FORM 10-K

REGENERX BIOPHARMACEUTICALS INC - RGRX

Filed: March 29, 2017 (period: December 31, 2016)

Annual report with a comprehensive overview of the company

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, 2016

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	20850
(Address of principal executive offices)	(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(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 Web site, 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 ☐ (Do not check if a smaller reporting company) Smaller reporting company ☑

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

As of June 30, 2016, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $24.6 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 June 30, 2016.

The number of shares outstanding of the registrant's common stock as of March 24, 2017 was 106,787,151.

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 Tβ4, for tissue and organ protection, repair, and regeneration. We have formulated Tβ4 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.

In addition to our three pharmaceutical product candidates, we are also evaluating the commercial development of peptide fragments and derivatives of Tβ4 for potential cosmeceutical and other personal care uses. These fragments are select amino acid sequences, and variations thereof, within the Tβ4 molecule that have demonstrated activity in several *in vitro* preclinical research studies that we have sponsored. We believe the biological activities of these fragments may be useful, for example, in developing novel cosmeceutical products for the anti-aging market. Our strategy is to collaborate with another company to develop cosmeceutical formulations based on these peptides.

Current Clinical Status

On January 28, 2015, we announced that we had entered into a Joint Venture Agreement (the "Joint Venture Agreement") with GtreeBNT Co., Ltd., a Korean pharmaceutical company ("GtreeBNT") and shareholder of the Company. The Joint Venture Agreement provides for the creation of an entity, ReGenTree, LLC (the "Joint Venture" or "ReGenTree"), jointly owned by us and GtreeBNT, that will commercialize RGN-259 for treatment of dry eye and neurotrophic keratopathy, an orphan indication in the United States. GtreeBNT will be responsible for funding all product development and commercialization efforts, and holds a majority interest of 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 agreement (the "License Agreement") 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 License 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. We are also entitled to royalties as a percentage of net sales ranging from the single digits to the low-double digits based on the medical indications approved and whether the Joint Venture commercializes products directly or through a third party. RegeneRx possesses one of three board seats of ReGenTree and certain major decisions and transactions within ReGenTree, such as commercialization strategy, mergers, and acquisitions, require RegeneRx's board designee's consent.

Our initial ownership interest in ReGenTree was 49% which was reduced to 42% after filing of the final clinical study report with the FDA for the Phase 2/3 trial for Dry Eye Syndrome completed earlier in 2016. 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 42% 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 keratopathy ("NK"), both in the U.S. In May 2016, we reported the results of the 317-patient Phase 2/3 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. The FDA approved ReGenTree's Phase 3 protocol for DES in late summer 2016 and we initiated a second Phase 3 trial that has begun enrolling approximately 500 patients.

The NK trial, a smaller study in an orphan population, has enrolled twelve patients thus far, and has several additional patients being screened, with a goal of forty-six. There are currently ten clinical sites for the study, three of which joined in the past three months with several other sites expected in the future. ReGenTree has expanded its efforts to accelerate patient enrollment by offering incentives to each site based on numbers of enrollees as well as payments to referral sites.

In February 2017, our licensee for RGN-137, GtreeBNT, 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. The Phase 3 trial will be a randomized, multi-center, double-blind, placebo-controlled study to evaluate the efficacy and safety of RGN-137 topically administered to approximately 200 EB patients at clinical sites throughout the U.S., GtreeBNT will be sponsoring and funding the clinical trial, which is planned to begin in the third quarter of 2017.

Currently, we have active partnerships in three major territories: the U.S., 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., Pan Asia, and Europe, RGN-259 in the EU, and RGN-137, our dermal wound healing gel. 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 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.

On June 27, 2016, we entered into a Securities Purchase Agreement ("SPA") with Sabby Healthcare Master Fund, Ltd., and Sabby Volatility Warrant Master Fund, Ltd. (collectively, "Sabby") pursuant to which we issued an aggregate of 5,147,059 shares of common stock and warrants to purchase 5,147,059 shares of common stock, which we refer to as the 2016 Offering. We received net proceeds of approximately $1,520,000 from the offering which was projected to fund our operations at the current level for approximately 6 months beyond this report date. We will need to secure additional operating capital to continue operations beyond the third quarter of 2017. We continuously monitor our cash use as well as the clinical timelines. We will need to secure additional operating capital in 2017 and are evaluating options including the licensing of additional rights to commercialize our clinical products as well as raising capital through the capital markets.

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 to stimulate healing only and have, to date, failed to demonstrate dramatic improvements in the healing process. Unlike growth factors, 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. It acts by reducing oxidative enzymes.

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. Patients were randomly assigned to receive either RGN-259 or placebo in this double-masked, placebo-controlled trial. All patients received either RGN-259 (0.1% concentration) or placebo, twice daily for 30 days. Various signs and symptoms of dry eye, such as the degree of ocular surface damage, ocular itching, burning and grittiness, among others, were graded periodically during and following the treatment period. The trial was conducted by Ora Inc., an ophthalmic contract research organization that specializes in dry eye research and clinical trials, and utilized Ora's Controlled Adverse Environment (CAE®) chamber, which is a model that exacerbates and standardizes signs and symptoms in the dry eye patient.

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.

The co-primary outcome measures evaluated in the trial were inferior corneal fluorescein staining and decreased ocular discomfort on day 29, 24 hours after CAE® challenge. Various secondary outcome efficacy measures were also evaluated in the trial. These outcome measures were based on the best available animal data at the time but without the benefit of any actual human clinical experience in dry eye. While the study did not meet statistical significance for reducing inferior corneal fluorescein staining, it did show a positive trend in this exploratory trial. RGN-259 did, however, show a statistically significant efficacy result in the other co-primary endpoint of decreased ocular discomfort and also demonstrated statistical significance in several secondary endpoints such as reduction of central corneal and superior corneal staining, important signs in dry eye patients and approvable endpoints by the FDA.

Key outcome measures were as follows:

- Patients receiving RGN-259 experienced a 325% greater reduction from baseline in central corneal fluorescein staining compared to placebo at the 24 hour recovery period ($p = 0.0075$). Reduction of fluorescein staining is indicative of a reduction in ocular surface damage of the central cornea;
- Patients receiving RGN-259 experienced a 257% greater reduction from baseline in exacerbation of superior corneal fluorescein staining in the CAE® chamber as compared to the placebo ($p = 0.0210$); and
- Patients receiving RGN-259 experienced a 27.3% greater reduction in exacerbation of ocular discomfort at day 28 during a 75-minute challenge in the CAE chamber compared to the placebo group ($p = 0.0244$). Reduction indicates that RGN-259 can slow progression of ocular symptoms in patients with dry eye syndrome.

- Other CAE®-related findings, such as peripheral (combination of the average of superior and inferior) corneal staining reduction, were observed having statistical significance, while others had positive trends after treatment with RGN-259. These observations are in line with the known biological properties and mechanisms of action of RGN-259 reported in various nonclinical studies.

With respect to inferior corneal fluorescein staining, we did see a positive trend toward improvement, at day 28 during exposure to adverse conditions in the CAE® chamber in patients receiving RGN-259 compared to placebo, although this improvement was not deemed to be statistically significant ($p = 0.0968$).

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.

In the trial, nine patients with severe dry eye (18 eyes) were treated with RGN-259 or vehicle control six times daily over a period of 28 days. They were evaluated upon entering the study after a two-week washout period, at weekly intervals during the treatment phase, at the end of the 28-day treatment period, and at a follow-up visit 28 days after treatment. Statistically significant differences in sign and symptom assessments, such as ocular discomfort and corneal fluorescein staining, were seen at various time points throughout the study. Of particular note were the differences between RGN-259 and vehicle control 28 days post-treatment, or the follow-up period. The RGN-259-treated group had a 35.1% reduction of ocular discomfort (symptom) compared to vehicle control ($p = 0.0141$), and a 59.1% reduction of total corneal fluorescein staining (sign) compared to vehicle control ($p = 0.0108$) at 28 days after treatment showing that the repair was sustained long after treatment cessation.

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 recently published in an appropriate medical journal.

Strategic Partnerships

Lee's Pharmaceuticals. In July 2012, we entered into a License 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. Lee's previously 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. We have not yet been informed of a projected starting date for Phase 2 trials but expect it to be sometime in mid-2017.

GtreeBNT. In March 2014, we entered into a License Agreement with GtreeBNT for the license of RGN-259. GtreeBNT licensed certain development and commercialization rights for RGN-259, in Asia (excluding China, Hong Kong, Macau and Taiwan). Separately, we licensed GtreeBNT the rights to RGN-137 for development in the U.S. where they are sponsoring a Phase 3 clinical trial planned to begin in the third quarter of 2017 in patients with epidermolysis bullolsa (EB). GtreeBNT is currently our second largest shareholder. 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.

U.S. Joint Venture (ReGenTree, LLC). On January 28, 2015, we announced that we entered into a Joint Venture Agreement (the "Joint Venture Agreement") with GtreeBNT. The Joint Venture Agreement provides for the creation of an entity (the "Joint Venture" or "ReGenTree"), owned by us and GtreeBNT, that will commercialize RGN-259 for treatment of dry eye and neurotrophic keratopathy in the United States. GtreeBNT is responsible for funding product development and commercialization efforts and holds a majority interest of ReGenTree. RegeneRx possesses one of three board seats and certain major decisions and transactions within ReGenTree, such as commercialization strategy, mergers, and acquisitions, require RegeneRx's board designee's consent. In conjunction with the Joint Venture Agreement, we also entered into a royalty-bearing license agreement (the "License Agreement") with ReGenTree pursuant to which we granted to ReGenTree the right to develop and exclusively commercialize RGN-259 in the United States. 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 42% after filing of the final clinical study report with the FDA for the Phase 2/3 trial for Dry Eye Syndrome completed earlier in 2016. 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 42% 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.

In September 2015, ReGenTree began a multi-centered, randomized, double-masked Phase 2/3 clinical trial in patients with dry eye syndrome ("DES") and a multi-centered, randomized, double-masked Phase 3 clinical trial in patients with neurotrophic keratopathy ("NK"), both in the U.S. The DES trial has completed full enrollment, treatment and follow-up of all patients. Data from the DES trial was released in early May 2016. The FDA approved ReGenTree's Phase 3 protocol for DES in late summer 2016 and we initiated a second Phase 3 trial that has begun enrolling approximately 500 patients.

The NK trial, a smaller study in an orphan population, has enrolled twelve patients thus far, and has several additional patients being screened, with a goal of forty-six.

In February 2017, our licensee for RGN-137, GtreeBNT, 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. The Phase 3 trial will be a randomized, multi-center, double-blind, placebo-controlled study to evaluate the efficacy and safety of RGN-137 topically administered to approximately 200 EB patients at clinical sites throughout the U.S. GtreeBNT will be sponsoring and funding the clinical trial, which is planned to begin in the third quarter of 2017.

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 format 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.

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 Practice (cGMP) regulations. We have since learned that the manufacturer has 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 have 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 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 discussing possible partnership opportunities with companies interested in developing RGN-352 for this indication.

Based on our Phase 1 data and the preclinical research discussed above, we are evaluating various opportunities for government funding 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). In 2005, we began enrolling patients in 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. A portion of this trial was funded by a grant of $681,000 received from the FDA. In this randomized, double-blind, placebo-controlled, dose-response trial, nine U.S. clinical sites evaluated the safety, tolerability, and wound healing effectiveness of three different concentrations of RGN-137 compared to placebo. RGN-137 was applied topically to the skin, once daily for up to 56 consecutive days. We completed enrollment of 30 out of the original target of 36 patients and closed the Phase 2 trial in late 2011 as the availability of eligible patients had been exhausted. We submitted the final report to the FDA in 2014. In February 2017, our licensee for RGN-137, GtreeBNT, received permission from the U.S. FDA to sponsor a Phase 3 clinical trial using RGN-137 to treat patients with EB. The Phase 3 trial will be a randomized, multi-center, double-blind, placebo-controlled study to evaluate the efficacy and safety of RGN-137 topically administered to approximately 200 EB patients at clinical sites throughout the U.S. GtreeBNT will be sponsoring and funding the clinical trial, which is planned to begin in the third quarter of 2017.

Clinical Development — Pressure Ulcers. In late 2005, we began enrolling patients in 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 this randomized, double-blind, placebo-controlled, dose-response trial, 15 clinical sites in the United States enrolled a total of 72 patients to evaluate the safety, tolerability, and wound healing effectiveness of three different concentrations of RGN-137 compared to placebo. RGN-137 was applied topically to patients' ulcers, once daily for up to 84 consecutive days. Patients in the trial were between 19 and 85 years old and had at least one stable Stage III or IV pressure ulcer with a surface area between 5 and 70 cm^2. Stage III and IV pressure ulcers are full thickness wounds that penetrate through the skin and muscle, sometimes completely to the bone.

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. As for efficacy, all Tß4 doses performed similarly compared to placebo, with no statistically significant efficacy results. However, patients treated with the middle dose showed a 17% improvement of wound healing, which was the highest rate among the three active doses evaluated. The improvement in ulcer healing in this middle dose group following nine weeks of treatment was equal to the improvement in patients treated with placebo after 12 weeks of treatment. 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 are clinically significant, they were not statistically significant.

Clinical Development — Venous Stasis Ulcers. In mid-2006 we began enrolling patients in 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 this double-blind, placebo-controlled, dose-response study, 8 European sites in Italy (N=5) and Poland (N=3) make up the 72 patients randomized to receive three different concentrations of RGN-137 or placebo. RGN-137 or placebo was applied topically to patients' ulcers once daily for consecutive days. A patient's ulcer size and ulcer stability for enrollment were between 3 and 30 cm^2 and at least 6 weeks in duration, respectively.

In 2009, we reported final data from that trial. All doses of RGN-137 were well tolerated. More patients achieved healing in the RGN-137 mid dose (0.03% Tβ4 gel product) than in any other dose group. The mid dose showed both an increased incidence of wound healing and a faster healing time compared to placebo. The mid dose decreased the median time to healing by 45% among those wounds that completely healed. A follow-on evaluation, reported at the 3rd International Symposium on the Thymosins in Health and Disease in March 2012, showed that for those venous stasis ulcer patients' wounds greater than 3 cm^2 that healed, the RGN-137 mid dose (0.03% Tβ4 gel product) accelerated wound closure with a median time to healing of 49 days as compared to 78 days for the placebo. Those results were both clinically and statistically significant.

GtreeBNT. In March 2014, we entered into a License Agreement with GtreeBNT to license certain development and commercialization rights for RGN-137 in the U.S. In February 2017, GtreeBNT received permission from the U.S. FDA to sponsor a Phase 3 clinical trial using RGN-137 to treat patients with epidermolysis bullosa, a genetic disease that causes severe blistering of the skin and internal organs. GtreeBNT will be sponsoring and funding the clinical trial, which is planned to begin in the third quarter of 2017.

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 several important licensing and joint venture agreements with pharmaceutical companies to develop our product candidates.

Our initial ownership interest in ReGenTree was 49% which was reduced to 42% upon filing of the final clinical study report with the FDA for the Phase 2b trial for Dry Eye Syndrome completed earlier in 2016. 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 42% 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 Joint Venture with GtreeBNT follows two previous transactions with GtreeBNT signed in March 2014 when we had entered into License Agreements for the license of our RGN-259 and RGN-137 product candidates. 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.

We have entered into a License Agreement with Lee's Pharmaceutical (HK) Limited, 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.

We previously entered into a strategic partnership with Defiante Farmaceutica S.A., ("Defiante"), formerly a wholly-owned subsidiary of Sigma-Tau Group, a leading international pharmaceutical company, which collectively comprise our largest shareholder, or Sigma-Tau, for development and marketing of RGN-137 and RGN-352 for specified indications in Europe and other contiguous countries. Defiante merged with Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. in 2013 and Sigma-Tau recently merged with Alfa Wasserman S.p.A., an Italian pharmaceutical company. Currently, there is no ongoing development of our products by Alfa Wasserman.

Manufacturing

We use a major contract manufacturer to produce bulk Tß4, which is the active pharmaceutical ingredient, or 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 such agreements 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. is 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. RegeneRx will have access to the data resulting from this endeavor should we need to use it for purposes outside the licensed territories.

We 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.

One of the compelling reasons to create a joint venture with GtreeBNT to develop RGN-259 in the U.S. for ophthalmology products was their recent manufacturing experience gained from their development of RGN-259 in Korea. This experience has allowed ReGenTree to move rapidly from Phase 2 to Phase 3 clinical trials in the U.S. without duplication of required Chemistry, Manufacturing, and Control (CMC) efforts, which are quite substantial when moving into Phase 3 and in anticipation of commercialization. GtreeBNT has been working with companies to manufacture RGN-259 in blow-filled sealed containers, which are currently being utilized for Phase 3 clinical trials and will be used for commercial marketing upon FDA approval.

As described elsewhere in this report, in 2011 our formulation and vialing contractor for RGN-352 underwent a manufacturing inspection by the FDA and was found not to be in compliance with cGMP, resulting in a clinical hold of our Phase 2 AMI clinical trial. This company has since closed its manufacturing facility and filed for bankruptcy protection. If we are to continue clinical development of RGN-352, we will need to secure a cGMP-compliant formulation and filling manufacturer of RGN-352. We have identified several cGMP-compliant companies able to perform this service.

Competition

We are engaged in a business that is highly competitive, and our target medical indications are ones with significant unmet needs. Moreover, the cosmetic and cosmeceutical industries are rapidly developing new products based on new scientific research. 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, the only commercially available and FDA-approved eye drop to treat dry eye. Restasis, and other products, have been approved for marketing in certain other countries where we have licensed RGN-259. Shire PLC is developing its product candidate, Lifitegrast, and is in pivotal Phase 3 clinical trials in the U.S. Shire has said it plans to resubmit an NDA for Lifitegrast in 2016. We believe RGN-259 is different than any other product candidate 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.

RGN-352. Currently, there are no approved pharmaceutical products for regenerating cardiac tissue following a heart attack, nor are there approved pharmaceutical products 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.

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 all 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. As described in this report, in 2011 one of our prior contract manufacturers was alleged by the FDA to have not complied with current Good Manufacturing Practices, which impaired our ability to conduct a Phase 2 AMI trial with RGN-352.

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 keratopathy 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, as well as for cosmetic and consumer product applications. 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. During 2007, patents were issued in Europe and the United States related to the original NIH patent application, which patents expire in July 2019. Corresponding patents have 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. 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, reducing the minimum annual royalty beginning in 2014 to $2,000 and fixing the maximum sublicense participation fee. Through December 31, 2016, we have complied with all minimum royalty requirements and no milestone payments have been required under the agreement.

We hold a U.S. patent relating to the use of Tß4 for treatment of alopecia, an autoimmune skin disease that results in hair loss, which expires in 2017, with corresponding patents in Europe and Singapore that expire in 2018. In 2006, we were issued a patent in China for the use of Tß4 to treat EB, which expires in 2022.

We hold a U.S. patent relating to the use of Tß4 for the treatment of congestive heart failure. This patent issued in January 2012, and will expire in 2027. Other patent applications for our various product candidates, if issued, will offer protection in the U.S. and certain other territories through 2033.

We have also filed numerous 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 2013. 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.

We have also evaluated a number of 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 have entered into 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 is $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, 2016, we have complied with all minimum royalty requirements, and no milestone payments have been required under the agreement.

Defiante/Sigma-Tau/Alfa Wassermann

We have exclusively licensed certain internal and external wound healing European rights to Tß4 to Defiante, which merged with Sigma-Tau Industrie Farmaceutiche Riunite S. P. A. in 2013. In 2015, Sigma-Tau merged into Alfa Wassermann, an Italian pharma company. These licensed rights to Tß4 include its use to treat indications that are the subject of all of our current dermal clinical trials of RGN-137, as well as the treatment of heart attacks. The license excludes the use of Tß4 in any ophthalmic indications and other indications that are disease-based and not the result of a wound. Under the agreement, Alfa Wassermann may develop Tß4 for the treatment of internal and external wounds in Europe and certain other contiguous and geographically relevant countries. The license agreement expires on a country-by-country basis upon the last to expire of any granted patent in the territory having at least one valid claim covering the products then on the market, the expiration of any other exclusive or proprietary marketing rights.

Under the license agreement, Alfa Wassermann is obligated to pay us a royalty on commercial sales, if any, and we will supply all required Tß4 for development. Upon the completion of a Phase 2 clinical trial for the covered indications that yields positive results in terms of efficacy and safety, Alfa Wassermann must either pay us a $5 million milestone payment or initiate and fund a pivotal Phase 3 clinical trial for the applicable product candidate in order to maintain the license. We have completed two Phase 2 clinical trials of RGN-137 for the treatment of pressure ulcers and venous stasis ulcers which, due to the lack of statistical significance of the primary efficacy endpoints, did not trigger any payment obligations to us.

The license agreement with Defiante also contains future clinical and regulatory milestones in the licensed territory. If those milestones are attained, certain performance criteria regarding commercial registration and minimum annual royalties will be payable to us in each licensed country. The agreement does not prevent us from sublicensing the technology in countries outside the licensed territory and has no impact on any U.S. rights. RegeneRx may seek to reacquire the licensed rights back from Alfa Wassermann at some point in the future.

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. Lee's paid us $200,000 upon signing of a term sheet with respect to the transaction on March 27, 2012, and Lee's paid us an additional $200,000 upon signing of the definitive license agreement.

The terms of the license 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.

The two companies have discussed Lee's development plans and we have continued to provide information as requested. Lee's previously filed an investigational new drug application IND with the Chinese FDA (CFDA) to conduct begin phase 2, randomized, double-masked, dose-response clinical trial with RGN-259 in China for dry-eye syndrome. In 2015, the CFDA declined Lee's IND because the clinical trial drug product (RGN-259) was manufactured by RegeneRx outside of China, which substantially affected the proposed start of the trial. The CFDA then reversed its ruling, which once again affected the proposed trial. Lee's is in the process of preparing new documentation for the CFDA with the hope to initiate a Phase II clinical trial in patients with dry eye syndrome later this year.

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 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 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 Company's licensed product sold by GtreeBNT in the 137 Territory.

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 will provide a certain limited amount of Tß4 to GtreeBNT at no charge for initial clinical trials in Korea, Japan and Australia for RGN-259 and in the U.S. for RGN-137 and will provide Tß4 to GtreeBNT for all other developmental and clinical work on a cost plus basis. We retain the manufacturing and supply rights for Tß4 in the respective Territories and the parties will negotiate in good faith an exclusive supply agreement for Tß4 as soon as practicable. 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 development of the licensed product candidates.

U.S. Joint Venture

On January 28, 2015, the Company 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 keratopathy 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 retains 49% ownership 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 keratopathy, respectively.

Our initial ownership interest in ReGenTree was 49% and was reduced to 42% after filing of the final clinical study report with the FDA for the Phase 2/3 trial for Dry Eye Syndrome completed earlier in 2016. 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 42% 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 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 License Agreement or 25 years from the first commercial sale under the License Agreement. The License Agreement may be earlier terminated if the Joint Venture fails to meet certain commercialization milestones, or if either party breaches the License 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

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 also employ two part time employees. We also retain seven 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 resources will only be sufficient to fund our operations beyond the third quarter of 2017.

On June 27, 2016, we entered into a SPA with Sabby pursuant to which we received net proceeds of approximately $1,520,000 from the offering which was projected to fund our operations at the current level for approximately 6 months beyond this report date. We will need to secure additional operating capital to continue operations beyond the third quarter of 2017. We continuously monitor our cash use as well as the clinical timelines. We will need to secure additional operating capital in 2017 and are evaluating options including the licensing of additional rights to commercialize our clinical products as well as raising capital through the capital markets which may 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 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. At this time we estimate that our existing capital resources will fund operations for approximately 6 months beyond this report date. We will need to secure additional operating capital to continue operations beyond the third quarter of 2017..

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, 2016, our accumulated deficit totaled approximately $105 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 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.

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, 2016 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 completed the sale of common stock and warrants to institutional investors and received net proceeds of approximately $1,520,000 and we estimate that our existing capital resources will fund our operations for approximately 6 months beyond this report date. We will need to secure additional operating capital to continue operations beyond the third quarter of 2017.. 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

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 have also 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.

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 our, or our partners', clinical trials 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.

In March 2014 we completed two licensing agreements for the development and commercialization of RGN-259 and RGN-137 in certain territories, with GtreeBNT, headquartered outside of Seoul, Korea. In January 2015 we entered into a Joint Venture Agreement with GtreeBNT and entered into a license agreement with the Joint Venture, pursuant to which granted to the Joint Venture the right to develop and exclusively commercialize RGN-259 in the United States and Canada as amended in April 2016. Although we will share control of the Joint Venture with GtreeBNT, GtreeBNT will have greater control over the Joint Venture than we will meaning that GtreeBNT will have significant control over the commercialization of RGN-259.

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.

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 Lifitegrast for the treatment of dry eye and will be launching 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 initially targeted our product candidate RGN-352 for cardiovascular indications. Most large pharmaceutical companies and many smaller biomedical companies are vigorously pursuing the development of therapeutics to treat patients after heart attacks and for other cardiovascular 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. Moreover, 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 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 Sigma-Tau S.p.A, 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, was also a director and officer of entities affiliated with Sigma-Tau and is a director of Lee's Pharmaceuticals, relationships which could give rise to a conflict of interest for Mr. Bove.

Mauro Bove is a member of our Board of Directors, and, until March 31, 2014, was a director and officer of entities affiliated with Sigma-Tau, which collectively make up our largest stockholder group. At this time Mr. Bove remains engaged with Sigma-Tau as a consultant. Sigma-Tau has subsequently merged into Alfa Wassermann, S.p.A., an Italian pharmaceutical company. Sigma-Tau/Alfa Wassermann previously provided us with significant funding and is also our strategic partner in Europe with respect to the development of certain of our drug candidates. We have issued shares of common stock, convertible promissory notes and common stock warrants to Sigma-Tau and its affiliates in several private placement financing transactions, including as recently as September 2013. We have licensed certain rights to our product candidates generally for the treatment of dermal and internal wounds to Sigma-Tau/Alfa Wassermann. Under the license agreement, upon the completion of a Phase 2 clinical trial of either of these product candidates that yields positive results in terms of clinical efficacy and safety, Sigma-Tau/Alfa Wassermann is obligated to either make a $5 million milestone payment to us or to initiate and fund a pivotal Phase 3 clinical trial of the product candidate. In 2009, we completed two Phase 2 clinical trials of RGN-137, but these trials were not sufficient to trigger the milestone obligation. There can be no assurance that we will ever receive this payment or be able to initiate a pivotal Phase 3 clinical trial of RGN-137 that would be funded by Sigma-Tau/Alfa Wassermann. As a result of Mr. Bove's relationship with Sigma-Tau/Alfa Wassermann, there could be a conflict of interest between Sigma-Tau/Alfa Wasserman and our other stockholders with respect to these and other agreements and circumstances that may require the exercise of the Board's discretion with respect to Sigma-Tau/Alfa Wassermann. Any decision in the best interests of Sigma-Tau/Alfa Wassermann may not be in the best interest of our other stockholders.

Additionally, Mr. Bove is a non-executive director of Lee's Pharmaceuticals, in which affiliates of Sigma-Tau have a significant equity interest. In July 2012, we entered into a license agreement for Tß4 in any pharmaceutical form, including our RGN-259, RGN-352 and RGN-137 product candidates for development in China, Hong Kong, Macau and Taiwan. There can be no assurance that we will ever receive any further payments from Lee's under the agreement. As a result of Mr. Bove's relationship with Lee's and Sigma-Tau, Mr. Bove may have interests that are different from our other stockholders in connection with these and other agreements and circumstances that may require the exercise of the Board's discretion with respect to Lee's or Sigma-Tau. These conflicts could result in decisions that are not in the best interest of our other stockholders.

Risks Related To Our Intellectual Property

We are partially reliant on our license from the National Institutes of Health for the rights to Tß4, and any loss of these rights could adversely affect our business.

We have received an exclusive worldwide license to intellectual property discovered at the National Institutes of Health, or NIH, pertaining to the use of Tß4 in wound healing and tissue repair. The intellectual property rights from this license, along with independent patent applications we have filed, as well as patents and patent applications under licenses we acquired, form the basis for our current commercial development focus with Tß4. The NIH license terminates upon the last to expire of the patent applications that are filed, or any patents that may issue from such applications, in connection with the license. This license requires us to pay a minimum annual royalty to the NIH, regardless of the success of our product development efforts, plus certain other royalties upon the sale of products created by the intellectual property granted under the license. 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 the 2013 calendar year against the 2013 minimum annual royalty of $25,000. Beginning in 2014 the minimum annual royalty is $2,000. While to date we believe that we have complied with all requirements to maintain the license, the loss of this license could have an adverse effect on our business and business prospects.

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 substantially beyond 12 months without additional funding. As a result of our current financial condition, 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.

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. Pursuant to an exclusive worldwide license from the NIH, we have exclusive rights to use Tß4 in the treatment of non-healing wounds. 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. 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, 2015 through March 24, 2017 the closing price of our common stock has ranged from $0.13 to $0.75, with an average daily trading volume of approximately 59,000 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 49.8% of our outstanding common stock. Included in this group is Sigma-Tau (merged with Alfa Wasserman S.p.A.) and its affiliates, which together hold outstanding shares representing approximately 28.1% of our outstanding common stock and GtreeBNT which owns approximately 18.3% 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 do not currently have and may never obtain research coverage by securities and industry 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 we obtain securities or industry analyst coverage, if 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, 2016, there were outstanding options to purchase an aggregate of 7,698,711 shares of our common stock under our 2000 and 2010 incentive equity plans at exercise prices ranging from $0.14 per share to $0.64 per share and outstanding warrants to purchase 5,804,412 shares of our common stock at a weighted average exercise price of $0.48 per share (warrants issued in 2016 offering include down round protection until August 3, 2017). In addition to the outstanding options and warrants we have also issued five series of convertible promissory notes which are presently convertible into an aggregate of 13,683,334 shares of our common stock. In October 2012, we sold convertible promissory notes totaling $300,000 that are convertible into 2,000,000 shares of common stock at a conversion price of $0.15 per share. In October 2014, the maturity date of these notes was extended for an additional three years. In 2013, we sold three additional series of convertible promissory notes, which notes totaled $646,000 and are initially convertible into 10,766,667 shares of common stock at a conversion price of $0.06 per share. In January 2014, we sold a fifth 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 issued in 2013 and January 2014 contain down round provisions under which the conversion prices of these notes could be decreased as a result of future equity offerings below the conversion price of the notes. 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.

In addition, most of the outstanding warrants to purchase shares of our common stock have an exercise price above the current market price for our common stock. As a result, these warrants may not be exercised prior to their expiration, in which case we would not realize any proceeds from their exercise.

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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters are located in Rockville, Maryland where we lease office space. Beginning in June 2014 we consolidated our office space and amended our lease agreement for the reduced space. The lease arrangement was amended recently to include three additional years. We believe that our facilities are generally suitable to meet our needs for the foreseeable future; however, we will continue to seek alternate or additional space as needed.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

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 $0.31 on March 24, 2017.

The following table sets forth the high and low bid 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.

	2016		2015	
	High	Low	High	Low
First Quarter	$ 0.75	$ 0.37	$ 0.38	$ 0.13
Second Quarter	$ 0.75	$ 0.28	$ 0.60	$ 0.25
Third Quarter	$ 0.47	$ 0.32	$ 0.50	$ 0.32
Fourth Quarter	$ 0.40	$ 0.25	$ 0.45	$ 0.35

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.

On May 4, 2015, we issued 30,000 shares of our common stock, valued at approximately $16,500 to ProActive Capital Resources Group LLC in consideration for investor relations services. This issuance was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended, on the basis that the transactions did not involve a public offering.

On May 11, 2015, we issued 249,671 shares of our common stock to Lincoln Park Capital, LLC upon the cashless exercise of a warrant. This issuance was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended, on the basis that the transactions did not involve a public offering.

On June 27, 2016, we issued Sabby an aggregate of 5,147,059 shares of common stock and warrants to purchase 5,147,059 shares of common stock. We received approximately $1,520,000 in net proceeds. The shares and warrants were registered on Form S-1 which was declared effective by the SEC on August 5, 2016.

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.

In addition to our three pharmaceutical product candidates, we are also evaluating the potential use of peptide fragments and derivatives of Tß4 for cosmeceutical and other personal care uses. These fragments are select amino acid sequences, and variations thereof, within the Tß4 molecule that have demonstrated activity in several *in vitro* preclinical research studies that we have sponsored. We believe the biological activities of these fragments may be useful, for example, in developing novel cosmeceutical products for the anti-aging market. Our strategy is to collaborate with another company to develop cosmeceutical formulations based on these peptides.

Current Financial Circumstances

Our current capital resources will only be sufficient to fund operations for approximately 6 months beyond this report date. We will need to secure additional operating capital to continue operations beyond the third quarter of 2017..

Current Clinical Status

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 keratopathy, 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 License 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.

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 keratopathy ("NK"), both in the U.S. In May 2016, we reported the results of the 317-patient Phase 2/3 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. The FDA approved ReGenTree's Phase 3 protocol for DES in late summer 2016 and we initiated a second Phase 3 trial that has begun enrolling approximately 500 patients.

The NK trial, a smaller study in an orphan population, has enrolled twelve patients thus far, and has several additional patients being screened, with a goal of forty-six. There are currently ten clinical sites for the study, three of which joined in the past three months with several other sites expected in the future. ReGenTree has expanded its efforts to accelerate patient enrollment by offering incentives to each site based on numbers of enrollees as well as payments to referral sites.

In February 2017, our licensee for RGN-137, GtreeBNT, 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. The Phase 3 trial will be a randomized, multi-center, double-blind, placebo-controlled study to evaluate the efficacy and safety of RGN-137 topically administered to approximately 200 EB patients at clinical sites throughout the U.S. GtreeBNT will be sponsoring and funding the clinical trial, which is planned to begin in the third quarter of 2017.

Currently, we have active partnerships in three major territories: the U.S., 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., 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 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.

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.

We will need additional funds to continue operations beyond the third quarter of 2017 and will require substantial capital if we wish to internally 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, 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, travel and other miscellaneous costs of our internal R&D personnel, three persons in total, who are wholly dedicated on a part-time 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 the outcome of current studies, 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

We recognize revenue in accordance with the authoritative guidance for revenue recognition. We recognize revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery (or passage of title) has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured. We also comply with the authoritative guidance for revenue recognition regarding arrangements with multiple deliverables. Multiple-element arrangements are analyzed to determine whether the deliverables, which may include a license together with performance obligations such as providing a clinical supply of product and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting. Revenue associated with licensing agreements consists of non-refundable upfront license fees and milestone payments. Non-refundable upfront license fees received under license agreements, whereby continued performance or future obligations are considered inconsequential to the relevant license technology, are recognized as revenue upon delivery of the technology.

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 the 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.

If we cannot reasonably estimate the level of effort required to complete our performance obligations under an arrangement, the performance obligations are 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 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.

We recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

- The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone;
- The consideration relates solely to past performance; and
- The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us.

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

Variable Interest Entities

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. As a result, the Company is not recognizing its 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 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, 2016, 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.

Convertible Notes with Detachable Warrants.

In accordance with Accounting Standards Codification ("ASC") 470-20, *Debt with Conversion and Other Options*, the proceeds received from convertible notes are allocated between the convertible notes and the detachable warrants based on the relative fair value of the convertible notes without the warrants and the relative fair value of the warrants. 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. In other instances these instruments are classified as equity instruments in the Company's financial statements.

The Company estimates the fair values of its derivative financial 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.

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. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period. 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, 2016 and 2015

Revenues. For the year ended December 31, 2016, we recorded revenue in the amount of $93,308 versus $60,612 recorded for the year ended December 31, 2015. The increase in revenue for 2016 reflects the amortization over 25 years of the two $500,000 payments we received under the original joint venture license agreement as well as the $250,000 payment we received for the expansion of the territorial rights to include Canada in April 2016. The amount recorded in 2016 was $48,308 versus $20,612 in 2015. Both years reflect revenue related to the sale of unformulated Tß4 to GtreeBNT for use in their product development work in Korea. There were no associated costs with this transaction as the cost of Tß4 had been expensed in a prior period. Revenue recorded for these sales were approximately $45,000 and $40,000 in 2016 and 2015, respectively.

Expenses — Research and development. For the year ended December 31, 2016, our R&D expenditures increased by $34,000, or 17%, to $237,000, from approximately $203,000 in 2015. The increase is attributable to a small increase in R&D personnel costs (increase of $5,000) and the level of stock option compensation recognized for the year (increase of $44,000) versus the prior year. This was partially offset by decreases from 2015 for insurance (decrease of $11,000) and outside services (decrease of $4,000). 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, 2016, our G&A expenses decreased by approximately $37,000, or 2%, to $1,529,983 from $1,566,962 in 2015. Decreases in 2016 are a result of decreases in the cost of professional services ($291,000), travel and related expenses ($31,000), facility and related expenses ($5,000), investor relations ($7,000) and personnel costs ($5,000). These decreases were partially offset by increases in insurance ($21,000), stock option expense ($67,000) and offering expenses related to our 2016 Offering of approximately ($214,000) which represents the portion of transactional costs allocated to the liability-classified derivative financial instruments. The significant decrease in professional services reflects the absence of the legal costs incurred in association with completing the ReGenTree joint venture agreement in 2015. We believe that our G&A expenses, net of offering 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 Income and Net Loss. In 2016 we had net income of $229,125 versus a net loss of $5,270,433 in 2015. The 2016 net income reflects the change in the value of the conversion feature related to the derivative liability related to our convertible debt as well as the reduction of the value of the investor rights associated with the 2016 Offering. The total decrease in the value of the derivative liabilities for the year ended December 31, 2016 was $2,076,499. For 2015, a significant portion of the net loss resulted from an increase in the value of the derivative liabilities pursuant to our evaluation of the derivative liability associated with the conversion feature of the debt instruments issued by the Company from March 2013 through January 2014. The value of this conversion feature is indexed to the share price of our common stock and increases as our share price increases and decreases as our share price decreases. The share price of our common stock decreased from $0.44 on December 31, 2015 to $0.32 on December 31, 2016, which resulted in a decrease in the fair value of our derivative liabilities and the recording of a gain of $2,076,499 for 2016. In the prior year, the share price of our common stock increased from $0.14 on December 31, 2014 to $0.44 on December 31, 2015, which resulted in an increase in the fair value of our convertible debt derivative component and the recording of a loss of $3,388,166 for 2015. Losses from operations were approximately the same for 2016 and 2015, $1,674,019 and $1,709,535, 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, 2016 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.

We had net income of $229,125 for the year ended December 31, 2016. We had cash and cash equivalents of $769,495 at December 31, 2016. This amount primarily reflects the net proceeds of our 2016 Offering of approximately $1,520,000. Our current cash and cash equivalents should fund our planned operations for approximately 6 months beyond this report date. We will need to secure additional operating capital to continue operations beyond the third quarter of 2017.. 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. 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 $1,068,000 and $525,000 for the years ended December 31, 2016 and 2015, respectively. In 2015, our statement of cash flows reflects a net inflow of $979,000 related to payments received under the license agreement with the Joint Venture versus $202,000 from the same source in 2016. Other material items contributing to the increase in cash used in operating activities are change in fair value of derivative liability of $2,076,499, share-based compensation of $342,483 and offering costs of $214,229.

Net Cash Used in Investing Activities. We did not use any cash for investing activities in 2016. Net cash used in investing activities for 2015 was $1,000 for capital expenditures.

Net Cash Provided by Financing Activities. Net cash provided by financing activities totaled $1,520,000 and $0 for the years ended December 31, 2016 and 2015, respectively. In 2016, the cash provided by financing activities consisted of the proceeds from the 2016 Offering completed in June 2016.

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 three major territories: the U.S., 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, top line data from the U.S. dry eye trial was released in early May and data from the NK study toward the end of 2017 or possibly later.

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 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.

Our current capital resources are only sufficient to fund operations for approximately 6 months beyond this report date. We will need to secure additional operating capital to continue operations beyond the third quarter of 2017.. 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.

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.

In June 2014, we consolidated our office space and amended our lease agreement for the reduced space. The lease commitment was for 36 months and has been extended for another three years and our rental payments for this period will be approximately $4,800 per month.

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 addition to a series of five convertible debt placements from October 2012 to January 2014. Most recently, on June 27, 2016, we entered into a Securities Purchase Agreement with Sabby to which we agreed to sell, and the purchasers agreed to purchase, an aggregate of 5,147,059 shares of common stock and warrants to purchase 5,147,059 shares of common stock, which we refer to as the 2016 Offering. We received approximately $1,520,000 in net proceeds from the 2016 Offering. We believe our current capital resources will fund our operations for approximately 6 months beyond this report date. We will need to secure additional operating capital to continue operations beyond the third quarter of 2017.. On January 28, 2015, we announced that we had entered into a Joint Venture Agreement with GtreeBNT, a shareholder of the Company. The Joint Venture Agreement provides for the creation of an entity, ReGenTree, LLC, jointly owned by us and GtreeBNT, which will commercialize RGN-259 for treatment of dry eye and neurotrophic keratopathy, an orphan indication in the United States. On April 28, 2016 the license agreement with ReGenTree was amended to expand the territory to include Canada. GtreeBNT is responsible for funding all product development and commercialization efforts.

RegeneRx's initial ownership interest in ReGenTree was 49% and was reduced to 42% when the clinical study report was filed with the FDA for the Phase 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 42% and 25%, with 25% being the final equity ownership upon approval of an NDA for Dry Eye Syndrome in the U.S. In conjunction with the Joint Venture Agreement, we also entered into a royalty-bearing license agreement (the "License Agreement") 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 $1,000,000 in two tranches under the terms of the License 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.

We are also entitled to royalties as a percentage of net sales ranging from the single digits to the low-double digits based on the medical indications approved and whether the Joint Venture commercializes products directly or through a third party. 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. RegeneRx possesses one of three board seats and certain major decisions and transactions within ReGenTree, such as commercialization strategy, mergers, and acquisitions, require RegeneRx's board designee's consent. 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.

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 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 have a license agreement with Sigma-Tau/Alfa Wassermann that provides the opportunity for us to receive milestone payments upon specified events and royalty payments in connection with commercial sales of Tß4 for certain medical indications in Europe. However, we have not received any milestone payments to date, and there can be no assurance that we will be able to attain such milestones and generate any such payments under the agreement.

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. However, there are no assurances that we will be able to attain any such milestones or generate any such royalty payments under the agreement.

Government Grants

We have pursued, and 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, 2016 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, 2016.

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, 2016.

Changes in Internal Control over Financial Reporting

There were no changes to the Company's Internal Controls over Financial Reporting in the quarter ended December 31, 2016.

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, 2017 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	65	President, Chief Executive Officer and Director
Directors:		
Dr. Allan L. Goldstein	79	Founder, Chairman of the Board and Chief Scientific Officer
Mr. R. Don Elsey	63	Director
Mr. Joseph C. McNay	83	Director
Mr. Mauro Bove	62	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 34 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 currently chairs the MdBio Foundation, 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 Tα1, which is marketed worldwide, and Tβ4, 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 Tβ4 development efforts.

Mr. Elsey has served as a member of our Board of Directors since September 2010. Currently Mr. Elsey serves as CFO of Senseonics, Inc. 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 National Public Radio, Trustee of the Dana Farber Cancer Institute, and is a Trustee and member of the Children's Hospital Investment Committee. 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 serving as a Business Development consultant to emerging pharmaceutical companies in Asia, including Lee's Pharmaceuticals after leading for more than 20 years Corporate & Business Development of Sigma-Tau Finanziaria S.p.A., the holding company of Sigma-Tau Group, a leading international pharmaceutical company (Sigma-Tau Finanziaria 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.

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, 2016, 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, 2016 and 2015, compensation awarded to or paid to, or earned by, our chief executive officer who was our only named executive officers for fiscal 2016. For purposes of this report, we sometimes refer to our chief executive officer as our named executive officer.

Of note, our annual rates of compensation for our named executive officer and all employees were reduced effective December 1, 2011. Beginning in January 2012, all employees became part-time hourly employees with reduced work schedules. Additionally, in January 2012, we discontinued providing employee health benefits and company-sponsored 401(k) matching contributions. On April 16, 2014 we entered into a new employment agreement with Mr. Finkelstein under which Mr. Finkelstein's base salary was set at $125,000 annually, and on January 1, 2015 Mr. Finkelstein's base salary was increased to $150,000.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards(1) ($)	All Other Compensation(2) ($)	Total ($)
J.J. Finkelstein, President and	2016	150,000	—	91,090	3,360	244,450
Chief Executive Officer	2015	154,519	—	127,104	3,360	284,983

(1) The 2016 & 2015 amounts reflect the aggregate total grant date fair values (computed in accordance with FASB ASC Topic 718 or ASC Topic 505)

(2) The 2016 & 2015 amount reflects 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. 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. 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, 2016

The following table shows certain information regarding outstanding equity awards at December 31, 2016 for the named executive officer, all of which were stock options granted under our Amended and Restated 2000 Stock Option and Incentive Plan or our 2010 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	114,748	—	0.57	4/10/2019	
	125,000	—	0.27	07/14/2017	
	125,000	—	0.22	8/3/2018	
	80,135	—	0.16	12/12/2018	
	500,000	—	0.14	1/24/2019	
	35,000	—	0.16	4/4/2019	
	375,000	125,000	0.21	3/25/2021	(1)
	250,000	250,000	0.36	6/30/2022	(1)
	50,000	150,000	0.64	3/17/2023	(1)

(1) These options vests in equal installments upon grant and on the first three anniversaries of the grant date. In each case these options were granted seven 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 2016 or 2015. 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, 2016 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 2016 or 2015.

In 2016 each independent director was granted 100,000 options to purchase shares of common stock at an exercise price of $0.64 per share, which vests in four segments pursuant to each director's continued service. In 2015 each independent director was granted 100,000 options in each February and June with exercise prices per share of $0.19 and $0.36, respectively. Each of 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 2016 and 2015.

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 2016

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)	All Other Compensation ($)	Total ($)
Allan Goldstein, Ph.D.	—	91,090	90,000(2)	181,090
R. Don Elsey	—	45,545	—	45,545
Joseph McNay	—	45,545	—	45,545
Mauro Bove	—	45,545	—	45,545

(1) As described above, during 2011, our Board of Directors elected to cease paying cash compensation to non-employee directors to help the company preserve capital.

Options held by each Board member as of December 31, 2016, are as follows:

Allan Goldstein, Ph.D.	1,584,077
R. Don Elsey	530,000
Joseph McNay	518,024
Mauro Bove	547,155

(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 2016. In 2016 Dr. Goldstein was also granted options to purchase 200,000 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, 2017 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 previously affiliated with Essetifin S.p.A., Via Sudafrica, 20, Rome, Italy 00144	34,082,011[2]	30.7%
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]	18.3%
Named Executive Officers and Directors:		
J.J. Finkelstein	3,421,404[4]	3.1%
Allan L. Goldstein	3,254,153[5]	3.0%
Joseph C. McNay	5,857,135[6]	5.3%
Mauro Bove	397,155[7]	*
R. Don Elsey	463,333[8]	*
All directors and executive officers as a group (5 persons)	**13,393,181[9]**	11.5%

* 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 106,787,151 shares of common stock outstanding on March 15, 2017, adjusted as required by rules promulgated by the Securities and Exchange Commission (the "SEC").

(2) Consists of 984,615 shares of common stock held of record held by Essetifin S.p.A. (f/k/a Sigma-Tau Finanziaria, S.p.A.) ("Essetifin"); 12,937,111 shares of common stock held of record held by Defiante Farmaceutica S.A. ("Defiante"), a subsidiary of Essetifin; 6,348,878 shares of common stock held of record held by Taufin International S.A. ("Taufin"), an entity wholly owned by Taufin S.p.A., which is owned directly by the estate of Claudio Cavazza, who directly and indirectly owns 57% of Essetifin; and 9,711,407 shares of common stock held of record, 3,833,333 shares of common stock issuable upon conversion of a convertible promissory note and 266,667 shares of common stock issuable upon exercise of warrants held by Sinaf S.A. ("Sinaf"), an indirect wholly-owned subsidiary of Aptafin S.p.A., which is owned by Paolo Cavazza and members of his family, that are exercisable within 60 days of March 15, 2017. Paolo Cavazza directly and indirectly owns 38% of Essetifin. The beneficial ownership of Essetifin and its affiliates is derived from the Schedule 13D/A filed by Sigma-Tau Finanziaria S.p.A. (now Essetifin) on December 23,2013.

(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 1,388,188 shares of common stock held of record by Mr. Finkelstein, 1,829,883 shares of common stock issuable upon exercise of options, 20,000 shares of common stock issuable upon exercise of warrants and 183,333 shares of common stock issuable upon conversion of a convertible promissory note, in each case exercisable within 60 days of March 15, 2017.

(5) Consists of 681,743 shares of common stock held of record by Dr. Goldstein, 1,166,667 shares of common stock issuable upon conversion of a convertible promissory note, 1,359,077 shares of common stock issuable upon exercise of options and 46,666 shares of common stock issuable upon exercise of warrants, in each case exercisable within 60 days of March 15, 2017.

(6) Consists of 1,339,111 shares of common stock held of record by Mr. McNay, 4,083,333 shares of common stock issuable upon conversion of a convertible promissory note, 368,024 shares of common stock issuable upon exercise of options and 66,667 shares of common stock issuable upon exercise of warrants, in each case exercisable within 60 days of March 15, 2017.

(7) Consists of 397,155 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2017. Mr. Bove was previously an officer of Sigma-Tau, but he had no beneficial ownership over the reported securities as he has no voting or dispositive power with respect to the securities held by Sigma-Tau and its affiliates described in footnote 2 above.

(8) Consists of 380,000 shares of common stock issuable upon exercise of options and 83,333 shares of common stock issuable upon conversion of a convertible promissory note, in each case exercisable within 60 days of March 15, 2017.

(9) Consists of 3,409,042 shares of common stock held of record, 5,516,667 shares of common stock issuable upon conversion of convertible promissory notes, 4,334,139 shares of common stock issuable upon exercise of options and 133,333 shares of common stock issuable upon exercise of warrants, in each case exercisable within 60 days of March 15, 2017.

Equity Compensation Plan Information

The following table provides information as of December 31, 2016 about the securities authorized for issuance to our employees, directors and other eligible participants under our equity compensation plans, consisting of the Amended and Restated 2000 Stock Option and Incentive Plan and the 2010 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	7,698,711	$ 0.29	608,029
Equity compensation plans not approved by security holders	—	—	—
Total	7,698,711	$ 0.29	608,029

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 2016 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.

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 keratopathy, 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 License 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 42% after filing of the final clinical study report with the FDA for the Phase 2/3 trial for Dry Eye Syndrome completed earlier in 2016. 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 42% 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 keratopathy ("NK"), both in the U.S. In May 2016, we reported the results of the 317-patient Phase 2/3 trial. The FDA approved ReGenTree's Phase 3 protocol for DES in late summer 2016 and we initiated a second Phase 3 trial that has begun enrolling approxiamtely500 patients.

The NK trial, a smaller study in an orphan population, has enrolled twelve patients thus far, and has several additional patients being screened, with a goal of forty-six.

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 took into account the significant ownership of our common stock by Sigma-Tau and its affiliates and our License Agreement with Lee's Pharmaceuticals. The board of directors does not believe that any of the transactions with Lee's or Sigma-Tau 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, 2016 and 2015 by our independent registered public accounting firm CohnReznick LLP. All such fees described below were approved by the audit committee.

	2016	2015
Audit fees	$ 83,000	$ 71,000
Tax fees [1]	24,000	—
Total Fees	$ 107,000	$ 71,000

(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 29, 2017

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 29, 2017
/s/ J.J. Finkelstein J.J. Finkelstein	President, Chief Executive Officer, and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	March 29, 2017
/s/ R. Don Elsey R. Don Elsey	Director	March 29, 2017
/s/ Joseph C. McNay Joseph C. McNay	Director	March 29, 2017
/s/ Mauro Bove Mauro Bove	Director	March 29, 2017

RegeneRx Biopharmaceuticals, Inc.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
of RegeneRx Biopharmaceuticals, Inc.

We have audited the accompanying balance sheets of RegeneRx Biopharmaceuticals, Inc. as of December 31, 2016 and 2015, and the related statements of operations, changes in stockholders' deficit and cash flows for the years then ended. RegeneRx Biopharmaceuticals, Inc.'s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of RegeneRx Biopharmaceuticals, Inc. as of December 31, 2016 and 2015, 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 Stated of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1 to the financial statements, the Company has experienced negative cash flows from operations since inception and is dependent upon future financing in order to meet its planned operating activities. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ CohnReznick LLP

Tysons, Virginia
March 29, 2017

RegeneRx Biopharmaceuticals, Inc.
Balance Sheets

	December 31, 2016	2015
ASSETS		
Current assets		
Cash and cash equivalents	$ 769,495	$ 317,627
Prepaid expenses and other current assets	79,936	24,300
Total current assets	849,431	341,927
Property and equipment, net of accumulated depreciation of $92,120 and $88,794	7,219	10,544
Other assets	5,752	5,752
Total assets	$ 862,402	$ 358,223
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 75,695	$ 141,130
Unearned revenue	50,822	-
Accrued expenses	233,239	217,911
Convertible promisory note	300,000	-
Total current liabilities	659,756	359,041
Long-term liabilities		
Unearned revenue	1,530,345	1,379,388
Convertible promisory note	-	300,000
Convertible promisory notes, net of derivative liability	512,022	388,854
Fair value of derivative liabilities	4,226,837	4,673,336
Total liabilities	6,928,960	7,100,619
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, 106,787,151 and 101,640,092 issued and outstanding	106,787	101,640
Additional paid-in capital	98,672,368	98,230,802
Accumulated deficit	(104,845,713)	(105,074,838)
Total stockholders' deficit	(6,066,558)	(6,742,396)
Total liabilities and stockholders' deficit	$ 862,402	$ 358,223

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Operations

	Years ended December 31,	
	2016	2015
Revenues	$ 93,308	$ 60,612
Operating expenses		
Research and development	237,344	203,185
General and administrative	1,529,983	1,566,962
Total operating expenses	1,767,327	1,770,147
Loss from operations	(1,674,019)	(1,709,535)
Interest and other income	-	101
Interest expense	(173,355)	(172,883)
Change in fair value of derivative liabilities	2,076,499	(3,388,166)
Net income (loss)	$ 229,125	$ (5,270,483)
Basic net income (loss) per common share	$ 0.00	$ (0.05)
Diluted net income (loss) per common share	$ 0.00	$ (0.05)
Weighted average number of common shares outstanding - basic	106,787,151	101,527,676
Weighted average number of common shares outstanding - diluted	125,922,455	101,527,676

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Changes in Stockholders' Deficit
Years ended December 31, 2016 and 2015

	Common stock		Additional	Accumulated	Total stockholders'
	Shares	Amount	paid-in capital	deficit	deficit
Balance, December 31, 2014	101,316,580	$ 101,317	$ 97,991,419	$ (99,804,355)	$ (1,711,619)
Issuance of common stock & warrants	323,512	323	7,776	-	8,099
Share-based compensation expense	-	-	231,607	-	231,607
Net loss	-	-	-	(5,270,483)	(5,270,483)
Balance, December 31, 2015	101,640,092	101,640	98,230,802	(105,074,838)	(6,742,396)
Issuance of common stock & warrants	5,147,059	5,147	99,083	-	104,230
Share-based compensation expense	-	-	342,483	-	342,483
Net income	-	-	-	229,125	229,125
Balance, December 31, 2016	106,787,151	$ 106,787	$ 98,672,368	$(104,845,713)	$ (6,066,558)

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Cash Flows

	Years ended December 31,	
	2016	2015
Operating activities:		
Net income (loss)	$ 229,125	$ (5,270,483)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	3,326	3,403
Non-cash share-based compensation	342,483	231,607
Non-cash interest expense	123,168	122,833
Non-cash expense - issuance of stock for services	-	8,100
Offering costs allocated to derivative liabilities	214,229	-
Change in fair value of derivative liabilities	(2,076,499)	3,388,166
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(55,636)	62,225
Accounts payable	(65,436)	(91,481)
Accrued expenses	15,328	40,902
Unearned revenue	201,780	979,388
Net cash used in operating activities	(1,068,132)	(525,340)
Investing activities:		
Purchase of property and equipment	-	(1,076)
Net cash used in investing activities	-	(1,076)
Financing activities:		
Proceeds from sale of common stock and issuance of warrants	1,520,000	-
Net cash provided by financing activities	1,520,000	-
Net increase (decrease) in cash and cash equivalents	451,868	(526,416)
Cash and cash equivalents at beginning of year	317,627	844,043
Cash and cash equivalents at end of year	$ 769,495	$ 317,627
Supplemental Disclosure of Non-Cash Operating and Financing Activities		
Cashless exercise of warrants	$ -	$ 294
Fair value of warrants issued to placement agent	$ 83,799	$ -
Fair value of derivative liabilities	$ 1,630,000	$ -

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

RegeneRx Biopharmaceuticals, Inc.
Notes to Financial Statements
December 31, 2016

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.

On June 27, 2016, we entered into a Securities Purchase Agreement ("SPA") with an institutional investor pursuant to which we issued an aggregate of 5,147,059 shares of common stock and warrants to purchase 5,147,059 shares of common stock, which we refer to as the 2016 Offering. We received net proceeds of approximately $1,520,000 from the offering which was projected to fund our operations at the current level for approximately 6 months beyond this report date. We will need to secure additional operating capital to continue operations beyond the third quarter of 2017.. We continuously monitor our cash use as well as the clinical timelines. We will need to secure additional operating capital in 2017 and are evaluating options including the licensing of additional rights to commercialize our clinical products as well as raising capital through the capital markets.

Several years ago we adopted a strategy 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 three major territories: the U.S., 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., 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 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.

On January 28, 2015, we announced that we had entered into a Joint Venture Agreement (the "Joint Venture Agreement") with GtreeBNT Co., Ltd., a Korean pharmaceutical company ("GtreeBNT") and shareholder of the Company. The Joint Venture Agreement provides for the creation of an entity, ReGenTree, LLC (the "Joint Venture" or "ReGenTree"), jointly owned by us and GtreeBNT, that will commercialize RGN-259 for treatment of dry eye and neurotrophic keratopathy, an orphan indication in the United States. GtreeBNT will be responsible for funding all product development and commercialization efforts, and holds a majority interest of 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 agreement (the "License Agreement") 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 License 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. We are also entitled to royalties as a percentage of net sales ranging from the single digits to the low-double digits based on the medical indications approved and whether the Joint Venture commercializes products directly or through a third party. RegeneRx possesses one of three board seats of ReGenTree and certain major decisions and transactions within ReGenTree, such as commercialization strategy, mergers, and acquisitions, require RegeneRx's board designee's consent.

Our initial ownership interest in ReGenTree was 49% which was reduced to 42% after filing of the final clinical study report with the FDA for the Phase 2/3 trial for Dry Eye Syndrome completed earlier in 2016. 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 42% 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.

Since inception, and through December 31, 2016, we have an accumulated deficit of $105 million and we had cash and cash equivalents of $769,495 as of December 31, 2016. We anticipate incurring additional 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 to advance development of our product candidates with multiple clinical trials starting in 2017. We will need additional funds to continue operations for approximately 6 months beyond this report date. We will need to secure additional operating capital to continue operations beyond the third quarter of 2017 as well as 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, clinical trial accruals, valuation of derivatives 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 consists 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 $3,326 and $3,403 for the years ended December 31, 2016 and 2015, 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, 2016 and 2015 no impairment losses were recorded.

Convertible Notes with Detachable Warrants. In accordance with Accounting Standards Codification (ASC) 470-20, *Debt with Conversion and Other Options*, the proceeds received from convertible notes are allocated between the convertible notes and the detachable warrants based on the relative fair value of the convertible notes without the warrants and the warrants. 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 financial instruments 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.

Revenue Recognition. We recognize revenue in accordance with the authoritative guidance for revenue recognition. We recognize revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery (or passage of title) has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured. We also comply with the authoritative guidance for revenue recognition regarding arrangements with multiple deliverables. Multiple-element arrangements are analyzed to determine whether the deliverables, which may include a license together with performance obligations such as providing a clinical supply of product and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting. Revenue associated with licensing agreements consists of non-refundable upfront license fees and milestone payments. Non-refundable upfront license fees received under license agreements, whereby continued performance or future obligations are considered inconsequential to the relevant license technology, are recognized as revenue upon delivery of the technology.

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 the 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.

If we cannot reasonably estimate the level of effort required to complete our performance obligations under an arrangement, the performance obligations are 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 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.

We recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

- The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone;
- The consideration relates solely to past performance; and
- The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us.

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

Variable Interest Entities

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. As a result, the Company is not recognizing its share (42%) 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, 2016, 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. Research and development ("R&D") costs are expensed as incurred and 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 Tβ4; formulation of Tβ4 into the various product candidates; stability for both Tβ4 and the various formulations; pre-clinical 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, employee benefits, travel and other miscellaneous costs of our internal R&D personnel, four persons in total, who are wholly dedicated to R&D efforts. R&D also includes a pro-ration of our common infrastructure costs for office space and communications.

Cost of Preclinical Studies and Clinical Trials. We accrue estimated costs for preclinical studies based on estimates of work performed. We estimate expenses incurred for clinical trials that are in process based on patient enrollment and based on clinical data collection and management. Costs based on clinical data collection and management are recognized based on estimates of unbilled goods and services received in the reporting period. We monitor the progress of the trials and their related activities and adjust the accruals accordingly. Adjustments to accruals are charged to expense in the period in which the facts that give rise to the adjustment become known. In the event of early termination of a clinical trial, we would accrue an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial.

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. 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 "Income taxes" in our statements of operations.

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, 2016 and 2015. 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 Income (Loss) Per Common Share. Basic net income (loss) per common share for the years 2016 and 2015, respectively, is based on the weighted-average number of shares of common stock outstanding during the periods. Diluted loss per share is based on the weighted-average number of shares of common stock outstanding during each period in which a loss is incurred, potentially dilutive shares are excluded because the effect is antidilutive. In periods 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 reporting period. The potentially dilutive securities include 27,186,456 shares and 22,261,951 shares in 2016 and 2015, respectively, reserved for the conversion of convertible debt or exercise of outstanding options and warrants. For the year ended December 31, 2016, 19,135,304 dilutive securities related to convertible debt, options and warrants were included in the diluted income per share calculation.

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 $342,483 and $231,607 in share-based compensation expense for the years ended December 31, 2016 and 2015, 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.

Recent Accounting Pronouncements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers,* which provides guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. In July 2015, the FASB delayed the effective date of this standard by one year. The new standard will be effective for the Company's reporting year beginning on January 1, 2018, and early adoption of the standard as of January 1, 2017 is permitted. In March 2016, the FASB issued an accounting standard update to clarify the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued an accounting standard update to clarify the identification of performance obligations and the licensing implementation guidance, while retaining the related principles for those areas. In May 2016, the FASB issued an accounting standard update to clarify guidance in certain areas and add some practical expedients to the guidance. The amendments in these 2016 updates do not change the core principle of the previously issued guidance in May 2014. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In November 2015, the FASB issued new guidance on the balance sheet classification of deferred taxes. To simplify presentation, the new guidance requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The accounting standard is effective for public business entities for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is permitted. The adoption of this guidance did not have an impact on our financial statements.

In January 2016, the FASB issued a new accounting standard on recognition and measurement of financial assets and financial liabilities. The accounting standard primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, it includes a clarification related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2017. Early adoption is permitted for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. The Company is currently evaluating the impact, if any, that the pronouncement will have on the financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which supersedes ASC Topic 840, *Leases*, and creates a new topic, ASC Topic 842, *Leases*. ASU 2016-02 requires lessees to recognize a lease liability and a lease asset for all leases, including operating leases, with a term greater than 12 months on its balance sheet. ASU 2016-02 also expands the required quantitative and qualitative disclosures surrounding leases. ASU 2016-02 is effective for the Company beginning January 1, 2019. Early adoption is permitted. The Company has determined that the adoption of ASU 2016-02 will have no impact on its financial statements.

In March 2016, the FASB issued ASU 2016-07, *Equity Method and Joint Ventures* affect all entities that have an investment that becomes qualified for the equity method of accounting as a result of an increase in the level of ownership or degree of influence. ASU 2016-07 is effective for the Company beginning on January 1, 2017, early adoption is permitted. The Company is currently evaluating the effect this ASU will have on its financial statements.

In March 2016, the FASB issued an accounting standard update which simplified several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The standard is effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods. We are currently evaluating the effect that the adoption of this ASU will have on our financial statements.

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, 2016 and 2015, our only qualifying assets that required measurement under the foregoing fair value hierarchy were money market funds included in Cash and Cash Equivalents valued at $769,000 and $318,000, respectively, using Level 1 inputs. Our balance sheets reflect qualifying liabilities resulting from the price protection provision in the convertible promissory notes issued in March, July and September of 2013 and January 2014 (see Note 7). Our balance sheet also reflects qualifying liabilities related to the issuance of common stock and warrants in our 2016 Offering. Certain price protection anti-dilution features of the Securities Purchase Agreement and Warrants were determined to be embedded derivatives. An independent valuation expert calculated the fair value of the embedded derivatives using a customized Monte Carlo simulation model. We evaluated the derivative liability embedded in the series of convertible notes using the Black Scholes model to determine if an adjustment to the carrying value of the liability was required at December 31, 2016 using the following assumptions.

	March 2013	July 2013	Sept 2013	Jan 2014	2016 Offering Warrants	2016 Offering Shares
Dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Risk-free rate of return	0.85%	1.20%	1.20%	1.20%	1.93%	1.93%
Expected life in years	1.25	1.5	1.7	2	5	0.59
Volatility	78.3%	72.4%	72.2%	82.1%	80.0%	80.0%

Given the conditions surrounding the trading of the Company's equity securities, the Company values its derivative instruments related to embedded conversion features from the issuance of convertible debentures in accordance with the Level 3 guidelines. For the year ended December 31, 2016, the following table reconciles the beginning and ending balances for financial instruments that are recognized at fair value in these financial statements.

	Balance at December 31, 2015	New Issuances	Change in Fair Values	Balance at December 31, 2016
Level 3 -				
Derivative liabilities from:				
Conversion features				
March 2013	$ 1,500,000	$ -	$ (525,000)	$ 975,000
July 2013	666,667	-	(233,333)	433,334
September 2013	2,140,000	-	(749,000)	1,391,000
January 2014	366,669	-	(119,166)	247,503
Anti-dilution Protection				
2016 Offering shares	-	60,000	130,000	190,000
2016 Offering warrants	-	1,570,000	(580,000)	990,000
Derivative instruments	$ 4,673,336	$ 1,630,000	$ (2,076,499)	$ 4,226,837

4. LICENSES, INTELLECTUAL PROPERTY, AND RELATED PARTY TRANSACTIONS

We have an exclusive, worldwide licensing agreement with the National Institutes of Health ("NIH") for all claims to Tβ4 within their broadly-defined patent application. In exchange for this exclusive worldwide license, we must make certain royalty and milestone payments to the NIH. 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 of $25,000. Beginning in 2014 the minimum annual royalty is $2,000. No assurance can be given as to whether or when a patent will be issued, or as to any claims that may be included or excluded within the patent. We have also filed numerous additional patent applications covering various compositions, uses, formulations and other components of Tβ4, as well as to novel peptides resulting from our research efforts. Some of these patents have 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 for 2013, 2014, 2015 or 2016 as of the date of this report. 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.

We have entered into a License and Supply Agreement (the "Agreement") with Defiante Farmaceutica S.A. ("Defiante") a Portuguese company that is a wholly owned subsidiary of Sigma-Tau, S.p.A., an international pharmaceutical company and an affiliate of Sigma-Tau Finanziaria S.p.A., who together with its affiliates comprise our largest stockholder group (the "Sigma-Tau Group"). This Agreement grants to Defiante the exclusive right to use Tβ4 to conduct research and development activities in Europe. Under the Agreement, we will receive fees and royalty payments based on a percentage of specified sales of Tβ4-related products by Defiante. The term of the Agreement continues until the later of the expiration of any patents developed under the Agreement, the expiration of marketing rights, or December 31, 2016. Defiante merged with Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. in 2013 and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. merged with Alfa Wassermann, S.p.A.

In 2012, we entered into a License Agreement (the "Agreement") with Lee's Pharmaceutical (HK) Limited, 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 License 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. As of December 31, 2016 and 2015, we have unearned revenue totaling $400,000 pursuant to this 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 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 Company's licensed product sold by GtreeBNT in the 137 Territory.

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 will provide a certain limited amount of Tß4 to GtreeBNT at no charge for initial clinical trials in Korea, Japan and Australia for RGN-259 and in the U.S. for RGN-137 and will provide Tß4 to GtreeBNT for all other developmental and clinical work on a cost plus basis. 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 keratopathy in the United States 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 42% 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 42% 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 License Agreement or 25 years from the first commercial sale under the License 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. The Company has determined that the deliverables within the License Agreement, including a delivered element (providing the license) and an undelivered element (participation on the joint development committee), do not have stand-alone value and, as such, are treated as a single unit of accounting. As a result, the Company is recognizing the up-front milestone payments as revenue ratably over the anticipated life of the joint development committee, or 25 years. The joint development committee commenced activities as of April 1, 2015, therefore the Company began recognizing the revenue for the license fee in 2015. 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,	
	2016	2015
Prepaid insurance	$ 64,721	$ 10,552
Prepaid and other	15,215	13,748
	$ 79,936	$ 24,300

Accrued expenses are comprised of the following:

	December 31,	
	2016	2015
Accrued professional fees	$ 390	$ 31,788
Accrued other	20,940	30,000
Accrued compensation	27,848	22,249
Accrued interest on convertible notes	184,061	133,874
	$ 233,239	$ 217,911

6. EMPLOYEE BENEFIT PLANS

In 2016 and 2015 the Company provided health and dental insurance to one employee under a group plan. No retirement plan was in place for 2016 or 2015.

7. CONVERTIBLE NOTES

2012 Convertible Note

On October 19, 2012, we completed a private placement of convertible notes (the "2012 Notes") raising an aggregate of $300,000 in gross proceeds. The 2012 Notes were originally scheduled to mature after twenty-four (24) months from issuance. The 2012 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 fifteen cents ($0.15) per share (subject to adjustment as described in the 2012 Notes) at any time prior to repayment, at the election of the Investors. In the aggregate, the 2012 Notes are convertible into up to 2,000,000 shares of our common stock excluding interest.

At any time prior to maturity of the 2012 Notes, with the consent of the holders of a majority in interest of the 2012 Notes, we may prepay the outstanding principal amount of the 2012 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 2012 Notes will accelerate and automatically become immediately due and payable.

In connection with the issuance of the 2012 Notes, we also issued warrants to each Investor. The warrants are exercisable for an aggregate of 400,000 shares of common stock with an exercise price of fifteen cents ($0.15) per share for a period of five years. The relative fair value of the warrants issued is $27,097, calculated using the Black-Scholes-Merton valuation model value of $0.07 with an expected and contractual life of 5 years, an assumed volatility of 74.36%, and a risk-free interest rate of 0.77%. The warrants were recorded as additional paid-in-capital and a discount on the 2012 Notes of $27,097.

The Investors, and the principal amount of their respective 2012 Notes and number of shares of common stock issuable upon exercise of their respective warrants, are as set forth below:

Investor	Note Principal	Warrants
Sinaf S.A.	$ 200,000	266,667
Joseph C. McNay	$ 50,000	66,667
Allan L. Goldstein	$ 35,000	46,666
J.J. Finkelstein	$ 15,000	20,000

Sinaf S. A. is a direct wholly-owned subsidiary of Aptafin S.p.A., or Aptafin. Aptafin is owned directly by Paolo Cavazza and members of his family, who directly and indirectly own 38% of Sigma-Tau, our largest stockholder. The other Investors are members of our Board of Directors including Mr. Finkelstein who serves as our CEO and also the Chairman of our Board of Directors Dr. Goldstein who also serves as our Chief Scientific Officer.

During 2014, the Company amended the existing October 2012 convertible debt agreement with the lenders, solely to extend the due date of the principal and accrued unpaid until interest October 19, 2017. No other terms of the original debt were amended or modified, and the lenders did not reduce the borrowed amount or change the interest rate of the debt. The Company considered the restructuring a troubled debt restructuring as a result of the Company's financial condition (see Note 1 discussion of "going concern"). At the date of the amendment, all existing debt discounts and deferred financing fees were fully amortized and the amendment did not involve any additional fees paid to the lender or third parties; as such there was no gain recognized as a result of the amendment.

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 bear interest at a rate of five percent (5%) per annum, mature sixty (60) months after their date of issuance and are 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 investor. In the aggregate, the March 2013 Notes are 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 may 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 will accelerate and automatically become immediately due and payable.

The investors in the offering included two directors of the Company, 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 has evaluated the terms of the March 2013 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 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. 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 will be accreted as an addition to the debt through the maturity of the notes.

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 bear interest at a rate of five percent (5%) per annum, mature sixty (60) months after their date of issuance and are 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 investor. In the aggregate, the July 2013 Notes are 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 may 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 will accelerate and automatically become immediately due and payable.

The investors in the offering included four directors of the Company, 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 has evaluated the terms of the July 2013 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 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. 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 will be accreted back to debt through the maturity of the notes.

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 bear interest at a rate of five percent (5%) per annum, mature sixty (60) months after their date of issuance and are 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 are 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 may 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 will accelerate and automatically become immediately due and payable.

The investors in the offering included an affiliate and three current and one prior directors of the Company. The principal amounts of the affiliate and directors 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 has evaluated the terms of the September 2013 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 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. 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 will be accreted back to debt through the maturity of the notes.

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 bear interest at a rate of 5% per annum, mature 60 months after their date of issuance and are convertible into shares of our common stock at a conversion price of $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 Notes are 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 may 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 will accelerate and automatically become immediately due and payable.

The Investors in the offering included two current and one prior directors of the Company. The principal amounts of their respective Notes are as set forth below:

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

The Company has 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. 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 will be accreted back to debt through the maturity of the notes.

The outstanding balance of the derivative liability is as follows:

	December 31, 2016	December 31, 2015
March 2013 Notes	$ 975,000	$ 1,500,000
July 2013 Notes	433,334	666,667
September 2013 Notes	1,391,000	2,140,000
January 2014 Notes	247,503	366,669
Warrant liability	990,000	-
Rights liability	190,000	-
Total fair value of derivative liability	$ 4,226,837	$ 4,673,336

The change in fair value of the derivative liability is as follows:

	For the years ended	
	December 31, 2016	December 31, 2015
March 2013 Notes	$ (525,000)	$ 1,087,500
July 2013 Notes	(233,333)	483,333
September 2013 Notes	(749,000)	1,551,500
January 2014 Notes	(119,166)	265,833
Warrant liability	(580,000)	-
Rights liability	130,000	-
Total change in fair value of derivative	$ (2,076,499)	$ 3,388,166

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

	For the years ended	
	December 31, 2016	December 31, 2015
2012 Notes	$ 15,038	$ 15,000
March 2013 Notes	56,404	56,250
July 2013 Notes	18,384	18,333
September 2013 Notes	69,741	69,550
January 2014 Notes	13,788	13,750
Total interest expense	$ 173,355	$ 172,883

8. STOCKHOLDERS' EQUITY

Common Stock. On June 27, 2016, we entered into a SPA with an institutional investor pursuant to which we agreed to sell, and the purchasers agreed to purchase, an aggregate of 5,147,059 shares of common stock and warrants to purchase 5,147,059 shares of common stock, which we refer to as the 2016 Offering, and in conjunction with the closing of such transaction we issued warrants to purchase 257,353 shares of common stock to our placement agent.

The SPA contains customary representations, warranties and covenants by the Company and the purchasers. In addition, the SPA provides that each purchaser has a right, subject to certain exceptions described in the agreement, to participate in future issuances of equity and debt securities by us for a period of 12 months following the effective date of this registration statement, and certain price protections that provide for the grant of additional shares of common stock if we sell shares for less than $0.34 per share (the purchase price in the 2016 Offering) during such 12-month period. Moreover, we agreed, subject to certain exceptions, not to sell or announce the sale of our securities for five months from the effective date of this registration statement.

The Company evaluated various features of the SPA and Warrant Agreements issued in the offering. The SPA includes certain embedded features that were evaluated under the guidance in ASC 815, *Derivatives and Hedging,* including a "right" to receive additional shares of common shares for no further consideration, and is a form of non-standard "down-round" anti-dilution protection. The "right" was determined to be a "stand alone" derivative and also is considered an "embedded derivative", the "right" was required to be bifurcated from the host instrument and accounted for as a mark-to-market derivative liability until it lapses.

The investor warrants contain "non-standard" adjustments (down-round anti-dilution protection) for 12 months following issuance. The Company determined that the warrants contain certain embedded features that have to be evaluated under the guidance in ASC 815 and determined that they are also "embedded derivatives" that require bifurcation and are to be accounted for as a mark-to-market derivative liability until it lapses.

In connection with the offering, the Company incurred approximately $230,000 of direct and incremental issuance costs. The portion of these costs allocated to liability-classified derivative financial instruments, approximately $214,000, was expensed in 2016 and is reflected under general and administrative expense in the accompanying statement of operations. The remainder of the costs was allocated to the equity-classified common stock and recognized as a direct charge to additional paid-in capital.

The Company has concluded the following accounting treatment for the various instruments and embedded features:

- Common stock – equity classified

- Placement agent warrants – equity classified
- Investor warrants – derivative liability
- Right - derivative liability

The Company allocated the total proceeds from the 2016 Offering as follows:

Investor warrants - based on fair value relative to the fair value of the "right	$ 1,570,000
"Right" - based on fair value relative to the fair value of the investor warrants	60,000
Common stock and placement agent warrants – residual value (par and APIC)	120,000
	$ 1,750,000

An independent valuation expert calculated the fair value of the embedded derivatives using a complex, customized Monte Carlo simulation model. The model uses the risk neutral methodology adapted to value corporate securities. This model utilized subjective and theoretical assumptions that can materially affect fair values from period to period.

In April 2015, we entered into a contract with an investor relations firm to provide services for six months. Under the agreement the Company paid $5,000 per month and issued 30,000 shares of common stock as compensation. In addition, in May 2015 the Company issued 293,512 shares of common stock pursuant to the "cashless" exercise of warrants issued in 2010.

On August 29, 2014, the Company received gross proceeds of $1,000,000 and pursuant to the warrant exercise issued 8,333,333 shares of common stock at $0.12 per share pursuant to the securities purchase and licensing agreements signed with GtreeBNT on March 7, 2014. Under the securities purchase agreement, GtreeBNT invested $1,350,000 for the issuance of 11,250,000 common shares at $0.12 per share and was required to invest an additional $1,000,000 at $0.12 per share on or before August 31, 2014. Under the terms of the security purchase agreement, GtreeBNT also has the right to make an optional investment to acquire an additional 5.5 million shares of common stock at $0.15 per share. Such optional investment right expired unexercised on January 31, 2015.

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 $342,483 and $231,607 in stock-based compensation expense for the years ended December 31, 2016 and 2015, respectively. Given our current estimates of future forfeitures, we expect to recognize the compensation cost related to non-vested options as of December 31, 2016 of $398,000 over the weighted average remaining recognition period of 0.9 years.

Stock Option and Incentive Plans. On July 14, 2010, at our Annual Meeting of Stockholders, our stockholders approved the 2010 Equity Incentive Plan (the "2010 Plan"). The terms of the 2010 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. At inception of the 2010 Plan, 5,000,000 shares of our common stock were reserved for future issuance. On September 10, 2014 at our Annual Meeting of Stockholders, our stockholders approved an increase in the number of shares available under the 2010 Equity Incentive Plan (the "2010 Plan"). The increase of 3,000,000 results in a total of 8,000,000 shares of common stock reserved for issuance.

We previously adopted an equity incentive plan, known as the Amended and Restated 2000 Stock Option and Incentive Plan (the "2000 Plan"). The 2000 Plan has a term of ten years that expired in December 2010. All outstanding option awards granted under the 2000 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 2000 Plan. Shares remaining available for issuance under the share reserve of the 2000 Plan will not be subject to future awards under the 2010 Plan, and shares subject to outstanding awards under the 2000 Plan that are terminated or forfeited in the future will not be subject to future awards under the 2010 Plan.

The following summarizes share-based compensation expense for the years ended December 31, 2016 and 2015, which was allocated as follows:

	Years ended December 31,	
	2016	2015
Research and development	$ 116,327	$ 72,766
General and administrative	226,156	158,841
	$ 342,483	$ 231,607

The following summarizes stock option activity for the years ended December 31, 2016 and 2015:

		Options outstanding		
	Shares available for grant	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2014	3,273,029	6,263,711	$ 0.14 – 3.21	$ 0.58
Grants	—	1,725,000	0.19 – 0.40	0.33
Exercises	—	—	—	—
Cancellations*	—	(857,500)	0.14 – 3.21	0.41
December 31, 2015	1,548,029	7,131,211	$ 0.14 – 3.00	$ 0.30
Grants	—	940,000	0.64	0.64
Exercises	—	—	—	—
Cancellations*	—	(372,500)	0.76 – 3.00	1.23
December 31, 2016	608,029	7,698,711	$ 0.14 – 0.64	$ 0.29
Vested and expected to vest at December 31, 2016	7,616,021			
Exercisable at December 31, 2016	5,632,461			

*Note: Cancellations in 2016 and 2015 were for options issued out of the 2000 Equity Incentive Plan and therefore they are not available for reissuance.

The following summarizes information about stock options outstanding at December 31, 2016:

	Outstanding options			Exercisable options		
Range of exercise prices	Number of shares outstanding	Weighted-average remaining contractual life (in years)	Weighted-average exercise price	Number of shares exercisable	Weighted-average remaining contractual life (in years)	Weighted-average exercise price
$0.14 – $0.28	5,051,971	3.1	$ 0.19	4,315,721	2.8	$ 0.19
$0.36 – $0.64	2,646,740	5.4	0.49	1,241,740	5.4	0.47
	7,698,711	3.9	0.29	5,557,461	3.3	0.25
Intrinsic value of in-the-money options, using the December 31, 2016 closing price of $0.32	$ 648,567			$ 572,580		

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, 2016 and 2015:

	2016	2015
Dividend yield	0.0%	0.0%
Risk-free rate of return	1.41%	1.43-1.63%
Expected life in years	4.75 - 7	4.75 - 7
Volatility	87-95%	90-94%
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. We estimate forfeiture rates at the time of grant and adjust these estimates, if necessary, periodically based on the extent to which future actual forfeitures differ, or are expected to differ, from such estimates. Accordingly, we have estimated forfeiture percentages for the unvested portion of previously granted awards that remain outstanding at the date of adoption and for awards granted subsequent to the date of adoption. Forfeitures are estimated based on the demographics of current option holders and standard probabilities of employee turnover. Using Black-Scholes and these factors, the weighted average fair value of stock options granted to employees and directors was $0.46 for the year ended December 31, 2016. 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.

Warrants to Purchase Common Stock

The following table summarizes our warrant activity for 2016 and 2015:

		Warrants outstanding	
	Number of shares	**Exercise price range**	**Weighted average exercise price**
December 31, 2014	14,103,048	$ 0.15 – 0.56	$ 0.35
Exercises	(957,641)	0.38 - 0.45	0.40
Cancellations	(11,338,000)	0.15 - 0.56	0.41
December 31, 2015	1,807,407	$ 0.15 – $0.38	$ 0.32
Grants	5,404,412	0.37 – 0.51	0.50
Cancellations	(1,407,407)	0.38	0.38
December 31, 2016	5,804,412	$ 0.15 – $0.51	$ 0.48

9. INCOME TAXES

The Company did not recognize a provision (benefit) for income taxes in its statements of operations for 2016 and 2015. The Company has provided a full valuation allowance against its net deferred tax assets, as it appears more likely than not that its net deferred tax assets will not be realized.

Significant components of the Company's deferred tax assets at December 31, 2016 and 2015 and related valuation reserves are presented below:

	December 31,	
	2016	2015
Net deferred tax assets:		
Net operating loss carryforwards	$ 18,229,000	$ 17,856,000
Research and development tax credit carryforward	2,263,000	2,257,000
Charitable contribution carryforward	2,000	3,000
Accrued expenses and deferred revenue	643,000	565,000
Amortization	1,000	2,000
Depreciation	(1,000)	1,000
Non-cash share- based compensation	1,145,000	1,083,000
	22,282,000	21,767,000
Less — valuation allowance	(22,282,000)	(21,767,000)
Net deferred tax asset	$ —	$ —

At December 31, 2016, we had net operating loss carryforwards for income tax purposes of approximately $47 million, which are available to offset future federal and state taxable income, if any, and, research and development tax credit carryforwards of approximately $2.3 million. The carryforwards, if not utilized, will expire in increments through 2036.

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 at December 31, 2016 and 2015. 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, 2016 and 2015, due to the following:

	December 31,	
	2016	2015
Federal tax benefit at statutory rate	$ 78,000	$ (1,782,000)
State taxes	12,000	(285,000)
Change in fair value of derivative liabilities	(735,000)	1,336,000
Other permanent differences and other	137,000	98,000
Research and experimental tax credits	(7,000)	(8,000)
Change in valuation allowance	515,000	641,000
	$ —	$ —

As discussed in Note 2, we recognize the effect of income tax positions only if those positions more likely than not of being sustained. At December 31, 2016 and 2015, 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, 2016 and 2015.

The 2006 through 2016 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. COMMITMENTS

Lease. 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.

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, 2016 these obligations, if triggered, could amount to a maximum of approximately $120,000 for termination without cause or $240,000 with a change of control in the aggregate.

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)
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, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets at December 31, 2016 and 2015; (ii) Statements of Operations for the years ended December 31, 2016 and 2015; (iii) Statements of Cash Flows for the years ended December 31, 2016 and 2015; and (iv) 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 dated March 29, 2017, on our audits of the financial statements of RegeneRx Biopharmaceuticals, Inc., which includes an explanatory paragraph relating to the Company's ability to continue as a going concern, as of December 31, 2016 and 2015 and for the years then ended, included in this Annual Report on Form 10-K for the year ended December 31, 2016.

/s/ CohnReznick LLP

Tysons, Virginia
March 29, 2017

EXHIBIT 31.1

CERTIFICATION

I, J.J. Finkelstein, certify that:

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

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

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

4. The registrant's other certifying officer 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:

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

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

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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

5. 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):

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

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

Date: March 29, 2017

/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, 2016, 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:

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

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of 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 29, 2017

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