014	Exhibit 10.3 to Quarterly Report on Form10-Q (File No. 001-15070) (filed August 14, 2014)
10.38	Form of First Amendment to Promissory Note dated October 3, 2014	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed October 9, 2014)
10.39	Joint Venture Agreement between the Company and GtreeBNT Co., Ltd. dated January 28, 2015	Exhibit 10.1 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed May 15, 2015)

10.40	License Agreement between the Company and ReGenTree, LLC dated January 28, 2015	Exhibit 10.2 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed May 15, 2015)
10.41	2014 Amendment to Lease Agreement	Exhibit 10.41 to Annual Report on Form 10-K (File No. 001-15070) (filed April 11, 2016)
10.42	Securities Purchase Agreement between the Company and Purchasers identified therein dated June 27, 2016.	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed July 1, 2016).
10.43	Registration Rights Agreement between the Company and Purchasers identified therein dated June 27, 2016.	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed July 1, 2016).
10.44	Amendment No. 2 to the RGN-259 License Agreement between the Company and ReGenTree, LLC dated April 28, 2016.	Exhibit 10.1 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed August 22, 2016)
10.45	Amendment No. 2. to Joint Venture Agreement between the Company and GtreeBNT Co., Ltd. dated May 11, 2016.	Exhibit 10.2 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed August 22, 2016)
10.46	Amendment No 2. Dated as of August 28, 2017, REN-137 License Agreement between the Company and GTreeBNT Co., LTD, dated March 7, 2014	Exhibit 10.1 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed November 14, 2017)**
10.47	Warrant Reprice Agreement between the Company and the Purchasers identified therein dated March 2, 2018	Exhibit 10.47 to Annual Report (File No. 001-15070) (filed March 29, 2018)
10.48	Form of Common Stock Warrant	Exhibit 10.48 to Annual Report (File No. 001-15070) (filed March 29, 2018)
10.49	2018 Equity Incentive Plan dated June 13, 2018	Exhibit 10.49 to Annual Report on Form 10-K (File No. 001-15070) (filed March 29, 2019)
10.50	Form of Convertible Note Purchase Agreement February 2019	Exhibit 10.1 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed May 15, 2019)
10.51	Form of Convertible Promissory Note February 2019	Exhibit 10.2 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed May 15, 2019)
10.52	Form of Stock Warrant February 2019	Exhibit 10.3 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed May 15, 2019)
10.53	Amendment N. 1 to License Agreement dated February 25, 2019 between the Company and Lee's Pharmaceutical (HK) Limited	Exhibit 10.1 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed November 14, 2019)
10.54	Amendment No. 1 to RGN-259 License (PAN ASIA) dated September 17, 2019 between Company and GtreeBNT Co., Ltd.	Exhibit 10.2 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed November 14, 2019)
23.1	Consent of CohnReznick LLP	Filed herewith
24.1	Powers of Attorney	Included on signature page
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934	Filed herewith

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	Filed herewith***
101	The following materials from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets at December 31, 2019 and 2018; (ii) Statements of Operations for the years ended December 31, 2019 and 2018; (iii) Statements of Changes in Stockholders' Deficit; (iv) Statements of Cash Flows for the years ended December 31, 2019 and 2018; and (v) Notes to Financial Statements.	Filed herewith

* Except where noted, the exhibits referred to in this column have heretofore been filed with the Securities and Exchange Commission as exhibits to the documents indicated and are hereby incorporated by reference thereto. The Registration Statements referred to are Registration Statements of the Company.

** The registrant has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have been filed separately with the Securities and Exchange Commission.

*** This certification is being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

^ Compensatory plan, contract or arrangement.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Registration Nos. 333-168252, 333-152250 and 333-111386) of RegeneRx Biopharmaceuticals, Inc. (the "Company") of our report, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern, dated March 20, 2020, on our audits of the financial statements of RegeneRx Biopharmaceuticals, Inc. as of December 31, 2019 and 2018 and for the years then ended, included in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ CohnReznick LLP

Tysons, Virginia
March 20, 2020

EXHIBIT 31.1

CERTIFICATION

I, J.J. Finkelstein, certify that:

I have reviewed this annual report on Form 10-K of RegeneRx Biopharmaceuticals, Inc.;

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;

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;

The registrant's other certifying officer and I are 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:

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 consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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;

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

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 (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

The registrant's other certifying officer 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 (or persons performing the equivalent functions):

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

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 20, 2020

/s/ J.J. Finkelstein

J.J. Finkelstein
President and Chief Executive Officer (Principal Executive Officer, Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of RegeneRx Biopharmaceuticals, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, J.J. Finkelstein, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods presented in this report.

This certification accompanies this Report to which it relates, shall not be deemed "filed" with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Date: March 20, 2020

/s/ J.J. Finkelstein
J.J. Finkelstein
President and Chief Executive Officer (Principal Executive Officer, Principal Financial Officer)