FORM 10-K

REGENERX BIOPHARMACEUTICALS INC - RGRX

Filed: March 29, 2018 (period: December 31, 2017)

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, 2017

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 ☐	Smaller reporting company ☑
(Do not check if a smaller reporting company)	Emerging growth company ☐

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

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

As of March 23, 2018, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $13.8 million. Such aggregate market value was computed by reference to the closing price of the Common Stock as quoted on the Over-the-Counter Bulletin Board, or the OTC Bulletin Board, on March 23, 2018.

The number of shares outstanding of the registrant's common stock as of March 23, 2018 was 114,936,762.

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.

Current Financial Status

On June 27, 2016, we entered into a Securities Purchase Agreement with Sabby Healthcare Master Fund, Ltd., and Sabby Volatility Warrant Master Fund, Ltd. (collectively, "Sabby") 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. On March 2, 2018, we entered into a warrant reprice and exercise and issuance agreement (the "Reprice Agreement") with the holders of the warrants issued in June 2016 as part of the offering we completed at that time. Under the terms of the Reprice Agreement, in consideration of the holders exercising in full all of the 2016 Offering warrants, the exercise price per share of the warrants was reduced to $0.20 per share. In addition, and as further consideration, we issued to the holders of the 2016 Offering warrants 3,860,294 new warrants with an exercise price of $0.2301 per share. We received gross proceeds of approximately $1,000,000 pursuant the exercise and issued 5,147,059 of common stock. In March 2014, we entered into a License Agreement with GtreeBNT Co. Ltd.'s, a Korean pharmaceutical company ("GtreeBNT") to license certain development and commercialization rights for RGN-137 in the U.S., ("RGN-137 License Agreement"). In August 2017, we amended the RGN-137 License Agreement with GtreeBNT in exchange for a series of payments the last of which will be received in June 2018. The amendment payments and warrant reprice proceeds, plus our year end cash balance, will fund planned operations into the first quarter of 2019. We continuously monitor our cash use as well as the clinical timelines. We continue to evaluate options including the licensing of additional rights to commercialize our clinical products as well as raising capital through the capital markets.

Current Clinical Status

In January 2015, we entered into a Joint Venture Agreement with GtreeBNT whereby we created ReGenTree LLC, ("ReGenTree or Joint Venture"), jointly owned by us and GtreeBNT, which will commercialize RGN-259 for treatment of dry eye and neurotrophic keratopathy, an orphan indication in the United States. We are entitled to royalties as a percentage of net sales ranging from single digits to 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. We currently hold a 38.5% ownership interest in ReGenTree. This ownership interest may be further reduced to as low as 25% once ReGenTree obtains FDA approval of an NDA for Dry Eye Syndrome in the U.S. 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.

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

The NK trial, a smaller study in an orphan population, has enrolled sixteen 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. 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.

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. We believe 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.

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, when and if conducted, will be an open study to evaluate the efficacy and safety of RGN-137 topically administered to EB patients. In August 2017, the Company amended the License Agreement for RGN-137 held by GtreeBNT. Under the amendment, the Territory was expanded to include Europe, Canada, South Korea, Australia and Japan. The expanded territory is expected to facilitate enrollment of the planned Phase 3 clinical trial and eventual commercialization.

Currently, we have active partnerships in four major territories: the U.S., EU, China and Pan Asia. Our partners have been moving forward and making progress in each territory. In each case, the cost of development is being borne by our partners with no financial obligation for RegeneRx. We still have significant clinical assets to develop, primarily RGN-352 (injectable formulation of Tß4 for cardiac and CNS disorders) in the U.S., most of Asia, and Europe; and RGN-259 in the EU. In August 2017, we amended the RGN-137 License Agreement with GtreeBNT, expanding the territory to include Europe, Canada, South Korea, Australia and Japan. Regarding RGN-259, our goal is to wait until satisfactory results are obtained from the current ophthalmic clinical program in the U.S. before moving into the EU, although we continue to evaluate strategic opportunities. 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, central nervous system indications and other medical indications where systemic administration may be appropriate, either by obtaining grants to fund a Phase 2a clinical trial in these or finding a suitable partner with the resources and capabilities to develop it as we have with RGN-259.

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

Overview of Tß4

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

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

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

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

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

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

- ***Anti-Apoptosis.*** Tß4 has been shown to prevent apoptosis, or programmed cell death, in two animal models and in two tissue types. In the rodent model, corneal apoptosis, or loss of corneal epithelial cells leading to corneal epithelial thinning, was prevented through topical administration of Tß4 eye drops. In the heart muscle of ischemic animal models, such as in mice and pigs, cell death was prevented by either local or systemic administration of Tß4. 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. In November 2011, we reported preliminary safety and efficacy results from the trial. RGN-259 was deemed safe and well-tolerated, with no observed drug-related adverse events.

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

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

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

The ARISE-2 study, which was conducted together with Ora, Inc., demonstrated a number of statistically significant improvements in both signs and symptoms of dry eye syndrome with 0.1% RGN-259 versus placebo, while showing excellent safety, comfort, and tolerability profiles. The ocular discomfort symptom showed a statistically significant reduction in the RGN-259-treated group at day 15 as compared to placebo ($p=0.0149$) in the change from baseline. For sign, RGN-259 also improved the dry eye patient's ability to withstand an exacerbated condition in a patient subgroup with both compromised corneal fluorescein staining and Schirmer's test at baseline. In this population, RGN-259 showed superiority over placebo in reducing corneal fluorescein staining in the change from baseline at days 15 and 29 ($p=0.0207$ and 0.0254, respectively). RGN-259 confirmed its global effects on dry eye syndrome and fast onset in multiple sign and symptom efficacies with no safety issues in the ARISE-1 and ARISE-2 studies as well as in the pooled data, although ARISE-2 was not successful in duplicating the results of ARISE-1 where the study population was limited and less diversified. ReGenTree is proceeding with its RGN-259 development plan and intends to meet with the FDA in April 2018.

Strategic Partnerships

Lee's Pharmaceuticals. We are a party to 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 (the "Lee's License Agreement"). 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.

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

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. Per the terms of the license agreement, GtreeBNT will be sponsoring and funding the clinical trial.

U.S. Joint Venture (ReGenTree, LLC). We are a party to the ReGenTree Joint Venture discussed above in this report.

RGN-352

In 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). Starting in 2005, we began conducting a Phase 2 clinical trial designed to assess the safety and effectiveness of RGN-137 for the treatment of patients with EB. EB is a genetic disease of approximately 10 gene mutations that results in fragile skin and other epithelial structures (e.g., cornea and GI tract) that can blister spontaneously or separate at the slightest trauma or friction, creating a wound that at times does not heal or heals poorly. In severe cases, recurrent blistering and tissue loss may be life threatening. EB has been designated as an "orphan" indication by the FDA's Office of Orphan Drugs. We closed the Phase 2 trial in late 2011 and we submitted the final report to the FDA in 2014.

Clinical Development — Pressure Ulcers. In late 2005, we began conducting Phase 2 clinical trial designed to assess the safety and effectiveness of RGN-137 for the treatment of patients with chronic pressure ulcers, commonly known as bedsores. In January 2009, we reported final data from this trial. RGN-137 was well-tolerated at all three dose levels studied, with no dose-limiting adverse events, which achieved the primary objective of the study. A follow-on evaluation, reported at the 3rd International Symposium on the Thymosins in Health and Disease in March 2012, showed that for those pressure ulcer patients' wounds that healed, RGN-137 mid dose (0.02% Tβ4 gel product) accelerated wound closure with a median time to healing of 22 days as compared to 57 days for the placebo. Although those results are clinically significant, they were not statistically significant.

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

Our Strategy

We seek to monetize our product candidates by advancing their clinical development and then identifying suitable partners for further development, regulatory approval, and marketing. We intend to engage in strategic partnerships with companies with clinical development and commercialization strengths in desired pharmaceutical therapeutic fields. We are actively seeking partners with suitable infrastructure, expertise and a long-term initiative in our medical fields of interest. To that end, we have entered the licensing and joint ventures discussed above.

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 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, a FDA-approved eye drop used to treat dry eye. Restasis, and other products, have been approved for marketing in certain other countries where we have licensed RGN-259. Shire PLC is marketing its recently FDA-approved product, Xiidra. We believe RGN-259 is different than any other product or product candidate available for dry eye in that it actively promotes repair using a multi-faceted approach of increasing cell migration and laminin-5 production, and decreasing inflammation and apoptosis, without any noted adverse effects.

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

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

Government Regulation

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

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

The results of 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. In 2007, patents were issued in Europe and the United States related to the original NIH patent application. These patents expire in July 2019. Corresponding patents have also been granted in Hong Kong, Australia and China and certain other territories. The issued European patent was opposed by a third party at the European Patent Office and, in December 2009, we argued the case before the Opposition Division of the European Patent Office in Munich, Germany and prevailed with certain amendments to the claims. In exchange for the exclusive license, we agreed to make certain minimum royalty and milestone payments to the NIH.

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

We 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 2015. There can be no assurance that these, or any other future patent applications under which we have rights, will result in the issuance of a patent or that any patent issued will not be subject to challenge or opposition. In the case of a claim of patent infringement by or against us, there can be no assurance that we will be able to afford the expense of any litigation that may be necessary to enforce our proprietary rights.

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

Material Agreements

National Institutes of Health

We are party to a license agreement with NIH under which we are obligated to pay an annual minimum royalty of $2,000. In 2013, we amended certain provisions of the exclusive license; we were permitted to credit amounts paid to prosecute or maintain the licensed patent rights during 2013 calendar year against the 2013 minimum annual royalty. Beginning in 2014, the minimum annual royalty 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, 2017, we have complied with all minimum royalty requirements, and no milestone payments have been required under the agreement.

Defiante/Sigma-Tau/Alfa Wassermann

In 2004, we entered into a strategic partnership for development and marketing of RGN-137 and RGN-352 for specified fields of use in Europe and other contiguous countries with Sigma-Tau Group, which was subsequently acquired by Alfa Wassermann S.p.A., both Italian pharmaceutical companies. Pursuant to the terms of the license, we notified Alfa Wassermann that the license expired by its terms and we, therefore, reacquired rights to our Tß4-based products in the licensed territory. In August 2017, the Company amended the License Agreement for RGN-137 held by GtreeBNT to include some of the rights to RGN-137 reacquired from Alfa Wassermann as discussed below.

Lee's Pharmaceuticals

On July 15, 2012, we entered into a License Agreement with Lee's Pharmaceutical for the license of Tß4 in any pharmaceutical formulation, including our RGN-259, RGN-352 and RGN-137 product candidates, in China, Hong Kong, Macau and Taiwan. The terms of the 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 Company has 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 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.

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. Under an amendment to the RGN-137 License, for which the Company was compensated, the Territory was expanded to include Europe, Canada, South Korea, Australia and Japan.

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 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.

ReGenTree - 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 received and initial equity stake of 49% of ReGenTree. GtreeBNT's equity stake may increase (and RegeneRx's would proportionally decrease) upon ReGenTree achieving certain product development milestones (including receipt of a new drug application ("NDA") by the U.S. FDA). GtreeBNT has subsequently funded the initial Phase 2b/3 and the ongoing Phase 3 U.S. clinical trials for dry eye syndrome and neurotrophic keratopathy, respectively.

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

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

ReGenTree is 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

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

Employees

We currently have three full time employees including our President and CEO. 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 into the first quarter of 2019.

Even though we entered into the Reprice Agreement the result of which was the receipt of net proceeds of approximately $1,000,000, these proceeds, coupled with payments received and to be received under the amendment of the RGN-137 are projected to fund our operations at the current level into the first quarter of 2019 We will need to secure additional operating capital to continue operations beyond the first quarter of 2019. We continuously monitor our cash use as well as the clinical timelines. We will need to secure additional operating capital in 2018 or early 2019 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 short-term capital needs and our long-term liquidity requirements would have a material negative impact on our business, including the possibility of surrendering our rights to some technologies or product opportunities, delaying our clinical trials or ceasing our operations.

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

We have not commercialized any product candidates to date and incurred net operating losses every year since our inception in 1982. We believe these losses will continue for the foreseeable future, and may increase, as we pursue our product development efforts related to Tß4. As of December 31, 2017, 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 continue to sustain losses over an extended period of time and are not otherwise able to raise necessary funds to continue our development efforts and maintain our operations, we may be forced to cease operations.

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

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

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

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

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, 2017 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, in August 2017, we amended the RGN-137 License Agreement with GtreeBNT in exchange for a series of payments the last of which is scheduled for June 2018. On March 2, 2018, we received gross proceeds of approximately $1,000,000 under a Reprice Agreement These proceeds, plus our year end cash balance coupled with payments received and to be received under the amendment of the RGN-137, will fund planned operations into the first quarter of 2019. We will need to secure additional operating capital to continue operations beyond the first quarter of 2019. 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 learned that the contract manufacturer has closed its manufacturing facility and has filed for bankruptcy protection. Significant preparatory time and procedures will be required before any new suitable manufacturer would be able to manufacture RGN-352 for the AMI trial. Since we are unable to estimate the length of time that the trial will be on clinical hold, we have elected to cease activities on this trial until the FDA clinical hold is resolved and the requisite funding might be secured. Consequently, there can be no assurance that we will be able to timely initiate trial activities or complete this trial, if at all. As of the date of this report, we have received no new information on that status of this trial.

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

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

We may never be able to commercialize our product candidates.

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

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

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

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

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

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

- the FDA or other health regulatory authorities, or institutional review boards, or IRBs, do not approve a clinical trial protocol or place a clinical trial on hold;
- suitable patients do not enroll in a clinical trial in sufficient numbers or at the expected rate, for reasons such as the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the perceptions of investigators and patients regarding safety, and the availability of other treatment options;
- clinical trial data is adversely affected by trial conduct or patient withdrawal prior to completion of the trial;
- there may be competition with ongoing clinical trials and scheduling conflicts with participating clinicians;
- patients experience serious adverse events, including adverse side effects of our drug candidates, for a variety of reasons that may or may not be related to our product candidates, including the advanced stage of their disease and other medical problems;
- patients in the placebo or untreated control group exhibit greater than expected improvements or fewer than expected adverse events;
- third-party clinical investigators do not perform the clinical trials on the anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- service providers, collaborators or co-sponsors do not adequately perform their obligations in relation to the clinical trial or cause the trial to be delayed or terminated;
- we are unable to obtain a sufficient supply of manufactured clinical trial materials;
- regulatory inspections of manufacturing facilities, which may, among other things, require us or a co-sponsor to undertake corrective action or suspend the clinical trials, such as the clinical hold with respect to our Phase 2 clinical trial of RGN-352;
- the interim results of the clinical trial are inconclusive or negative;
- the clinical trial, although approved and completed, generates data that is not considered by the FDA or others to be clinically relevant or sufficient to demonstrate safety and efficacy; and
- changes in governmental regulations or administrative actions affect the conduct of the clinical trial or the interpretation of its results.

There can be no assurance that 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.

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

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

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

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

We have 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. Other companies are developing genetic therapies to treat wound healing of the skin and internal organs. Wound healing is a large and highly fragmented marketplace attracting many companies, large and small, to develop products for treating acute and chronic wounds, including, for example, honey-based ointments, hyperbaric oxygen therapy, and low frequency cavitational ultrasound.

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

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

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

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

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

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

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

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

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

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

Any changes related to these and other factors could adversely affect our business if and to the extent we enter markets outside the United States. Additionally, we have entered into license agreements with 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 is a director of Lee's Pharmaceuticals a relationship which could give rise to a conflict of interest for Mr. Bove.

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

Risks Related To Our Intellectual Property

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

Our success will depend in part on our, or our partners' ability to obtain, defend and enforce patents, both in the United States and abroad. We have attempted to create a substantial intellectual property portfolio, submitting patent applications for various compositions of matter, methods of use and fragments and derivatives of Tß4. As described elsewhere in this report, we currently do not have adequate financial resources to fund our ongoing business activities beyond the second quarter of 2018 without additional funding. Thus, we continuously evaluate our issued patents and patent applications and may decide to limit their therapeutic and/or geographic coverage in an effort to enhance our ability to focus on certain medical conditions and countries within our financial constraints. As a result, we may not be able to protect our intellectual property rights in indications and/or territories that we otherwise would, and, therefore, our ability to commercialize Tß4, if at all, could be substantially limited, which could have a material adverse impact on our future results of operations.

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. Moreover, a divisional patent that is filed after a parent patent, if granted, would begin its term beginning when the parent patent was initially filed, thus having an impact on the divisional patent's practical patent life, Future changes to patent laws could shorten our period of patent exclusivity and may decrease the revenues that we might derive from the patents and the value of our patent portfolio.

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

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

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

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

Risks Related To Our Securities

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

For the period from January 1, 2017 through March 23, 2018 the closing price of our common stock has ranged from $0.15 to $0.37, with an average daily trading volume of approximately 61,000 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 50.9% of our outstanding common stock. Included in this group are previous stockholders of Sigma-Tau and their affiliates, which together hold outstanding shares representing approximately 29.1% of our outstanding common stock and GtreeBNT which owns approximately 17.8% of our outstanding common stock. These stockholders also hold options, warrants, convertible promissory notes and stock purchase rights that provide them with the right to acquire significantly more shares of common stock. Accordingly, if these stockholders acted together they could control the outcome of all stockholder votes. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock, and therefore may not be in the best interest of our other stockholders.

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

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

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

As of December 31, 2017, there were outstanding options to purchase an aggregate of 8,058,788 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 5,404,412 shares of our common stock at a weighted average exercise price of $0.50 per share. On March 2, 2018 we entered into a warrant reprice and exercise and issuance agreement (the "Reprice Agreement") with the holders of the warrants issued in June 2016. Under the terms of the Reprice Agreement, in consideration of the holders exercising in full all of the 2016 Offering warrants the exercise price per share of 5,147,059 warrants was reduced to $0.20 per share. As further consideration, we issued to the holders of the 2016 Offering warrants 3,860,294 new warrants with an exercise price of $0.2301 per share. In addition to the outstanding options and warrants we have also issued five series of convertible promissory notes of which four remain outstanding. These four are presently convertible into an aggregate of 11,683,334 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 and Matured and were converted by the holders in October 2017. 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.

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 in February 2017 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 $0.23 on March 23, 2018.

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

	2017		2016	
	High	Low	High	Low
First Quarter	$ 0.33	$ 0.28	$ 0.75	$ 0.37
Second Quarter	$ 0.30	$ 0.26	$ 0.75	$ 0.28
Third Quarter	$ 0.34	$ 0.25	$ 0.47	$ 0.32
Fourth Quarter	$ 0.37	$ 0.15	$ 0.40	$ 0.25

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

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

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.

The Company issued 95,608 shares of common stock during the three-month period ended June 30, 2017 pursuant to the exercise of stock options granted in December 2011 and April 2012.

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

On March 2, 2018, we entered into a warrant reprice and exercise and issuance agreement (the "Reprice Agreement") with the holders of the warrants issued in June 2016. Under the terms of the Reprice Agreement, in consideration of the holders exercising in full all of the 2016 Offering warrants, the exercise price per share of the warrants was reduced to $0.20 per share. In addition, and as further consideration, we issued to the holders of the 2016 Offering warrants 3,860,294 new warrants with an exercise price of $0.2301 per share. We received gross proceeds of approximately $1,000,000 pursuant the exercise and issued 5,147,059 of common stock. In August 2017, we amended the RGN-137 License Agreement with GtreeBNT in exchange for a series of payments the last of which will be received in June 2018. The amendment payments and warrant reprice proceeds plus our year end cash balance will fund planned operations into the first quarter of 2019. We continuously monitor our cash use as well as the clinical timelines. We continue to evaluate options including the licensing of additional rights to commercialize our clinical products as well as raising capital through the capital markets.

Current Clinical Status

In January 2015, we entered into the Joint Venture Agreement with GtreeBNT whereby we subsequently created 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. In conjunction with the Joint Venture Agreement, we also a party to a royalty-bearing License Agreement that grants ReGenTree the right to develop and exclusively commercialize RGN-259 in the United States and Canada. We are entitled to royalties as a percentage of net sales ranging from single digits to 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. We currently hold a 38.5% ownership interest in ReGenTree. This ownership interest may be further reduced to as low as 25% once ReGenTree obtains 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.

To date ReGenTree has sponsored a Phase 2/3 clinical trial ("ARISE-1") and a Phase 3 clinical trial in patients with dry eye syndrome ("DES") ("ARISE-2") and in patients with neurotrophic keratopathy ("NK") ("SEER-1"), all in the U.S. In May 2016, we reported the results of the 317-patient ARISE-1 trial and in October 2017, we reported the results of the ARISE-2 trial. The ARISE-2 study, which was conducted together with Ora, Inc., demonstrated a number of statistically significant improvements in both signs and symptoms of dry eye syndrome with 0.1% RGN-259 versus placebo, while showing excellent safety, comfort, and tolerability profiles. The ocular discomfort symptom showed a statistically significant reduction in the RGN-259-treated group at day 15 as compared to placebo (p=0.0149) in the change from baseline. For sign, RGN-259 also improved the dry eye patient's ability to withstand an exacerbated condition in a patient subgroup with both compromised corneal fluorescein staining and Schirmer's test at baseline. In this population, RGN-259 showed superiority over placebo in reducing corneal fluorescein staining in the change from baseline at days 15 and 29 (p=0.0207 and 0.0254, respectively). RGN-259 confirmed its global effects on dry eye syndrome and fast onset in multiple sign and symptom efficacies with no safety issues in the ARISE-1 and ARISE-2 studies as well as in the pooled data, although ARISE-2 was not successful in duplicating the results of ARISE-1 where the study population was limited and less diversified. ReGenTree is proceeding with its RGN-259 development plan and intends to meet with the FDA as soon as practicable.

The NK trial, a smaller study in an orphan population, has enrolled sixteen 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 six 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.

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.

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, when and if conducted, 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. In August 2017, the Company amended the License Agreement for RGN-137 held by GtreeBNT. Under the amendment the Territory was expanded to include Europe, Canada, South Korea, Australia and Japan. The expanded territory is expected to facilitate enrollment of the planned Phase 3 clinical trial.

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

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 first quarter of 2019 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 staff and our independent contractors who focus primarily on management of R&D related activities. 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 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

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

Because we are not obligated to fund the Joint Venture, and have not provided any financial support, and have no commitment to provide financial support in the future to the Joint Venture, the carrying value of its investment in the Joint Venture is zero. As a result, we are not recognizing our share of the Joint Venture's operating losses and will not recognize any such losses until the Joint Venture produces net income (as opposed to net losses) and at that point we will reduce our share of the Joint Venture's net income by our share of previously suspended net losses. As of December 31, 2017, because we have not provided any financial support, we have no financial exposure as a result of its variable interest in the Joint Venture.

Convertible Notes with Detachable Warrants.

In accordance with 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.

We do not use derivative financial instruments to hedge exposures to cash-flow, market or foreign-currency risks. However, we have 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 our financial statements. In other instances these instruments are classified as equity instruments in our financial statements.

We estimate the fair values of its derivative financial instrument using the Black-Scholes option pricing model and in certain instances have used a custom Monte Carlo model where appropriate as these models embody 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 our common stock, which has a high-historical volatility. Since derivative financial instruments are initially and subsequently carried at fair values, our 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. 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, 2017 and 2016

Revenues. For the year ended December 31, 2017, we recorded revenue in the amount of $56,652 versus $93,308 recorded for the year ended December 31, 2016. The 2017 revenue reflects the amortization over 25 years of the payments we received under the original joint venture license agreement, the payment we received for the expansion of the territorial rights to include Canada in April 2016 as well as the initial payments received under the 2017 RGN-137 license amendment. The licensing revenues recorded in 2017 was $56,652 versus $48,308 in 2016. The 2016 revenue reflects revenue related to the sale of unformulated Tß4 to GtreeBNT for use in their product development work in Korea. Revenue recorded for the 2016 sale was $45,000.

Expenses — Research and development. For the year ended December 31, 2017, our R&D expenditures decreased by $93,000, or 39%, to $144,000, from approximately $237,000 in 2016. The decrease reflects a further shift of our internal R&D efforts as our partners assume full responsibility for clinical development and is characterized by decreases in R&D personnel costs (decrease of $23,000) and stock option expense (decrease of $33,000) versus the prior year. Additional decreases reflected in 2017 include, R&D consulting (decrease of $22,000) and a decrease in internal allocations (decrease of $15,000). 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, 2017, our G&A expenses decreased by approximately $172,000, or 11%, to $1,357,000 from $1,530,000 in 2016. Increases are reflected in 2017 expenses for professional services (increase of $46,000), insurance (increase of $49,000), sponsorship (increase of $10,000) and internal allocations (increase of $15,000) which were offset by decreases in facility and related expenses (decrease of $10,000), investor relations (decrease of $30,000) and stock option expense (decrease of $38,000) and the absence of offering expenses which in 2016 was approximately $214,000 related to our 2016 Offering. We believe that our G&A expenses will remain at current levels as we wait for data from the upcoming clinical trials being conducted by our partners. If we enter into additional partnerships or other business transactions, including financings, we will incur additional legal and transaction related expenses.

Expenses - Provision for income tax. For the year ended December 31, 2017, our income tax expense increased by $99,000 which relates to the tax withholding of certain amounts from the initial payments received under the RGN-137 License Agreement amendment. The withholding is mandated under a United States of America and The Republic of Korea Tax treaty entered into in 1976.

Net Income. In 2017, we had net income of $286,487 versus net income of $229,125 in 2016. The net income in both years reflect the decrease in the value of the derivative liabilities recorded on our balance sheet at each year end. The 2017 decrease relates primarily to 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 change in the value of the derivative liabilities recorded on the December 31, 2017 balance sheet was a decrease of $2,941,668 which reflects a gain on the decrease in derivative liability value for the year ended December 31, 2017 of $2,000,605 as well as the reclassification of the residual liability for the value of the warrants issued in the 2016 Offering ($941,063) to additional paid-in capital. In 2016, the decrease in the value of the conversion feature related to the derivative liability related to our convertible debt (decrease of $1,626,499) as well as the change in value of the warrants and investor rights associated with the 2016 Offering (decrease of $450,000) which resulted in a gain on the decrease in derivative liability value for the year ended December 31, 2016 of $2,076,499. The value of the 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 $0.32 on December 31, 2016 to $0.17 on December 31, 2017. In the prior year, the share price of our common stock decreased from $0.44 on December 31, 2015 to $0.32 on December 31, 2016. Losses from operations decreased in 2017 versus 2016, $1,444,630 and $1,674,019, 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, 2017 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 $286,487 for the year ended December 31, 2017. We had cash and cash equivalents of $181,708 at December 31, 2017. In March 2018, we received gross proceeds of approximately $1,000,000 pursuant the warrant Reprice Agreement and, in August 2017, we amended the RGN-137 License Agreement with GtreeBNT in exchange for a series of payments the last of which will be received in June 2018. The amendment payments and warrant reprice proceeds, plus our year end cash balance, will fund planned operations into the first quarter of 2019. We may also receive funds from grants, new partnerships or the raising of additional capital if the market climate warrants. Additionally, we intend to continue to pursue additional partnering activities, particularly for RGN-352, our injectable systemic product candidate for cardiac and central nervous system indications. We will need to secure additional funding in order to advance operations beyond the first quarter of 2019. This estimate also does not include receipt of any funds from grants, new partnerships or the raising of additional capital if the market climate warrants. A sale of common stock and warrants, a convertible instrument or additional partnering of licensed rights are possible sources of operating capital in the future. Additionally, we intend to continue to pursue additional partnering activities, particularly for RGN-352, our injectable systemic product candidate for cardiac and central nervous system indications.

Net Cash Used in Operating Activities. Net cash used in operating activities was $663,000 and $1,068,000 for the years ended December 31, 2017 and 2016, respectively. In 2017, our statement of cash flows reflects a net inflow of $543,000 related to payments received under license agreements versus $202,000 from the same source in 2016.

Net Cash Used in Investing Activities. We did not use any cash for investing activities in 2017 or 2016.

Net Cash Provided by Financing Activities. Net cash provided by financing activities totaled $75,000 and $1,520,000 for the years ended December 31, 2017 and 2016, respectively. In 2017, the cash provided by financing activities consisted of the proceeds from the exercise of stock options and warrants while the 2016 cash provided by financing activities reflects 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 October and data from the NK study in 2018 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.

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 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.

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. In June of 2016, we raised $1,520,000 by selling 5,147,059 shares of common stock and warrants to purchase 5,147,059 shares of common stock to Sabby. Most recently, on March 2, 2018, we entered into a warrant reprice and exercise and issuance agreement with Sabby, which, in consideration of the holders exercising in full all of the 2016 Offering warrants the exercise price per share of the warrants was reduced to $0.20 per share. In addition, and as further consideration, we issued to the holders of the 2016 Offering warrants 3,860,294 new warrants with an exercise price of $0.2301 per share. We received gross proceeds of approximately $1,000,000 pursuant the exercise and issued 5,147,059 of common stock. In August 2017, we amended the RGN-137 License Agreement with GtreeBNT in exchange for a series of payments, the last of which will be received in June 2018. The amendment payments and warrant reprice proceeds plus our year end cash balance will fund planned operations into the first quarter of 2019. We continuously monitor our cash use as well as the clinical timelines. We continue to evaluate options including the licensing of additional rights to commercialize our clinical products as well as raising capital through the capital markets.

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

Licensing Agreements

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

We also have entered into a license agreement with Lee's Pharmaceuticals that provides for the opportunity for us to receive milestone payments upon specified events and royalty payments in connection with any commercial sales of Tß4-based products in China, Hong Kong, Macau and Taiwan. 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, 2017 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, 2017.

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, 2017.

Changes in Internal Control over Financial Reporting

There were no changes to the Company's Internal Controls over Financial Reporting in the year ended December 31, 2017.

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, 2018 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	66	President, Chief Executive Officer and Director
Directors:		
Dr. Allan L. Goldstein	80	Founder, Chairman of the Board and Chief Scientific Officer
Mr. R. Don Elsey	64	Director
Mr. Joseph C. McNay	84	Director
Mr. Mauro Bove	63	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 36 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 the Dana Farber Cancer Institute, member of the Children's Hospital Investment Committee and is on the Board of Brigham & Women's Hospital. 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 Senior Vice President of Business Development at Lee's Pharmaceutical Holdings Inc, based in Hong Kong and is a consultant to emerging pharmaceutical companies in Asia. Previously, Mr. Bove led for more than 20 years the Corporate & Business Development of Sigma-Tau Finanziaria S.p.A., formerly the holding company of Sigma-Tau Group, a leading international pharmaceutical company (Sigma-Tau Finanziaria S.p.A. - now Essetifin S.p.a. - and its affiliates are collectively our largest stockholder). Mr. Bove, who resigned this role with Sigma-Tau on March 31, 2014, has also held a number of senior positions in business, licensing and corporate development within Sigma-Tau Group. Mr. Bove obtained his law degree at the University of Parma, Italy, in 1980. In 1985, he attended the Academy of American and International Laws at the International and Comparative Law Center, Dallas, Texas. The Board believes that Mr. Bove's extensive business and management experience within the pharmaceutical industry allows him to recognize and advise the Board with respect to recent industry developments.

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, 2017, 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, 2017 and 2016, compensation awarded to or paid to, or earned by, our chief executive officer who was our only named executive officers for fiscal 2017. For purposes of this report, we sometimes refer to our chief executive officer as our named executive officer.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards(1) ($)	All Other Compensation(2) ($)	Total ($)
J.J. Finkelstein, President and Chief Executive Officer	2017	150,000	—	30,973	3,360	184,333
	2016	150,000	—	91,090	3,360	244,450

(1) The 2017 & 2016 amounts reflect the aggregate total grant date fair values (computed in accordance with FASB ASC Topic 718 or ASC Topic 505)

(2) The 2017 & 2016 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, 2017

The following table shows certain information regarding outstanding equity awards at December 31, 2017 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	
	100,000	100,000	0.64	3/17/2023	(1)
	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	
	500,000	—	0.21	3/25/2021	(1)
	375,000	125,000	0.36	6/30/2022	(1)
	37,500	112,500	0.28	9/1/2027	(2)

(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.

(2) 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 ten years prior to the listed expiration dates.

Post-Employment Compensation

We do not maintain any plans providing for payment or other benefits at, following, or in connection with retirement other than a 401(k) plan which was available to all employees through 2011. The Company did not make any plan contributions in 2017 or 2016. 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, 2017 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 2017 or 2016.

In 2017 each independent director was granted options to purchase 125,000 shares of common stock at an exercise price of $0.28 per share, which vests in four segments pursuant to each director's continued service. In 2016 each independent director was granted options to purchase 100,000 shares of common stock with an exercise price per share of $0.64. 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 2017 and 2016.

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 2017

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)	All Other Compensation ($)	Total ($)
Allan Goldstein, Ph.D.	—	30,973	90,000(2)	120,973
R. Don Elsey	—	25,811	—	25,811
Joseph McNay	—	25,811	—	25,811
Mauro Bove	—	25,811	—	25,811

(1) Options held by each Board member as of December 31, 2017, are as follows:

Allan Goldstein, Ph.D.	1,635,577
R. Don Elsey	615,000
Joseph McNay	623,024
Mauro Bove	652,155

(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 2017. In 2017 Dr. Goldstein was also granted options to purchase 150,000 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, 2018 by (i) each director; (ii) each named executive officer; (iii) all currently serving executive officers and directors as a group; and (iv) all those known by us to be beneficial owners of more than five percent of our common stock. The address for all directors and executive officers is c/o RegeneRx Biopharmaceuticals, Inc., 15245 Shady Grove Road, Suite 470, Rockville, MD 20850.

	Beneficial Ownership[1]	
Beneficial Owner	**Number of Shares**	**Percent of Total**
5% Stockholders:		
Entities affiliated previously affiliated with Essetifin S.p.A., Via Sudafrica, 20, Rome, Italy 00144	34,355,399[2]	29.3%
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]	17.0%
Named Executive Officers and Directors:		
J.J. Finkelstein	3,534,251[4]	3.1%
Allan L. Goldstein	3,114,796[5]	2.7%
Joseph C. McNay	6,027,876[6]	5.2%
Mauro Bove	483,405[7]	*
R. Don Elsey	529,583[8]	*
All directors and executive officers as a group (5 persons)	**13,689,911[9]**	11.0%

* 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 114,936,762 shares of common stock outstanding on March 15, 2018, adjusted as required by rules promulgated by the Securities and Exchange Commission (the "SEC").

(2) Consists of 13,921,723 shares of common stock held of record held by Essetifin S.p.A. (f/k/a Sigma-Tau Finanziaria, S.p.A.) ("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 11,584,795 shares of common stock held of record and 2,500,000 shares of common stock issuable upon conversion of a convertible promissory note and 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, 2018. 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 October 17, 2017.

(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 1,533,535 shares of common stock held of record by Mr. Finkelstein, 1,917,383 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, 2018.

(5) Consists of 770,886 shares of common stock held of record by Dr. Goldstein, 933,333 shares of common stock issuable upon conversion of a convertible promissory note and 1,410,577 shares of common stock issuable upon exercise of options, in each case exercisable within 60 days of March 15, 2018.

(6) Consists of 1,823,602 shares of common stock held of record by Mr. McNay, 3,750,000 shares of common stock issuable upon conversion of a convertible promissory note and 454,274 shares of common stock issuable upon exercise of options, in each case exercisable within 60 days of March 15, 2018.

(7) Consists of 483,405 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2018.

(8) Consists of 446,250 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, 2018.

(9) Consists of 4,128,023 shares of common stock held of record, 4,849,999 shares of common stock issuable upon conversion of convertible promissory notes and 4,711,889 shares of common stock issuable upon exercise of options, in each case exercisable within 60 days of March 15, 2018.

Equity Compensation Plan Information

The following table provides information as of December 31, 2017 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	8,058,788	$ 0.29	109,179
Equity compensation plans not approved by security holders	—	—	—
Total	8,058,788	$ 0.29	109,179

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 2017 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.

GtreeBNT

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

U.S. Joint Venture

On January 28, 2015, we announced that we had entered into a Joint Venture Agreement with GtreeBNT a shareholder of the Company. ReGenTree, LLC was created under the Agreement and is jointly owned by us and GtreeBNT. ReGenTree intends to commercialize RGN-259 for treatment of dry eye and neurotrophic 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 38.5% after filing of the final clinical study report with the FDA for the Phase 3 trial for Dry Eye Syndrome completed in 2017. Based on when, and if, ReGenTree achieves certain additional development milestones in the U.S. with RGN-259, our equity ownership may be incrementally reduced to between 38.5% and 25%, with 25% being the final equity ownership upon FDA approval of an NDA for Dry Eye Syndrome in the U.S. In addition to our equity ownership, RegeneRx retains a royalty on net sales that varies between single and low double digits, depending on whether commercial sales are made by ReGenTree or a licensee. In the event ReGenTree is acquired, or a change of control occurs following achievement of an NDA, RegeneRx shall be entitled to a minimum of 40% of all proceeds paid or payable and will forgo any future royalties.

In September 2015, ReGenTree began a Phase 2/3 clinical trial in patients with dry eye syndrome ("DES") and a Phase 3 clinical trial in patients with neurotrophic 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, 2017 and 2016 by our independent registered public accounting firm CohnReznick LLP. All such fees described below were approved by the audit committee.

	2017	2016
Audit fees	$ 84,000	$ 83,000
Tax fees [1]	53,000	24,000
Total Fees	$ 137,000	$ 107,000

(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, 2018

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, 2018
/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, 2018
/s/ R. Don Elsey R. Don Elsey	Director	March 29, 2018
/s/ Joseph C. McNay Joseph C. McNay	Director	March 29, 2018
/s/ Mauro Bove Mauro Bove	Director	March 29, 2018

RegeneRx Biopharmaceuticals, Inc.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Regenerx Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Regenerx Pharmaceuticals, Inc. (the "Company") as of December 31, 2017 and 2016, and the related statements of operations, changes in stockholders' deficit and cash flows for the years then ended and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

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

Basis for Opinion

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

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

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

/s/ CohnReznick LLP

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

Tysons, Virginia
March 29, 2018

RegeneRx Biopharmaceuticals, Inc.
Balance Sheets

	December 31, 2017	December 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	$ 181,708	$ 769,495
Prepaid expenses and other current assets	35,442	79,936
Total current assets	217,150	849,431
Property and equipment, net of accumulated depreciation of $95,168 and $92,120	4,171	7,219
Other assets	5,752	5,752
Total assets	$ 227,073	$ 862,402
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 66,461	$ 75,695
Unearned revenue	78,893	50,822
Accrued expenses	232,365	233,239
Convertible promisory note	-	300,000
Convertible promisory notes, net of derivative liability	591,036	-
Fair value of derivative liabilities	1,184,334	-
Total current liabilities	2,153,089	659,756
Long-term liabilities		
Unearned revenue	2,045,622	1,530,345
Convertible promisory notes, net of derivative liability	43,819	512,022
Fair value of derivative liabilities	100,835	4,226,837
Total liabilities	4,343,365	6,928,960
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, 109,789,703 and 106,787,151 issued and outstanding	109,790	106,787
Additional paid-in capital	100,333,144	98,672,368
Accumulated deficit	(104,559,226)	(104,845,713)
Total stockholders' deficit	(4,116,292)	(6,066,558)
Total liabilities and stockholders' deficit	$ 227,073	$ 862,402

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Operations

	Years ended December 31,	
	2017	**2016**
Revenues	$ 56,652	$ 93,308
Operating expenses		
Research and development	143,911	237,344
General and administrative	1,357,371	1,529,983
Total operating expenses	1,501,282	1,767,327
Loss from operations	(1,444,630)	(1,674,019)
Other income (expense)		
Interest expense	(170,883)	(173,355)
Change in fair value of derivative liabilities	2,000,605	2,076,499
Total other income (expense)	1,829,722	1,903,144
Income before taxes	385,092	229,125
Provision for income taxes	98,605	-
Net income	$ 286,487	$ 229,125
Basic net income per common share	$ 0.00	$ 0.00
Diluted net income per common share	$ 0.00	$ 0.00
Weighted average number of common shares outstanding - basic	107,442,936	106,787,151
Weighted average number of common shares outstanding - diluted	120,928,833	125,922,455

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Changes in Stockholders' Deficit
Years ended December 31, 2017 and 2016

	Common stock		Additional	Accumulated	Total stockholders'
	Shares	Amount	paid-in capital	deficit	deficit
Balance, December 31, 2015	101,640,092	$ 101,640	$ 98,230,802	$ (105,074,838)	$ (6,742,396)
Issuance of common stock and 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)
Issuance of common stock - option exercises	95,608	96	15,202	-	15,298
Issuance of common stock - note conversions	2,506,944	2,507	373,534	-	376,041
Issuance of common stock - warrant exercises	400,000	400	59,600	-	60,000
Reclassification of warrant liability	-	-	941,063	-	941,063
Share-based compensation expense	-	-	271,377	-	271,377
Net income	-	-	-	286,487	286,487
Balance, December 31, 2017	109,789,703	$ 109,790	$ 100,333,144	$ (104,559,226)	$ (4,116,292)

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Cash Flows

	Years ended December 31,	
	2017	**2016**
Operating activities:		
Net income	$ 286,487	$ 229,125
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	3,048	3,326
Non-cash share-based compensation	271,377	342,483
Non-cash interest expense	122,833	123,168
Offering costs allocated to derivative liabilities	-	214,229
Change in fair value of derivative liabilities	(2,000,605)	(2,076,499)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	44,494	(55,636)
Accounts payable	(9,234)	(65,436)
Accrued expenses	75,167	15,328
Unearned revenue	543,348	201,780
Net cash used in operating activities	(663,085)	(1,068,132)
Financing activities:		
Proceeds from exercise of common stock options	15,298	-
Proceeds from exercise of common stock warrants	60,000	-
Proceeds from sale of common stock and issuance of warrants net of offering proceeds	-	1,520,000
Net cash provided by financing activities	75,298	1,520,000
Net (decrease) increase in cash and cash equivalents	(587,787)	451,868
Cash and cash equivalents at beginning of year	769,495	317,627
Cash and cash equivalents at end of year	$ 181,708	$ 769,495
Supplemental Disclosure of Non-Cash Operating and Financing Activities		
Conversion of promissory notes to common stock	$ 300,000	$ -
Conversion of accrued interest to common stock	$ 76,041	$ -
Fair value of warrants reclassified to equity	$ 941,063	$ -
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, 2017

1. ORGANIZATION AND BUSINESS

Organization and Nature of Operations.

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

Management Plans to Address Operating Conditions.

Our strategy is aimed at being capital efficient while leveraging our portfolio of clinical assets by seeking strategic relationships with organizations with clinical development capabilities including development capital. Currently, we have active partnerships in 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 satisfactory results are obtained from the current ophthalmic clinical program in the U.S. before moving into the EU. This should allow us to obtain a higher value for the asset at that time. However, we intend to continue to develop RGN-352, our injectable systemic product candidate for cardiac and central nervous system indications, either by obtaining grants to fund a Phase 2a clinical trial in the cardiovascular or central nervous system fields or finding a suitable partner with the resources and capabilities to develop it as we have with RGN-259.

In 2004, we entered into a strategic partnership for development and marketing of RGN-137 and RGN-352 for specified fields of use in Europe and other contiguous countries with Sigma-Tau Group, which was subsequently acquired by Alfa Wassermann S.p.A., both Italian pharmaceutical companies. Pursuant to the terms of the license, we notified Alfa Wassermann that the license expired by its terms and we, therefore, reacquired rights to our Tß4-based products in the licensed territory. In August 2017, the Company amended the license agreement for RGN-137 held by GtreeBNT. Under the amendment, the Territory was expanded to include Europe, Canada, South Korea, Australia and Japan. Further, we now control the cardiovascular and neurovascular assets (RGN-352) in the EU and are able to consolidate them with similar assets in the U.S. and other territories in Asia to create a worldwide portfolio that we believe will be more attractive to multi-national pharmaceutical companies.

Since inception, and through December 31, 2017, we have an accumulated deficit of $105 million and we had cash and cash equivalents of $181,708 as of December 31, 2017. We anticipate incurring additional operating losses in the future as we continue to explore the potential clinical benefits of Tß4-based product candidates over multiple indications. We have entered into a series of strategic partnerships under licensing and joint venture agreements where our partners are responsible for advancing development of our product candidates by sponsoring multiple clinical trials. 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. In August 2017, we amended the RGN-137 License Agreement with GtreeBNT in exchange for a series of payments the last of which will be received in June 2018. On March 2, 2018, we entered into a warrant reprice and exercise and issuance agreement (the "Reprice Agreement") with the holders of the warrants issued in the 2016 Offering. Under the terms of the Reprice Agreement, in consideration of the holders exercising in full all of the 2016 Offering warrants, the exercise price per share of the warrants was reduced to $0.20 per share. In addition, and as further consideration, we issued to the holders of the 2016 Offering warrants 3,860,294 new warrants with an exercise price of $0.2301 per share. We received gross proceeds of approximately $1,000,000 pursuant to the exercise and issued 5,147,059 of common stock. The amendment payments and warrant reprice proceeds plus our year end cash balance will fund planned operations into the first quarter of 2019. We will need to secure additional operating capital to continue operations beyond the first quarter of 2019 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 $3,048 and $3,326 for the years ended December 31, 2017 and 2016, 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, 2017 and 2016, 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 financials instrument using the Black-Scholes option pricing model because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk-free rates) necessary to fair value these instruments. Estimating fair values of derivative financial instruments requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the trading market price of the Company's common stock, which has a high-historical volatility. Since derivative financial instruments are initially and subsequently carried at fair values, the Company's operating results reflect the volatility in these estimate and assumption changes in each reporting period.

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 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 (38.5%) of the Joint Venture's operating losses and will not recognize any such losses until the Joint Venture produces net income (as opposed to net losses) and at that point the Company will reduce its share of the Joint Venture's net income by its share of previously suspended net losses. As of December 31, 2017, 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, 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. The Tax Cuts and Jobs Act, which was enacted on December 22, 2017, includes a number of changes to existing U.S. tax laws, most notably the reduction of the U.S. corporate income tax rate from 35% to 21%, beginning in 2018. We measure our deferred tax assets and liabilities using the enacted tax rates that we believe will apply in the years in which the temporary differences are expected to be recovered or paid. As a result, we remeasured our deferred tax assets and deferred tax liabilities as of December 31, 2017 to reflect the reduction in the enacted U.S. corporate income tax rate.

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making that assessment. We recorded a full valuation allowance against all estimated net deferred tax assets at December 31, 2017 and 2016.

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.

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 Per Common Share. Basic net income per common share for the years 2017 and 2016 is based on the weighted-average number of shares of common stock outstanding during the years. Diluted loss per share is based on the weighted-average number of shares of common stock outstanding during each 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 25,146,533 shares and 27,186,456 shares in 2017 and 2016, respectively, reserved for the conversion of convertible debt or exercise of outstanding options and warrants. For the years ended December 31, 2017 and 2016, 13,485,896 and 19,135,304 dilutive securities related to convertible debt, options, as well as warrants in 2016, 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 $271,377 and $342,483 in share-based compensation expense for the years ended December 31, 2017 and 2016, 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 Accounting Standards Update ("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. 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. The Company has completed its evaluation and assessment of the potential impacts of adopting this pronouncement on its financial statements and related disclosures. Based on this assessment, the Company will adopt the pronouncement under the modified retrospective method of transition in the first quarter of 2018. The Company does not expect adoption of the new standard will have a material effect on the overall timing or amount of revenue recognized when compared to current accounting standards. The impact to the Company of adopting the new revenue standard primarily relates to additional and expanded disclosures.

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 became effective for public business entities for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. The adoption of this guidance did not have a significant impact on our financial statements.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments-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 adoption of this guidance in 2017 did not have a significant impact on our 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 currently not have a significant impact on its financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718) Scope of Modification Accounting. ASU 2017-09 provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. This ASU does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The Company is evaluating the impact of ASU 2017-09. The amendments of this ASU are effective for the Company in the first quarter of 2018, with early adoption permitted.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I of this Update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. Part II of this Update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification®. For public business entities, the amendments in Part I of this Update are effective for fiscal years beginning after December 15, 2018. Early adoption is permitted for all entities, including adoption in an interim period. The Company is currently assessing the impact that this standard will have on its 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, 2017 and 2016, 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 $182,000 and $769,000, 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 2016 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. These price protection anti-dilution features from the 2016 Offering lapsed in August 2017 and therefore our December 31, 2017 balance sheet no longer reflects these liabilities. 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, 2017 using the following assumptions:

	March 2013 Notes	July 2013 Notes	Sept 2013 Notes	Jan 2014 Notes
Dividend yield	0.00%	0.00%	0.00%	0.00%
Risk-free rate of return	1.39%	1.53%	1.53%	1.76%
Expected life in years	0.25	0.5	0.7	1
Volatility	12.7%	42.4%	42.8%	41.8%

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, 2017, 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, 2016	New Issuances	Change in Fair Values	Reclassifications	Balance at December 31, 2017
Level 3 -					
Derivative liabilities from:					
Conversion features					
March 2013	$ 975,000	$ -	$ (562,500)	$ -	$ 412,500
July 2013	433,334	-	(250,000)	-	183,334
September 2013	1,391,000	-	(802,500)	-	588,500
January 2014	247,503	-	(146,668)	-	100,835
Anti-dilution Protection					
2016 Offering shares	190,000	-	(190,000)	-	-
2016 Offering warrants	990,000	-	(48,937)	(941,063)	-
Derivative instruments	$ 4,226,837	$ -	$ (2,000,605)	$ (941,063)	$ 1,285,169

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. 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. 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 since. In addition, the agreements provide for payments upon the achievement of certain milestones in product development. The agreement also requires us to fund certain costs associated with the filing and prosecution of patent applications. In February 2013, this agreement was amended to include additional technology and intellectual property. The expanded license does not require payment of an initial license fee or additional annual maintenance fees but will be subject to payments upon the achievement of certain milestones for a product developed under the amended license of the additional technology and intellectual property.

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

In 2012, we entered into a License Agreement (the "Agreement") with Lee's Pharmaceutical (HK) Limited, 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. Lee's is an affiliate of Sigma-Tau, which collectively with its affiliates, is our largest stockholder. As of December 31, 2017 and 2016, 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. In August 2017, we amended the License Agreement for RGN-137 held by GtreeBNT. Under the amendment the Territory was expanded to include Europe, Canada, South Korea, Australia and Japan.

The Company has determined that the deliverables within the 2014 License Agreements, 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 received pursuant to the amendment of the RGN-137 License Agreement as revenue ratably over the anticipated remaining life of the agreement, or 23 years. The joint development committee commenced activities 2014. The Company began recognizing the revenue for the amendment when received in 2017. Revenue will be recognized for future royalty payments as they are earned.

Each license agreement contains diligence provisions that require the initiation of certain clinical trials within certain time periods that, if not met, would result in the loss of rights or exclusivity in certain countries. GtreeBNT will pay for all developmental costs associated with each product candidate. We 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 also for RGN-137 clinical trials 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 38.5% when the Clinical Study Report was filed for the Phase 2/3 dry eye clinical trial. Based on when, and if, certain additional development milestones are achieved in the U.S. with RGN-259, our equity ownership may be incrementally reduced to between 38.5% and 25%, with 25% being the final equity ownership upon approval of an NDA for DES in the U.S. In addition to our equity ownership, RegeneRx retains a royalty on net sales that varies between single and low double digits, depending on whether commercial sales are made by ReGenTree or a licensee. In the event ReGenTree is acquired or there is a change of control that occurs following achievement of an NDA, RegeneRx shall be entitled to a minimum of 40% of all proceeds paid or payable and will forgo any future royalties. The Company is not required or otherwise obligated to provide financial support to the Joint Venture.

The Joint Venture is responsible for executing all development and commercialization activities under the License Agreement, which activities will be directed by a joint development committee comprised of representatives of the Company and GtreeBNT. The License Agreement has a term that extends to the later of the expiration of the last patent covered by the 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 remaining life of the agreement or 30 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,	
	2017	2016
Prepaid insurance	$ 2,508	$ 64,721
Other	32,934	15,215
	$ 35,442	$ 79,936

Accrued expenses are comprised of the following:

	December 31,	
	2017	2016
Accrued professional fees	$ 9,156	$ 390
Accrued other	34,771	20,940
Accrued compensation	32,368	27,848
Accrued interest - convertible debt	156,070	184,061
	$ 232,365	$ 233,239

6. EMPLOYEE BENEFIT PLANS

In 2017 and 2016, the Company provided health and dental insurance to one employee under a group plan. No retirement plan was in place for 2017 or 2016.

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 interest until 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. The 2012 Notes matured, and the holders elected to convert the note balances of $300,000 and accrued interest of approximately $76,000 into common stock and also exercise the associated warrants in October 2017.

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.

2016 Offering

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.

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.

As discussed in Note 3, our 2016 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. These price protection anti-dilution features from the 2016 Offering lapsed in August 2017 and therefore our December 31, 2017 balance sheet no longer reflects these liabilities.

The outstanding balance of the derivative liability is as follows:

	December 31, 2017	December 31, 2016
March 2013 Notes	$ 412,500	$ 975,000
July 2013 Notes	183,334	433,334
September 2013 Notes	588,500	1,391,000
January 2014 Notes	100,835	247,503
Warrant liability	-	990,000
Rights liability	-	190,000
Total fair value of derivative liability	$ 1,285,169	$ 4,226,837

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

	For the years ended	
	December 31, 2017	December 31, 2016
March 2013 Notes	$ (562,500)	$ (525,000)
July 2013 Notes	(250,000)	(233,333)
September 2013 Notes	(802,500)	(749,000)
January 2014 Notes	(146,668)	(119,166)
Warrant liability	(190,000)	(580,000)
Rights liability	(48,937)	130,000
Total change in fair value of derivative	$ (2,000,605)	$ (2,076,499)

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

	For the years ended	
	December 31, 2017	December 31, 2016
2012 Notes	$ 12,999	$ 15,038
March 2013 Notes	56,250	56,404
July 2013 Notes	18,335	18,384
September 2013 Notes	69,550	69,741
January 2014 Notes	13,749	13,788
Total interest expense	$ 170,883	$ 173,355

8. STOCKHOLDERS' EQUITY

Common Stock. On October 19, 2017, the 2012 Convertible Notes matured, and the holders elected to convert the note balances and accrued interest into common stock and also exercise the associated warrants. As a result, we issued 2,906,944 shares of common stock. (see Note 7)

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 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. These features lapsed in August 2017.

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.

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 $271,377 and $342,483 in stock-based compensation expense for the years ended December 31, 2017 and 2016, respectively. We expect to recognize the compensation cost related to non-vested options as of December 31, 2017 of $313,000 over the weighted average remaining recognition period of 1.02 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, 2017 and 2016, which was allocated as follows:

	December 31,	
	2017	2016
Research and development	$ 83,425	$ 116,327
General and administrative	187,952	226,156
	$ 271,377	$ 342,483

The following summarizes stock option activity for the years ended December 31, 2017 and 2016:

		Options Outstanding		
	Shares available for grants	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2015	1,548,029	7,131,211	$ 0.14 - 3.00	$ 0.30
Grants	(940,000)	940,000	0.64	0.64
Exercises	-	-	-	-
Forfeitures	-	-	-	-
Expirations*	-	(372,500)	0.76 - 3.00	1.23
December 31, 2016	608,029	7,698,711	$ 0.14 - 0.64	$ 0.29
Grants	(1,000,000)	1,000,000	0.28	0.28
Exercises	-	(95,608)	0.16	0.16
Forfeitures*	124,750	(167,915)	0.21 - 0.64	0.40
Expirations	376,400	(376,400)	0.27	0.27
December 31, 2017	109,179	8,058,788	$ 0.14 - 0.64	$ 0.29
Vested and expected to vest at December 31, 2017		7,945,342		
Exercisable at December 31, 2017		6,358,788		

*Note: A portion of the forfeitures in 2017 and the 2016 expirations 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, 2017:

	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	5,498,963	3.7	$ 0.20	4,592,713	2.7	$ 0.19
$0.36 – $0.64	2,559,825	4.4	0.48	1,766,075	4.2	0.47
	8,058,788	3.9	0.29	6,358,788	3.1	0.27
Intrinsic value of in-the-money options, using the December 31, 2017 closing price of $0.17	$ 38,026			$ 38,026		

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, 2017 and 2016:

	2017	2016
Dividend yield	0.0%	0.0%
Risk-free rate of return	1.73%	1.41%
Expected life in years	5.88	4.5 - 7
Volatility	90%	87-95%
Forfeiture rate	2.6%	2.6%

Our dividend yield assumption is based on the fact that we have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. Our risk-free interest rate assumption is based on yields of U.S. Treasury notes in effect at the date of grant. Our expected life represents the period of time that options granted are expected to be outstanding and is calculated in accordance with the Securities and Exchange Commission ("SEC") guidance provided in the SEC's Staff Accounting Bulletin ("SAB") 107 and SAB 110, using a "simplified" method. The Company has used the simplified method and will continue to use the simplified method as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate an expected term. Our volatility assumption is based on reviews of the historical volatility of our common stock. Using Black-Scholes and these factors, the weighted average fair value of stock options granted to employees and directors was $0.21 and $0.46 for the years ended December 31, 2017 and 2016, respectively. We do not record tax-related effects on stock-based compensation given our historical and anticipated operating experience and offsetting changes in our valuation allowance which fully reserves against potential deferred tax assets.

The following table summarizes our warrant activity for 2017 and 2016:

	Warrants Outstanding		
	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2015	1,807,407	$ 0.15 - 0.38	$ 0.32
Issuances	5,404,412	0.37 - 0.51	0.50
Expirations	(1,407,407)	0.38	0.38
December 31, 2016	5,804,412	$ 0.15 - 0.51	$ 0.48
Exercises	(400,000)	0.15	0.15
December 31, 2017	5,404,412	$ 0.37 - 0.51	$ 0.50

9. INCOME TAXES

The Company's provision for income taxes consists of the following for the years ended December 31, 2017 and 2016:

	2017	2016
Current income tax provision (benefit)		
Federal	$ -	$ -
State	-	-
Foreign	98,605	-
Total	98,605	-
Deferred income tax provision (benefit)		
Federal	4,816,966	(443,227)
State	771,423	(70,990)
Foreign	-	-
Total	5,588,389	(514,217)
Change in valuation allowance	(5,588,389)	514,217
Total provision (benefit) for income taxes	$ 98,605	$ -

The Company's foreign income tax provision relates to its activities in the Republic of South Korean and specifically to South Korean income taxes paid by the Company upon the receipt of certain commercial and development milestone payments made by G-TreeBNT Co., Ltd. pursuant to its amended and restated license agreement for RGN 137. The income taxes paid to the Republic of South Korea can be used as a credit against future U.S. federal income taxes; however, the Company has fully reserved the deferred tax asset related to the tax credit with a valuation allowance since it is not be "more likely than not" that the Company will generate taxable income within the carryforward period of the credit. The tax credit will expire if not used in 2027.

Significant components of the Company's deferred tax assets at December 31, 2017 and 2016 and related valuation allowances are presented below:

	Year ended December 31,	
	2017	2016
Deferred tax assets:		
Net operating loss carryforwards	$ 13,045,000	$ 18,229,000
Research and experimentation tax credit carryforward	2,268,000	2,263,000
Foreign tax credit carryforward	99,000	-
Charitable contribution carryforward	4,000	2,000
Accrued expenses and deferred revenue	439,000	643,000
Depreciation and amortization	(1,000)	-
Share-based compensation	840,000	1,145,000
	16,694,000	22,282,000
Less: valuation allowance	(16,694,000)	(22,282,000)
Net deferred tax assets	$ -	$ -

At December 31, 2017, 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 experimental tax credit carryforwards of approximately $2.3 million. The carryforwards, if not utilized, will expire in increments through 2037.

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

The provision for income taxes on earnings subject to income taxes differs from the statutory federal rate for the years ended December 31, 2017 and 2016, due to the following:

	2017	2016
Federal tax benefit, at statutory rate	34.00%	34.00%
State taxes, net of federal benefit	5.45%	5.45%
Foreign taxes	25.61%	0.00%
Change in fair value of derivative liabilities	-204.92%	-320.60%
Share-based compensation	13.56%	34.57%
Other permanent differences and other	16.60%	24.01%
Research and experimental tax credits	-0.57%	-1.88%
Foreign tax credits	-25.61%	0.00%
Change in federal tax rate due to Tax Cuts and Jobs Act	1612.67%	0.00%
Change in valuation allowance	-1451.18%	224.45%
	25.61%	0.00%

The most significant impact on our effective tax rate in 2017 was the revaluation of our deferred tax assets and liabilities at the lower 21% U.S. corporate tax rate, as proscribed by the Tax Cuts and Jobs Act, which was enacted on December 22, 2017 and will lower the U.S. corporate tax rate from 35% to 21% beginning in 2018. We measure our deferred tax assets and liabilities using the tax rates that we believe will apply in the years in which the temporary differences are expected to be recovered or paid. As a result, we remeasured our deferred tax assets and deferred tax liabilities to reflect the reduction in the enacted U.S. corporate income tax rate.

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, 2017 and 2016, 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, 2017 and 2016.

The 2007 through 2017 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.

The future minimum rent payments as of December 31, are as follows:

2018	$ 46,700.00
2019	48,101.00
2020	28,850.00
Total	$123,651.00

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, 2017, 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.

11. SUBSEQUENT EVENTS

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

EXHIBIT INDEX

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

10.2^	2010 Equity Incentive Plan	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed July 20, 2010)
10.3	Form of Stock Option Grant Notice and Stock Option Agreement under the 2010 Equity Incentive Plan	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed July 20, 2010)
10.4	Patent License Agreement — Exclusive, dated January 24, 2001, between the Company and the U.S. Public Health Service	Exhibit B to Exhibit 10.1 to Amendment No. 1 to Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 (File No. 001-15070) (filed January 16, 2013)
10.5	Thymosin Beta 4 License and Supply Agreement, dated January 21, 2004, between the Company and Defiante Farmaceutica S.A.	Exhibit 10.10 to Registration Statement on Form SB-2 (File No. 333-113417) (filed March 9, 2004)**
10.6	Lease, by and between the Company and The Realty Associates Fund V, L.P., dated December 10, 2009	Exhibit 10.25 to Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-15070) (filed March 31, 2010)
10.7	Form of Warrant to Purchase Common Stock dated April 30, 2009	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed April 16, 2009)
10.8	Form of Common Stock Purchase Warrant, dated October 5, 2009	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed September 30, 2009)
10.9	Form of Warrant, dated October 15, 2009	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed October 5, 2009)
10.10	Representative's Warrant to Purchase Common Stock, dated May 21, 2010	Exhibit 4.3 to Current Report on Form 8-K (File No. 001-15070) (filed May 21, 2010)
10.11	Registration Rights Agreement, dated January 4, 2011	Exhibit 10.3 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.12	Warrant to Purchase Common Stock, dated January 7, 2011, issued to Lincoln Park Capital	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.13	Form of Warrant to Purchase Common Stock, dated January 7, 2011, issued to the Sigma-Tau Purchasers	Exhibit 4.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.14^	Amended and Restated Change in Control Agreement between the Company and J.J. Finkelstein, dated July 2, 2012	Exhibit 10.8 to Current Report on Form 10-Q (File No. 001-15070) (filed August 14, 2012)
10.15^	Amended and Restated Change in Control Agreement between the Company and Allan L. Goldstein, dated July 2, 2012	Exhibit 10.12 to Current Report on Form 10-Q (File No. 001-15070) (filed August 14, 2012)
10.16	Form of Convertible Promissory Note	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed October 24, 2012)
10.17	Form of Warrant	Exhibit 4.2 to Current Report on Form 8-K (File No. 001-15070) (filed October 24, 2012)
10.18	Convertible Note and Warrant Purchase Agreement	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed October 24, 2012)

10.19	License Agreement with Lee's Pharmaceutical (HK) Limited	Exhibit 10.1 to Amendment No. 1 to Form 10-Q (File No. 001-15070) for the quarter ended September 30, 2012 (filed January 16, 2013)**
10.20	Form of Convertible Promissory Note	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed April 2, 2013)
10.21	Convertible Note Purchase Agreement	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed April 2, 2013)
10.22	Form of Convertible Promissory Note	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed July 11, 2013)
10.23	Convertible Note Purchase Agreement	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed July 11, 2013)
10.24^	Letter Agreement between the Company and J.J. Finkelstein, dated July 5, 2013	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed July 11, 2013)
10.25^	Letter Agreement between the Company and Allan L. Goldstein, dated July 5, 2013	Exhibit 10.4 to Current Report on Form 8-K (File No. 001-15070) (filed July 11, 2013)
10.26	Form of Convertible Promissory Note	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed September 19, 2013)
10.27	Convertible Note Purchase Agreement	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed September 19, 2013)
10.28	Form of Convertible Promissory Note	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed January 9, 2014)
10.29	Convertible Note Purchase Agreement	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed January 9, 2014)
10.30^	Letter Agreement between the Company and J.J. Finkelstein, dated January 7, 2014	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 9, 2014)
10.31	Letter Agreement between the Company and Allan L. Goldstein, dated January 7, 2014	Exhibit 10.3 to Quarterly Report on Form10-Q (File No. 001-15070) (filed January 9, 2014)
10.32	Securities Purchase Agreement	Exhibit 10.5 to Quarterly Report on Form10-Q (File No. 001-15070) (filed May 15, 2014)
10.33	License Agreement RGN-259 dated March 7, 2014 with GtreeBNT (formerly Digital Aria)	Exhibit 10.6 to Quarterly Report on Form10-Q (File No. 001-15070) (filed May 15, 2014)**
10.34	License Agreement RGN-137 dated March 7, 2014 with GtreeBNT (formerly Digital Aria)	Exhibit 10.7 to Quarterly Report on Form10-Q (File No. 001-15070) (filed May 15, 2014)**
10.35^	Executive Employment Agreement between the Company and J.J. Finkelstein dated April 16, 2014	Exhibit 10.1 to Quarterly Report on Form10-Q (File No. 001-15070) (filed August 14, 2014)
10.36^	Executive Employment Agreement between the Company and Allan L. Goldstein dated April 16, 2014	Exhibit 10.2 to Quarterly Report on Form10-Q (File No. 001-15070) (filed August 14, 2014)
10.37^	Executive Employment Agreement between the Company and Dane Saglio dated April 16, 2014	Exhibit 10.3 to Quarterly Report on Form10-Q (File No. 001-15070) (filed August 14, 2014)

10.38	Form of First Amendment to Promissory Note dated October 3, 2014	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed October 9, 2014)
10.39	Joint Venture Agreement between the Company and GtreeBNT Co., Ltd. dated January 28, 2015	Exhibit 10.1 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed May 15, 2015)
10.40	License Agreement between the Company and ReGenTree, LLC dated January 28, 2015	Exhibit 10.2 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed May 15, 2015)
10.41	2014 Amendment to Lease Agreement	Exhibit 10.41 to Annual Report on Form 10-K (File No. 001-15070) (filed April 11, 2016)
10.42	Securities Purchase Agreement between the Company and Purchasers identified therein dated June 27, 2016.	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed July 1, 2016).
10.43	Registration Rights Agreement between the Company and Purchasers identified therein dated June 27, 2016.	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed July 1, 2016).
10.44	Amendment No. 2 to the RGN-259 License Agreement between the Company and ReGenTree, LLC dated April 28, 2016.	Exhibit 10.1 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed August 22, 2016)
10.45	Amendment No. 2. to Joint Venture Agreement between the Company and GtreeBNT Co., Ltd. dated May 11, 2016.	Exhibit 10.2 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed August 22, 2016)
10.46	Amendment No 2. Dated as of August 28, 2017, REN-137 License Agreement between the Company and GTreeBNT Co., LTD, dated March 7, 2014	Exhibit 10.1 to Quarterly Report on Form 10-Q (File No. 001-15070) (filed November 14, 2017)**
10.47	Warrant Reprice Agreement between the Company and the Purchasers identified therein dated March 2, 2018	Filed herewith
10.48	Form of Common Stock Warrant	Filed herewith
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, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets at December 31, 2017 and 2016; (ii) Statements of Operations for the years ended December 31, 2017 and 2016; (iii) Statements of Changes in Stockholders' Deficit; (iv) Statements of Cash Flows for the years ended December 31, 2017 and 2016; and (v) Notes to Financial Statements.	Filed herewith

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

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

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

^ Compensatory plan, contract or arrangement.

Exhibit 10.47

REGENERX BIOPHARMACEUTICALS, INC.

March 2, 2018

Sabby Healthcare Master Fund, Ltd.
c/o Sabby Management, LLC
10 Mountainview Road, Suite 205
Upper Saddle River, NJ 07458

Sabby Volatility Warrant Master Fund, Ltd.
c/o Sabby Management, LLC
10 Mountainview Road, Suite 205
Upper Saddle River, NJ 07458

Re: Reset Offer of Common Stock Purchase Warrants

To Whom It May Concern:

RegeneRx Biopharmaceuticals, Inc. (the "Company") is pleased to offer to you the opportunity to reprice the exercise of all of the Common Stock purchase warrants set forth on Annex I attached hereto (the "Existing Warrants") currently held by each of you (each a "Holder" and collectively the "Holders"). The shares of Common Stock underlying the Existing Warrants ("Warrant Shares") have been registered for resale by the Holders pursuant to a registration statement on Form S-1 (File No. 333-212606) (the "Registration Statement"). The Registration Statement is currently effective and, at the time of exercise of the Existing Warrants pursuant to this letter agreement, will be effective for the resale by the Holders of all of the Warrant Shares. **Capitalized terms not otherwise defined herein shall have the meanings set forth in the Securities Purchase Agreement, dated as of June 27, 2016, by and among the Company and the signatories thereto (the "Purchase Agreement").**

In consideration for exercising in full all of the Existing Warrants held by you (the "Warrant Exercise") as set forth on the signature page hereto, the Company hereby offers you a reduced exercise price of the Existing Warrants to **$0.20**. Notwithstanding anything herein to the contrary, in the event that the Warrant Exercise would otherwise cause the Holder to exceed the beneficial ownership limitations ("Beneficial Ownership Limitation") in the Existing Warrants, the Company shall only issue such number of Warrant Shares to the Holder (as instructed in writing by Holder) that would not cause such Holder to exceed the maximum number of Warrant Shares permitted thereunder with the balance to be held in abeyance until the balance (or portion thereof) may be issued in compliance with such limitations. Holder shall provide written notice to the Company promptly when any additional Warrant Shares may be issued in compliance with the Beneficial Ownership Limitation. The balance of the Warrant Shares shall promptly be issued when the Holder provides notice that the Holder holds less than the Beneficial Ownership Limitation.

Additionally, in consideration therefore, the Company shall issue to you or your designee Common Stock purchase warrants ("New Warrants") of the Company to purchase up to a number of shares of Common Stock equal to **75%** of the number of Warrant Shares issued pursuant to the undersigned's exercise hereunder and an exercise price equal to $0.2301, which New Warrants shall be in the form attached hereto as Exhibit A (the shares of Common Stock underlying the New Warrants, the "New Warrant Shares").

Expressly subject to the paragraph immediately following this paragraph below, Holder may accept this offer by signing this letter below, with such acceptance constituting Holder's exercise in full of the Existing Warrants for an aggregate exercise price of set forth on the Holder's signature page hereto (the "Warrants Exercise Price") on March __, 2018.

Additionally, the parties hereby agree to their respective representations, warranties and covenants set forth on Annex A attached hereto.

From the date hereof until six (6) months following the date hereof ("Standstill Period"), neither the Company nor any Subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents; provided, however, that this prohibition shall not apply to issuances by the Company of (i) securities to employees, officers, directors, Affiliates, Scientific Advisory Board members and collaborators of the Company which issuances are approved by a majority of the disinterested members of the Board of Directors for services rendered to the Company, provided that any issuances to collaborators of the Company shall be unregistered and shall not be registered during the Standstill Period and provided that, in connection with any issuances to Affiliates, such Affiliate shall enter into a Lock-up Agreement which shall include, but not be limited to, such Affiliate not selling, pledging, transferring, or assigning any such securities during the six (6) month period set forth in this paragraph, (ii) securities of Company upon the exercise or exchange of or conversion of any securities exercisable or exchangeable for or convertible into shares of Common Stock, or other similar rights, issued and outstanding on the date of this letter agreement, provided that such outstanding securities have not been amended since the date of this letter agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities or to extend the term of such securities and (iii) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that any such issuance shall only be to a Person (or to the equityholders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

If this Offer is accepted and the transaction documents are executed, then the Company shall file a Current Report on Form 8-K with the Commission disclosing all material terms of the transactions contemplated hereunder as soon as practicable on the date hereof, and in any event prior to 9:30 am ET on the Trading Day immediately following the date hereof (or such Trading Day if executed prior to 9:30 am ET). The Company shall also file an amendment to the prospectus supplement to the Registration Statement disclosing the reduced exercise price of the Existing Warrants and the issuance of the New Warrants by not later than Tuesday, March 6, 2018. The Company represents, warrants and covenants that, upon acceptance of this offer, the shares underlying the Existing Warrants shall be issued free of any legends or restrictions on resale by Holder and all of the Warrant Shares shall be delivered electronically through the Depository Trust Company within 1 business day of the date that the Company receives the aggregate Exercise Price (or, with respect to shares of Common Stock that would otherwise be in excess of the Beneficial Ownership Limitation, within 2 business days of the date that the Company is notified by Holder that its ownership is less than the Beneficial Ownership Limitation). The terms of the Existing Warrants, including but not limited to the obligations to deliver the Warrant Shares, shall otherwise remain in effect as if the acceptance of this offer were a formal Notice of Exercise (including but not limited to any liquidated damages and compensation in the event of late delivery of the Warrant Shares).

Within one business day from the Holder's execution of this letter, the Holder shall make available for "Delivery Versus Payment" to the Company immediately available funds equal to the number of Existing Warrants being exercised multiplied by $0.20 and the Company shall deliver the Warrant Shares via "Delivery Versus Payment" to the Holder and shall deliver the New Warrants to purchase up to _____ shares of Common Stock registered in the name of the Holder. In connection with the transactions contemplated by this letter agreement, the Company shall reimburse the Holder in the aggregate the non-accountable amount of $5,000 for their legal and due diligence expenses, which amount may be deducted, pro-rata from Holder's aggregate exercise price for Existing Warrants that is delivered to Company.

To accept this offer, Holder must counter execute this letter agreement and return the fully executed agreement to the Company at e-mail: _____, attn.:_____, with a copy to _____ on March, 2018.

Please do not hesitate to call me if you have any questions.

Sincerely yours,

REGENERX BIOPHARMACEUTICALS, INC.

By: /s/JJ Finkelstein
Name: J.J. Finkelstein
Title: Chief Executive Officer

[Holder signature page follows]

Accepted and Agreed to:

Name of Holder: _____

Signature of Authorized Signatory of Holder: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Existing Warrant Shares: _____

Aggregate Warrants Exercise Price: $ _____

New Warrant Shares (75% of Existing Warrants exercised): _____

DTC Instructions:

Company Bank Wire Instructions:

[signature page to RGRX Letter Agreement]

Annex A

Representations, Warranties and Covenants of the Company. The Company hereby makes the following representations and warranties to the undersigned:

(a) Affirmation of Prior Representations, Warranties and Covenants. The Company hereby represents and warrants to the undersigned that the Company's representations and warranties as set forth in Section 3.1 and the Company's covenants as set forth in Article IV of the Securities Purchase Agreement, dated as of June 27, 2016 (the "Purchase Agreement"), between the Company and the signatories thereto, together with any Disclosure Schedules, are true and correct as of the date hereof and have been fully performed as of the date hereof. **Capitalized terms not otherwise defined herein shall have the meanings set forth in the Purchase Agreement.**

(b) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this letter agreement and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement by the Company and the consummation by the Company of the transactions contemplated hereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, its board of directors or its stockholders in connection therewith. This letter agreement has been duly executed by the Company and, when delivered in accordance with the terms hereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(c) No Conflicts. The execution, delivery and performance of this letter agreement by the Company and the consummation by the Company of the transactions contemplated hereby do not and will not: (i) conflict with or violate any provision of the Company's certificate or articles of incorporation, bylaws or other organizational or charter documents; or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company in connection with, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any material agreement, credit facility, debt or other material instrument (evidencing Company debt or otherwise) or other material understanding to which such Company is a party or by which any property or asset of the Company is bound or affected; or (iii) subject to the Required Approvals (as defined in the Purchase Agreement), conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company is bound or affected, except, in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect (as defined in the Purchase Agreement).

(d) Issuance of the New Warrants. The issuance of the New Warrants is duly authorized and, upon the execution of this letter agreement by the undersigned, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens (as defined in the Purchase Agreement) imposed by the Company. The shares issuable upon exercise of the New Warrants (the "New Warrant Shares"), when issued in accordance with the terms of the New Warrants, will be validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock a number of shares of Common Stock for issuance of the New Warrant Shares in full.

(e) [RESERVED]

(f) Equal Consideration. Except as set forth in this letter agreement, no consideration has been offered or paid to any person to amend or consent to a waiver, modification, forbearance or otherwise of any provision of any of the Purchase Agreement or the Existing Warrants.

(g) [RESERVED]

(h) Listing or Quotation of Common Stock. The Company shall apply to list or quote all of the New Warrant Shares on the Trading Market and promptly secure the listing or quotation of all of the New Warrant Shares on such Trading Market.

(i) Effectiveness of the Registration Statement. The Company represents, warrants and covenants that the Registration Statement is effective for the resale of all of the Warrant Shares as of the date hereof and that the Company will use commercially reasonable best efforts to keep the Registration Statement effective for the issuance of all of the Warrant Shares for a period of no less than six months following the date hereof.

Annex I

Investor	Issue Date	Strike Price	Warrant Shares
Sabby Healthcare Master Fund, Ltd.	6/29/16	$0.20	3,676,471
Sabby Volatility Warrant Master Fund, Ltd.	6/29/16	$0.20	1,470,588

Exhibit 10.48

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES

COMMON STOCK PURCHASE WARRANT

REGENERX BIOPHARMACEUTICALS, INC.

Warrant Shares: X,XXX,XXX Issue Date: March 2, 2018

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, _____ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the earlier of (i) September 2, 2018 and (ii) the effective date of the registration statement registering for resale the Warrant Shares (the "Initial Exercise Date") and on or prior to the close of business on the three year anniversary of the Initial Exercise Date (the "Termination Date") but not thereafter, to subscribe for and purchase from RegeneRx Biopharmaceuticals, Inc., a Delaware corporation (the "Company"), up to _____ shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in that certain Securities Purchase Agreement (the "Purchase Agreement"), dated June 27, 2016, among the Company and the purchasers signatory thereto and the Reset Offer of Common Stock Purchase Agreement (the "Reset Offer") dated March __, 2018, among the Company and the purchasers signatory thereto.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed facsimile copy (or e-mail attachment) of the Notice of Exercise in the form annexed hereto and within two (2) Trading Days of the date said Notice of Exercise is delivered to the Company, the Company shall have received payment of the aggregate Exercise Price of the shares thereby purchased by wire transfer or cashier's check drawn on a United States bank or, if available, pursuant to the cashless exercise procedure specified in Section 2(c) below. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of the Common Stock under this Warrant shall be **$0.2301**, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at any time after a date that is six months after the Issue Date, there is no effective Registration Statement registering, or no current prospectus available for, the resale of the Warrant Shares by the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the characteristics of the Warrants being exercised, and the holding period of the Warrants being exercised may be tacked on to the holding period of the Warrant Shares. The Company agrees not to take any position contrary to this Section 2(c).

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. Warrant Shares purchased hereunder shall be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) the Warrant Shares are eligible for resale by the Holder without volume or manner-of-sale limitations pursuant to Rule 144 (assuming cashless exercise of the Warrants), and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is two (2) Trading Days after the delivery to the Company of the Notice of Exercise; provided payment of the Exercise Price (other than in the case of a Cashless Exercise) is received within two Trading Days of delivery of the Exercise Notice (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares; provided payment of the aggregate Exercise Price (other than in the case of a Cashless Exercise) is received within two Trading Days of delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exerciseable.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61 st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Equity Sales. If the Company or any Subsidiary thereof, as applicable, at any time while this Warrant is outstanding, shall sell or grant any option to purchase, or sell or grant any right to reprice, or otherwise dispose of or issue (or announce any offer, sale, grant or any option to purchase or other disposition) any Common Stock or Common Stock Equivalents, at an effective price per share less than the Exercise Price then in effect (such lower price, the "Base Share Price" and such issuances collectively, a "Dilutive Issuance") (it being understood and agreed that if the holder of the Common Stock or Common Stock Equivalents so issued shall at any time, whether by operation of purchase price adjustments, reset provisions, floating conversion, exercise or exchange prices or otherwise, or due to warrants, options or rights per share which are issued in connection with such issuance, be entitled to receive shares of Common Stock at an effective price per share that is less than the Exercise Price, such issuance shall be deemed to have occurred for less than the Exercise Price on such date of the Dilutive Issuance at such effective price), then simultaneously with the consummation of each Dilutive Issuance the Exercise Price shall be reduced and only reduced to equal the Base Share Price; provided that the Base Share Price shall not be less than $0.125 (subject to adjustment for reverse and forward stock splits, recapitalizations and similar transactions following the date of the Purchase Agreement). Notwithstanding the foregoing, no adjustments shall be made, paid or issued under this Section 3(b) in respect of an Exempt Issuance. The Company shall notify the Holder, in writing, no later than the Trading Day following the issuance or deemed issuance of any Common Stock or Common Stock Equivalents subject to this Section 3(b), indicating therein the applicable issuance price, or applicable reset price, exchange price, conversion price and other pricing terms (such notice, the "Dilutive Issuance Notice"). For purposes of clarification, whether or not the Company provides a Dilutive Issuance Notice pursuant to this Section 3(b), upon the occurrence of any Dilutive Issuance, the Holder is entitled to receive a number of Warrant Shares based upon the Base Share Price regardless of whether the Holder accurately refers to the Base Share Price in the Notice of Exercise. If the Company enters into a Variable Rate Transaction, despite the prohibition thereon in the Purchase Agreement, the Company shall be deemed to have issued Common Stock or Common Stock Equivalents at the lowest possible conversion or exercise price at which such securities may be converted or exercised.

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction, other than a Fundamental Transaction that is an all cash transaction, in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein. Notwithstanding the foregoing, upon the occurrence of a Fundamental Transaction, the Company or any Successor Entity shall have the right, exercisable concurrently with the consummation of the Fundamental Transaction, to purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black and Scholes Option Pricing Model obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 10 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. Subject to compliance with any applicable securities laws and the conditions set forth in Section 4(d) hereof and to the provisions of Section 4.1 of the Purchase Agreement, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date the Holder delivers an assignment form to the Company assigning this Warrant full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the original Issue Date and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

d) Transfer Restrictions. If, at the time of the surrender of this Warrant in connection with any transfer of this Warrant, the transfer of this Warrant shall not be either (i) registered pursuant to an effective registration statement under the Securities Act and under applicable state securities or blue sky laws or (ii) eligible for resale without volume or manner-of-sale restrictions or current public information requirements pursuant to Rule 144, the Company may require, as a condition of allowing such transfer, that the Holder or transferee of this Warrant, as the case may be, comply with the provisions of Section 4.1(a) of the Purchase Agreement.

e) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Purchase Agreement.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies, notwithstanding the fact that all rights hereunder terminate on the Termination Date. If the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Purchase Agreement.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

REGENERX BIOPHARMACEUTICALS, INC.

By: _____
Name: J.J. Finkelstein
Title: Chief Executive Officer

NOTICE OF EXERCISE

TO: REGENERX BIOPHARMACEUTICALS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ in lawful money of the United States; or

☐ if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

(4) Accredited Investor. The undersigned is an "accredited investor" as defined in Regulation D promulgated under the Securities Act of 1933, as amended.

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

EXHIBIT B

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Dated: _____ __, _____

Holder's Signature: _____

Holder's Address: _____

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, 2018, 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, 2017 and 2016 and for the years then ended, included in this Annual Report on Form 10-K for the year ended December 31, 2017.

/s/ CohnReznick LLP

Tysons, Virginia
March 29, 2018

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, 2018

/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, 2017, 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, 2018

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