FORM 10-K

REGENERX BIOPHARMACEUTICALS INC - RGRX

Filed: April 04, 2012 (period: December 31, 2011)

Annual report with a comprehensive overview of the company

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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, 2011

or

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

For the transition period from to

Commission file number: 001-15070

RegeneRx Biopharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Warrants to Purchase Common Stock, $0.001 par value

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒

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

As of June 30, 2011, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $8.7 million. Such aggregate

market value was computed by reference to the closing price of the Common Stock as quoted on the Over-the-Counter Bulletin Board, or the OTC Bulletin Board, on June 30, 2011.

The number of shares outstanding of the registrant's common stock as of April 3, 2012 was 81,390,618.

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, 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

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 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 have a fourth formulation, RGN-457, in preclinical development. RGN-457 is a liquid aerosol formulation of Tß4 targeting cystic fibrosis and other pulmonary diseases by inhalation.

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 four pharmaceutical product candidates, we are also pursuing the commercial development of peptide fragments and derivatives of Tß4 for potential cosmeceutical use. These fragments are 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

Due to our current financial condition as described further in this report, beginning in late 2011, we began implementing significant cost-saving measures to conserve capital resources and maintain a minimal level of operations, while seeking to receive additional funding and/or complete a strategic transaction. To that end, we have greatly reduced salaries and work schedules of our employees and have increasingly relied on reimbursements under a grant that we received from the National Institutes of Health (NIH), to fund employee salaries. We have also engaged investment bankers to help us explore financing alternatives, including a possible equity financing or licensing transaction, in order to continue the development of our product candidates, as well as the exploration of other strategic alternatives, including a possible asset out-licensing, asset sale or sale of our company.

In March 2012, we entered into a term sheet with Lee's Pharmaceutical (HK) for the development of Tß4 in any pharmaceutical formulation in China, Hong Kong and Macau. At the time of the signing of the term sheet, we received a $200,000 payment from Lee's. Upon execution of the definitive license agreement, we will receive an additional $200,000 payment from Lee's. While we expect that these funds will allow us to continue our minimal level of operations through June 2012, we will still need to complete a financing or strategic transaction within the second quarter of 2012 to continue as a going concern, or we may be forced to cease operations, seek protection under the provisions of the U.S. Bankruptcy Code, or liquidate and dissolve our company.

Overview of Tß4

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

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

- ***Progenitor (Stem) Cell Differentiation.*** Research published in the journal *Nature* in November 2006 featured the discovery that Tß4 is the key signaling molecule that 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.
- ***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. 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.*** Uncontrolled inflammation is the underlying basis of many pathologies and injuries. 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 NF κB 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. Identifying a factor such as Tß4 that blocks activation of NF κB 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 and the prevention of disease.
- ***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.

The 2006 *Nature* publication also 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* in April 2008 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 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 tissue was published in the journal *Neuroscience* in September 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. In 2010, research published in the *Journal of Neurosurgery* showed that Tß4 could improve functional neurological outcome in an animal stroke model. In 2011, another study was published in the *Journal of Neurosurgery* demonstrating that administration of T β4 can significantly improve histological and functional outcomes in rats with traumatic brain injury, or TBI, indicating that T β4 has considerable therapeutic potential for patients with TBI.

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 are based on Tß4 and are manufactured by solid-phase peptide synthesis as a copy of the naturally occurring peptide and formulated for various routes of administration and applications.

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

In November 2011, we reported preliminary safety and efficacy results from the trial. RGN-259 was deemed safe and well-tolerated, with no observed drug-related adverse events.

The co-primary outcome measures evaluated in the trial were inferior corneal fluorescein staining and decreased ocular discomfort on day 29. Various secondary outcome measures were also evaluated in the trial. While the study did not meet the co-primary outcome measures, during and after challenge in the CAE chamber, RGN-259 showed statistically significant efficacy results in other measured endpoints, meaning a p-value equal to or less than 0.05, which indicates a 5% or less likelihood that the results were due to chance, as follows:

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

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

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

The co-primary outcome measures, selected at the outset of this initial exploratory trial, were based on the best available animal data at the time but without the benefit of any actual human clinical experience in dry eye. Therefore, we believe that our not having met the co-primary outcome measures at this stage is not as important as identifying statistically significant outcomes that could potentially serve as approvable endpoints in later stage or in pivotal Phase 3 clinical trials. We believe that the statistically significant observation of reduction in central corneal staining, as well as symptom improvements observed in the trial and described above, reflect actual patient benefits and represent acceptable outcome measures to the FDA for use in follow-up Phase 2 or confirmatory pivotal Phase 3 trials. We are currently preparing a clinical study report for submission to the FDA, which will confirm these results of the exploratory Phase 2 clinical trial.

Separately, we are continuing to support a small physician-sponsored clinical trial in patients with dry eye, in order to evaluate RGN-259's ability to repair and regenerate damaged ophthalmic tissues in a heterogeneous group of patients, some of whom have severe dry eye as a sequel to graft vs. host disease. Our support includes supplying RGN-259 and placebo for the trial and providing regulatory and clinical guidance.

Lee's Pharmaceuticals. On March 27, 2012, we announced that we had signed a term sheet 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 and Macau. Lee's paid us $200,000 upon signing of the term sheet, and Lee's will pay us an additional $200,000 upon signing of the definitive license agreement, which we expect to occur by May 31, 2012. Lee's is an affiliate of Sigma Tau, which collectively with its affiliates is our largest stockholder. For a discussion of the material terms of the term sheet and expected terms of the definitive license agreement, see "—Material Agreements—Lee's Pharmaceuticals."

Future Plans. We are in the process of seeking a financial sponsor to allow for the continued clinical development of RGN-259. Based on the results of our Phase 2a clinical trial in patients with dry eye syndrome conducted in 2011 and, subject to the availability of sufficient financial resources, we are designing a Phase 2b clinical trial utilizing Ora's CAE model that we believe could generate important registration data. We are also engaged in discussions with ophthalmic specialty companies regarding product licensing to advance clinical development of this product candidate.

RGN-352

During 2009, we completed a Phase 1 clinical trial evaluating the safety, tolerability and pharmacokinetics of the intravenous administration of RGN-352 in 60 healthy subjects. Based on the results of this Phase 1 trial 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 in patients who had suffered an AMI. We had planned to begin enrolling patients in this clinical trial 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 Practices, or cGMPs. We have since learned that the manufacturer has closed its manufacturing facility and filed for bankruptcy protection. The FDA has prohibited us from using any of the active drug or placebo formulated by this manufacturer in human trials; consequently, we must have RGN-352 manufactured by a new cGMP-compliant manufacturer in the event we seek to resume this trial.

Significant preparatory time and procedures will be required and expenses would need to be incurred before any new cGMP-compliant manufacturer would be able to manufacture RGN-352 for the AMI trial and for us to resume study start-up activities. Due to these factors, including the time required for revalidation of processes and assays related to production that were already in place with the original manufacturer, we have elected to postpone activities on this trial until the requisite funding 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* indicates that RGN-352 may also prove useful for patients with multiple sclerosis, or MS, as well as stroke and traumatic brain injury. In these 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. Based on this preclinical research, depending on our capital resources, and if we are able to separately procure cGMP-compliant clinical trial material, we may also support a proposed physician-sponsored Phase 1/2 clinical trial to be conducted at a major U.S. medical center to evaluate the therapeutic potential of RGN-352 in patients with MS and traumatic brain injury.

RGN-137

Clinical Development — Epidermolysis Bullosa. In 2005, we began enrolling patients in a Phase 2 trial designed to assess the safety and effectiveness of RGN-137 for the treatment of patients with EB. EB is a genetic defect that results in fragile skin and other epithelial tissues that can blister or separate at the slightest trauma or friction, creating a wound that at times does not heal or heals poorly. In this randomized, double-blind, placebo-controlled, dose-response trial, nine U.S. clinical sites have been enrolling patients to evaluate the safety, tolerability, and wound healing effectiveness of three different concentrations of RGN-137 compared to placebo. RGN-137 is being applied topically to the skin, once daily for up to 56 consecutive days. EB has been designated as an "orphan" indication by the FDA's Office of Orphan Drugs. A portion of this trial was funded by a grant of $681,000 received from the FDA. We have completed enrollment of 30 out of the original target of 36 patients and closed the Phase 2 trial in late 2011 as the availability of eligible patients has been exhausted.

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

In January 2009, we reported final data from this trial. RGN-137 was well-tolerated at all three dose levels studied, with no dose-limiting adverse events, which achieved the primary objective of the study. As for efficacy, all Tß4 doses performed similarly compared to placebo, with no statistically significant efficacy results. However, patients treated with the middle dose showed a 17% rate of wound healing, which was the highest rate among the three active doses evaluated. The improvement in ulcer healing in this middle dose group following nine weeks of treatment was equal to the improvement in patients treated with placebo after 12 weeks of treatment. A follow-on evaluation, reported at the 3rd International Symposium on the Thymosins in Health and Disease in March 2012, showed that for those pressure ulcer patients' wounds that healed, RGN-137 mid dose (0.02% T β4 gel product) accelerated wound closure with a median time to healing of 22 days as compared to 57 days for the placebo. However, those results were not statistically significant.

Clinical Development — Venous Stasis Ulcers. In 2006, we began enrolling patients in a Phase 2 trial designed to assess the safety and effectiveness of RGN-137 for the treatment of patients with venous stasis ulcers. In this randomized, double-blind dose-response trial, eight clinical sites in Italy and Poland enrolled a total of 73 patients to evaluate the safety, tolerability, and wound healing effectiveness of three different concentrations of RGN-137 compared to placebo. RGN-137 was applied topically to the ulcers, once daily for up to 84 consecutive days. Patients in the trial were between 18 to 79 years old and had at least one venous stasis ulcer with a surface area between 3 and 30 cm^2. We were the sponsor of the trial, which was conducted and funded by Sigma-Tau.

In March 2009, we reported final data from the trial. RGN-137 was well-tolerated at all three dose levels, with no dose-limiting adverse events, which achieved the primary objective of the study. Thirty-three percent (33%) of the patients who received the middle dose of RGN-137 had their ulcers heal completely after the 12 weeks of treatment, compared to 24% of patients receiving the placebo, 16% of patients receiving the lowest drug dose and 17% of patients receiving the highest drug dose. Of the patients receiving the middle dose whose ulcers healed completely, the median time to complete healing decreased by approximately 45%, as compared to a 37% decrease in the time to healing for patients in the placebo-treated group. None of the differences observed between RGN-137 and placebo were statistically significant. A follow-on evaluation, reported at the 3rd International Symposium on the Thymosins in Health and Disease in March 2012, showed that for venous stasis ulcers greater than 3 cm^2 that healed, the median time to healing for the RGN-137 (0.03% Tβ4) treated wounds was 49 days as compared to 78 days for placebo. Those results were statistically significant (p value ≤ 0.05).

Future Plans. Following the EB trial closure, we will analyze the data and submit a clinical study report to the FDA for review, if requisite funding to do so is secured. Results of the EB trial in conjunction with study outcomes from our two other completed Phase 2 trials of RGN-137 in pressure and venous stasis ulcers, along with preclinical data indicating Tß4's ability to reduce scarring, will allow us to further evaluate our strategy for the clinical development of RGN-137.

RGN-457

Our preclinical product candidate RGN-457 is based on Tß4 formulated as a liquid aerosol for inhalation therapy. We have completed a substantial amount of preclinical work necessary for an investigational new drug, or IND, application, and we are currently seeking a strategic partner to assist in the development of RGN-457 for the treatment of cystic fibrosis, or CF. The anti-inflammatory, mucoactive and antimicrobial properties of T β4 provide the scientific rationale for use of the RGN-457 in this indication. CF is a life-threatening, hereditary disease that impairs the patient's ability to breathe due to the accumulation of mucus secretions in the airways of the lungs. The predicted median age of survival for patients with cystic fibrosis is 37 years. There are estimated to be approximately 30,000 CF patients in the United States and approximately 40,000 CF patients in Europe. It is therefore considered to be an orphan disease in both territories. While we believe RGN-457 may prove beneficial in the treatment of CF, we remain focused primarily on development of our other product candidates while we continue strategic partnership discussions with respect to RGN-457.

Peptide Fragments for Cosmeceutical Applications

We are also seeking to identify and evaluate Tß4 peptide fragments and derivatives that may be useful as novel components in cosmeceutical and consumer products. We have identified several amino acid sequences, and variations thereof, within the Tß4 molecule that have demonstrated *in vitro* activity in preclinical research studies that we have sponsored, and we have filed a number of patent applications related to this research. We believe the biological activities of these fragments may be useful, for example, in developing novel cosmeceutical products for the anti-aging market. To date, research has suggested that these fragments suppress inflammation, accelerate the deposition of certain types of collagen, promote the production of elastin, and inhibit programmed cell death, among other activities. Our development and commercialization strategy is to identify suitable commercial partners to license these novel fragments for various cosmeceutical applications. We have held discussions with several multinational cosmetics and consumer products companies focused on potential collaborations to further develop and commercialize these fragments.

Our Strategy

We seek to maximize the value of our product candidates by advancing their clinical development and then identifying suitable partners for further development, regulatory approval, and marketing. We intend to engage in strategic partnerships with companies with clinical development and commercialization strengths in desired pharmaceutical therapeutic fields. We are actively seeking partners with suitable infrastructure, expertise and a long-term initiative in our medical fields of interest.

We have entered into a strategic partnership with Defiante Farmaceutica S.A., or Defiante, a subsidiary and one of several entities affiliated with Sigma-Tau Group, a leading international pharmaceutical company which collectively comprise our largest shareholder, or Sigma-Tau, for development and marketing of RGN-137 and RGN-352 for specified indications in Europe and other contiguous countries. Sigma-Tau also funded and co-managed our Phase 2 clinical trial of RGN-137 in Europe for the treatment of venous stasis ulcers.

We recently have signed a term sheet 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 and Macau. Lee's is an affiliate of Sigma Tau, which collectively with its affiliates is our largest stockholder. For a discussion of the material terms of the term sheet and expected terms of the definitive license agreement, see "—Material Agreements—Lee's Pharmaceuticals."

Manufacturing

We use a major contract manufacturer to produce bulk Tß4, which is the active pharmaceutical ingredient, or API, by an established and proven manufacturing process known as solid-phase peptide synthesis, and are in the early stages of qualifying a backup manufacturer. While we do not currently have long-term supply agreements in place, we 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 cGMP requirements of the FDA and ability to meet our established specifications and quality requirements. If we obtain sufficient capital, we will authorize our primary contract manufacturer to begin the cGMP validation process and consistency runs, among other things, to prepare for the manufacture of bulk T β4 for use in future clinical trials utilizing our formulated product candidates.

We also use a number of outside contract manufacturers to formulate bulk Tß4 into our product candidates, RGN-137, RGN-259 and RGN-352, and RGN-457. 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. As described elsewhere in this report, our contract manufacturer 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 manufacturer has 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 GMP-compliant manufacturer of RGN-352.

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 that cause corneal wounds and many eye lubrication products that are soothing to the eye and help eye healing, many of which are sold without prescriptions. Companies also market steroids to treat certain conditions within our area of interest. Allergan, Inc. markets Restasis™, Ophthalmic Emulsion, the only commercially available and FDA-approved eye drop to treat dry eye.

RGN-352. Currently, there are no approved pharmaceutical products for regenerating cardiac tissue following a heart attack, nor are there approved pharmaceutical products for the remyelination of axons for patients with multiple sclerosis or patients suffering from traumatic brain injury. However, many pharmaceutical companies and research organizations are developing products, 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 remyelinate neurons and provide functional improvement for patients suffering from multiple sclerosis, stroke and traumatic brain injury. If we were to successfully develop RGN-352 for other cardiovascular indications, such as acute or chronic heart failure, such a product would have to compete with other drugs or therapies currently marketed by large pharmaceutical companies for similar indications, as would products for the treatment of central nervous system disorders.

RGN-137. Johnson & Johnson has marketed Regranex ™ Gel for patients with diabetic foot ulcers. Companies such as Novartis are developing and marketing artificial skins, which would compete with RGN-137 in the treatment of dermal wound healing. There are other companies developing new pharmaceutical products for wound healing. 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.

RGN-457. CF is a genetic defect for which there is no cure. There are mucolytic agents and antibiotic drugs on the market, such as Genentech's pulmozyme and Novartis's TOBI ®, an inhaled version of tobramycin, respectively, that relieve the symptoms posed by CF and could potentially compete with RGN-457.

Cosmeceuticals. The cosmetics industry is highly competitive and dependent on effective marketing and distribution. There are multiple products available from several major international cosmetic companies that claim the same or similar benefits that may be claimed with our product candidates.

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, one of our prior contract manufacturers was alleged by the FDA to have not complied with current Good Manufacturing Practices, which has impaired our ability to conduct our pending Phase 2 AMI trial with RGN-352.

We have received orphan drug designation from the FDA for Tß4 for the treatment of EB. 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. There may be multiple designations of orphan drug status for a given drug and for different indications. Orphan drug designation does not guarantee that a product candidate will be approved by the FDA for marketing for the designation, and even if a sponsor of a product candidate for an indication for use with an orphan drug designation is the first to obtain FDA approval of an NDA for that designation and obtains marketing exclusivity, another sponsor's application for the same drug product may be approved by the FDA during the period of exclusivity if the FDA concludes that the competing product is clinically superior. In this instance, the orphan designation and marketing exclusivity originally granted would be lost in favor of the clinically superior product.

Intellectual Property

We hold worldwide patents and patent applications covering peptide compositions, uses and formulations related to dermal and ophthalmic indications and other organ and tissue repair activities, as well as for cosmetic and consumer product applications. In 2001, we entered into a license agreement with the NIH under which we received an exclusive worldwide license from the NIH for all claims within the scope of the NIH's patent application, and any issued patents, covering the use of Tß4 as a tissue repair and regeneration factor. During 2007, patents were issued in Europe and the United States related to the original NIH patent application, which patents expire in July 2019. Corresponding patents have been granted in Hong Kong, Australia and China and certain other territories. The issued European patent was opposed by a third party at the European Patent Office, and in December 2009, we argued the case before the Opposition Division of the European Patent Office in Munich, Germany and prevailed with certain amendments to the claims. In exchange for the exclusive license, we agreed to make certain minimum royalty and milestone payments to the NIH. Through December 31, 2011, we have complied with all minimum royalty requirements, and no milestone payments have been required under the agreement.

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

We hold a U.S. patent relating to the use of Tß4 for the treatment of congestive heart failure. This patent issued in January 2012, and will expire in 2032.

Under a research agreement with The George Washington University, or GWU, we funded Tß4 research at GWU and received a sole and exclusive worldwide license to any resulting patents. While we no longer fund any research under this agreement, we remain obligated to pay GWU a royalty of 4% of the net sales, if any, of specified products covered by patents issued in connection with the agreement. Pursuant to the research agreement, we have exclusive rights to patent applications filed in the United States and in Europe disclosing the use of Tß4 for the treatment of septic shock and associated syndromes, including Adult Respiratory Distress Syndrome. Two U.S. patents covered by this agreement have been issued, which expire in 2013 and 2014.

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 2011. 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.

Material Agreements

National Institutes of Health

We have entered into a license agreement with NIH under which we are obligated to pay an annual minimum royalty of $25,000. 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.

Defiante/Sigma-Tau

We have exclusively licensed certain internal and external wound healing European rights to Tß4 to Defiante. These licensed rights to Tß4 include its use to treat indications that are the subject of all of our current dermal clinical trials of RGN-137, as well as the treatment of heart attacks. The license excludes the use of Tß4 in any ophthalmic indications and other indications that are disease-based and not the result of a wound. Under the agreement, Sigma-Tau may develop Tß4 for the treatment of internal and external wounds in Europe and certain other contiguous and geographically relevant countries. The license agreement expires on a country-by-country basis upon the later of the expiration of the last to expire of any granted patent in the territory having at least one valid claim covering the products then on the market, the expiration of any other exclusive or proprietary marketing rights, or January 2016.

Under the license agreement, Sigma-Tau is obligated to pay us a royalty on commercial sales, if any, and we will supply all required Tß4 for development. Upon the completion of a Phase 2 clinical trial for the covered indications that yields positive results in terms of efficacy and safety, Sigma-Tau must either pay us a $5 million milestone payment or initiate and fund a pivotal Phase 3 clinical trial for the applicable product candidate in order to maintain the license. We have completed two Phase 2 clinical trials of RGN-137 for the treatment of pressure ulcers and venous stasis ulcers, which, due to the lack of statistical significance of the reported efficacy results, neither triggered any payment obligations to us.

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

Lee's Pharmaceuticals

On March 27, 2012 we entered into a term sheet 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 and Macau. Lee's paid us $200,000 upon execution of the term sheet and will pay us an additional $200,000 upon signing of the definitive license agreement, which we expect to occur by May 31, 2012.

The terms of the license agreement will 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. We will have an exclusive supply agreement for Tβ4 with Lee's, although Lee's will have the option to manufacture Tβ4 for the licensed territory.

Lee's will pay for all developmental costs associated with each product candidate. We will provide Tβ4 to Lee's at no charge for a Phase 2 ophthalmic clinical trial and will provide Tβ4 to Lee's for all other developmental and clinical work at a price equal to our cost.

The two companies will create a joint development committee to discuss and agree on 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.

The foregoing description of the expected license agreement is based on the term sheet with Lee's. The execution of a definitive agreement will involve the negotiation of additional provisions, which may be material, and there is a risk that we may not be able to enter into a definitive agreement on commercially reasonable terms or at all. Therefore, the foregoing description is qualified in its entirety by reference to the final agreement to be entered into with Lee's. See "Risk Factors—We may not be able to enter into a definitive license agreement with Lee's Pharmaceuticals, which would have a material adverse effect on our capital resources."

Development Agreements

We have entered into agreements with outside service providers for the manufacture and development of Tß4, the formulation of Tß4 into our product candidates, the conduct of nonclinical safety, toxicology and efficacy studies in animal models, and the management and execution of clinical trials in humans. Terms of these agreements vary in that they can last from a few months to more than a year in duration. Certain of these agreements require initial upfront payments ranging from 25% to 50% of the total estimated cost. 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

Due to our current financial condition, beginning in late 2011, we began implementing significant cost-saving measures to conserve capital resources and maintain a minimal level of operations, while seeking additional funding and/or complete a strategic transaction. To that end, in December 2011, we reduced salaries of all of our employees to approximately $2,800 per month, and we granted new stock options in lieu of a portion of the cash salary adjustment. Beginning in January 2012, all employees became part-time hourly employees with reduced work schedules. Additionally, in January 2012, we discontinued providing employee health benefits and company-sponsored 401(k) matching contributions. The majority of our research and development staff's efforts since this time have been directed to work under a grant that we received from the NIH. We currently have eight hourly employees and we retain several independent contractors. We believe that we have good relations with our employees.

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

Risks Related to Our Liquidity and Need for Financing

Before giving effect to any potential sales of our securities, we estimate that our existing capital resources, coupled with the receipt of the second Lee's payment, will only be sufficient to fund our operations through June 2012 .

We are focusing our current efforts on the development of RGN-259 for ophthalmic indications. We recently completed a Phase 2 clinical trial to evaluate RGN-259 in patients suffering from dry eye syndrome, and we intend to pursue partnering opportunities for RGN-259 based on the data from this trial. We are also supporting a small physician-sponsored Phase 2 study of RGN-259 in severe dry eye. We have completed enrolling 30 patients in our Phase 2 trial for RGN-137 in EB patients. We had intended to commence patient enrollment in a Phase 2 clinical trial of RGN-352 for AMI patients near the end of the first quarter of 2011, but this trial was placed on clinical hold by the FDA. The AMI trial remains on hold pending resolution of regulatory issues and our access to sufficient capital resources. Depending on our capital resources, and if regulatory and manufacturing issues with RGN-352 are resolved, we may also continue to support a proposed physician-sponsored Phase 1/2 clinical trial to evaluate the therapeutic potential of RGN-352 in patients with multiple sclerosis.

Even with the change in our clinical development priorities during 2011, we currently do not have sufficient capital resources to fund our ongoing research and development activities, and we will not be able to sponsor any clinical trials in 2012 without additional funding. We project that our existing capital resources will only be adequate to fund our operations into May 2012. We also expect to receive an additional $200,000 from Lee's Pharmaceuticals upon the execution of the definitive license agreement that is the subject of a term sheet, although we only expect these additional proceeds, if received, to be sufficient to fund our operations through June 2012. If our stock price increases from its current level, we may, however, make additional sales of common stock under our committed equity facility with Lincoln Park Capital, as described below, which would extend our resources, but our ability to use the committed equity facility depends upon our share price and trading volume. However, even if we are able to sell shares of our common stock under the LPC facility, based on our current stock price the amount of proceeds we would be able to raise, doing so would not extend our capital resources significantly beyond the second quarter of 2012 and, accordingly, we will also need to seek other sources of capital.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this report. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

We may not be able to enter into a definitive license agreement with Lee's Pharmaceuticals, which would have a material adverse effect on our capital resources.

In March 2012, we entered into a term sheet with Lee's Pharmaceuticals to license the development of T β4 in any pharmaceutical form, including our RGN-259, RGN-137 and RGN-352 product candidates, in China, Hong Kong and Macau. Upon signing the term sheet, Lee's paid us $200,000. We expect that the definitive license agreement with Lee's will be completed by the end of May 2012, and upon the execution of the definitive agreement, we will receive an additional $200,000 payment from Lee's. However, the execution of the definitive agreement with Lee's is subject to risks, including the negotiation of mutually acceptable terms. If we are unable to agree to the terms of a definitive agreement with Lee's within 60 days of the date of the term sheet, Lee's will be permitted to terminate discussions regarding the agreement, in which case we would not receive the additional payment and we would be required to refund the original $200,000 payment. Given our current financial circumstances, unless we are able to generate addition capital resources, we would likely be unable to refund this payment, which would have a material adverse impact on our financial condition and ability to continue operations.

We are not currently able to access the LPC committed equity facility and, if we are able to do so in the future, we may not be able to access the full amount available under the facility.

In January 2011, we entered into a committed equity facility with Lincoln Park Capital, or LPC, under which we may direct LPC to purchase up to $11,000,000 worth of shares of our common stock through October 2013, generally in amounts of up to 200,000 shares every two business days. The amount we can sell under the facility may be increased to 400,000 shares every two business days, as long as the closing sale price of our common stock is not below $0.35 per share on the purchase date. However, the extent to which we will rely on the facility as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and volume of trading and the extent to which we are able to secure working capital from other sources. Specifically, LPC does not have the obligation to purchase any shares of our common stock on any business day that the price of our common stock is less than $0.15 per share. As of the date of this report, we have sold a total of 1.5 million shares to LPC for gross proceeds of approximately $350,000.

Depending on the prevailing market price of our common stock, we may not be able to sell shares to LPC for the maximum $11,000,000 over the term of the facility. At the minimum price of $0.15 per share, we would be able to sell 200,000 shares for proceeds of $30,000 on each purchase date. Assuming that we sold shares to LPC ten times each month, we would receive $300,000 in proceeds per month, up to the maximum amount available over the remaining term of the facility. In the event that we make less frequent sales to LPC, the aggregate proceeds available to us will be even less.

Currently, we have only registered for resale 12,541,667 additional shares of our common stock that we may sell to LPC. These shares, if and when issued to LPC, would be a combination of shares purchased at the price per share set forth in our purchase agreement with LPC and shares issued as additional pro rata commitment shares for no additional consideration, based on the formula set forth in the agreement. However, because the registration statement related to those shares has ceased to be effective under the Securities Act, we would need to prepare and file a post-effective amendment to the registration statement and have that post-effective amendment declared effective by the SEC before we can sell any of these shares to LPC. Assuming a purchase price of $0.15 per share, which is the minimum issuance price of our common stock under the facility, we would generate net cash proceeds of approximately $1.9 million. In the event we elect to issue more than the originally registered 15,000,000 shares, we would be required to file a new registration statement and have it declared effective by the SEC before selling such additional shares.

As described elsewhere in this report, we do not currently expect that funding from LPC will be sufficient to extend our operations beyond the second quarter of 2012, and we will need to secure another source of funding in order to satisfy our near term working capital needs. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

In addition to our current development objectives, we will need substantial additional capital for the continued development of product candidates through marketing approval and for our longer-term future operations.

Beyond our current liquidity needs, we anticipate that substantial new capital resources will be required to continue our longer-term independent 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. We may be able to obtain funding under the committed equity facility with LPC in order to further some of these efforts. 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 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 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 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 license 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, including under our committed equity facility with LPC, 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 both our short-term and 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, 2011, our accumulated deficit totaled approximately $95.5 million.

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

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

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

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

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

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

The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2011 contains explanatory language that substantial doubt exists about our ability to continue as a going concern, without raising additional capital. As described in this report, we estimate that our existing capital resources, without giving effect to potential additional sales of common stock under our committed equity facility with LPC, will be adequate to fund our operations into May 2012. We also expect to receive an additional $200,000 from Lee's Pharmaceuticals upon the execution of the definitive license agreement that is the subject of a term sheet, although we only expect these additional proceeds, if received, to be sufficient to fund our operations through June 2012. We continue to seek other sources of capital, but if we are unable to obtain sufficient financing in the near term, 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 pending Phase 2 clinical trial of RGN-352 was placed on clinical hold by the FDA in March 2011 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 Practices. The FDA has prohibited us from using any of the active drug or placebo manufactured by this manufacturer in human trials, which will require us to identify a cGMP-compliant manufacturer and to have new material produced in the event that we seek to resume this trial. We have also learned that the contract manufacturer has closed its manufacturing facility and has filed for bankruptcy protection. Significant preparatory time and procedures will be required before any new suitable manufacturer would be able to manufacture RGN-352 for the AMI trial. Since we are unable to estimate the length of time that the trial will be on clinical hold, we have elected to cease activities on this trial until the FDA clinical hold is resolved and the requisite funding might be secured. Consequently, there can be no assurance that we will be able to timely resume or complete this trial, if at all.

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

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

We may never be able to commercialize our product candidates.

Although Tß4 has shown biological activity in *in vitro* and animal models and we observed some efficacy 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 collaborators 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 collaborator 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 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 either believes that we are exposing the subjects participating in the trials 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 do not achieve our objectives under our collaboration agreements;
- we or our collaborators are unable to obtain patent protection for the products or proprietary technologies we develop in our collaborations;
- we are unable to manage multiple simultaneous product development collaborations;
- our collaborators become competitors of ours or enter into agreements with our competitors;
- we or our collaborators encounter regulatory hurdles that prevent commercialization of our product candidates; or
- we develop products and processes or enter into additional collaborations that conflict with the business objectives of our other collaborators.

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 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.

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 outside-of-the-eye diseases and injuries. Amniotic membranes have been successfully used to treat corneal wounds in certain cases, as have topical steroids and antibacterial agents.

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

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

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

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

Our product candidates, all of which are based on the molecule Tß4, are new and unproven and there is no guarantee that health care providers or patients will be interested in our product candidates, even if they are approved for use. If any of our product candidates are approved by the FDA, our success will depend in part on our ability to demonstrate sufficient clinical benefits, reliability, safety, and cost effectiveness of our 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 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 we must overcome if we 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.

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 for RGN-352 has filed for bankruptcy and closed its manufacturing facility, and our clinical trials involving RGN-352 have 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 new 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 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 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 advisor, Allan Goldstein, our chief executive officer, J.J. Finkelstein or David Crockford, our VP of Clinical and Regulatory Affairs, could prevent or significantly delay the achievement of our goals. In December 2011, we terminated our employment agreements with Dr. Goldstein, Mr. Finkelstein and Mr. Crockford, who are currently engaged only as part-time employees. And substantially all of our employees are now working only part-time schedules. We cannot assure you that Dr. Goldstein, Mr. Finkelstein or Mr. Crockford, or any other key employees, will not elect to terminate their employment. We do not currently have a full-time chief financial officer. 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 also a director and officer of entities affiliated with Sigma-Tau and a director of Lee's Pharmaceuticals, relationships which could give rise to a conflict of interest involving Mr. Bove.

Mauro Bove, a member of our Board of Directors, is also a director and officer of entities affiliated with Sigma-Tau, which collectively make up our largest stockholder group. Sigma-Tau has provided us with significant funding, may continue doing so in the future, and is also our strategic partner in Europe with respect to the development of certain of our drug candidates. We have issued shares of common stock and common stock warrants to Sigma-Tau in several private placement financing transactions, including as recently as January 2011, but we retained the right to repurchase some of these shares under certain circumstances.

We have licensed certain rights to our product candidates generally for the treatment of dermal and internal wounds to Sigma-Tau. Under the license agreement, upon the completion of a Phase 2 clinical trial of either of these product candidates that yields positive results in terms of clinical efficacy and safety, Sigma-Tau is obligated to either make a $5 million milestone payment to us or to initiate and fund a pivotal Phase 3 clinical trial of the product candidate. In 2009, we completed two Phase 2 clinical trials of RGN-137, but these trials were not sufficient to trigger the milestone obligation. There can be no assurance that we will ever receive this payment or be able to initiate a pivotal Phase 3 clinical trial of RGN-137 that would be funded by Sigma-Tau. As a result of Mr. Bove's relationship with Sigma-Tau, there could be a conflict of interest between Sigma-Tau and our other stockholders with respect to these and other agreements and circumstances that may require the exercise of the Board's discretion with respect to Sigma-Tau. Any decision in the best interests of Sigma-Tau may not be in the best interest of our other stockholders.

Additionally, Mr. Bove is a non-executive director of Lee's Pharmaceuticals, in which affiliates of Sigma-Tau have a significant equity interest. In March 2012, we entered into a term sheet in connection with the license of TB4 in any pharmaceutical form, including our RGN-259, RGN-352 and RGN-137 product candidates for development in China, Hong Kong and Macau. Under the expected terms of the license agreement, we are to receive a $200,000 payment from Lee's upon the execution of the definitive license agreement. There can be no assurance that we will be able to enter into a definitive agreement with Lee's, or that we will ever receive this payment, or that we will ever receive any further payments from Lee's under the agreement. As a result of Mr. Bove's relationship with Lee's and Sigma-Tau, Mr. Bove may be subject to a conflict of interest in fulfilling his duties to Lee's, Sigma-Tau and us, in connection with these and other agreements and circumstances that may require the exercise of the Board's discretion with respect to Lee's. These conflicts could potentially result in decisions that may not be in the best interest of our other stockholders.

Risks Related To Our Intellectual Property

We are heavily reliant on our license from the National Institutes of Health for the rights to Tβ4, and any loss of these rights would adversely affect our business.

We have received an exclusive worldwide license to intellectual property discovered at the National Institutes of Health, or NIH, pertaining to the use of Tß4 in wound healing and tissue repair. The intellectual property rights from this license form the basis for our current commercial development focus with Tß4. This license terminates upon the last to expire of the patent applications that are filed, or any patents that may issue from such applications, in connection with the license. This license requires us to pay a minimum annual royalty to the NIH, regardless of the success of our product development efforts, plus certain other royalties upon the sale of products created by the intellectual property granted under the license. This license may be terminated for a number of reasons, including our non-payment of the royalty or lack of continued product development, among others. While to date we believe that we have complied with all requirements to maintain the license, the loss of this license would have a material adverse effect on our business and business prospects and may require us to cease development of our current line of Tß4-based product candidates.

If we 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 ability 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 collaborators, that the scope of any patent protection will be sufficient to provide us with competitive advantages, that any patents obtained by us or our collaborators 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 collaborators 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 collaborators' intellectual property. In addition, changes in, or different interpretations of, patent laws in the United States and other countries may also adversely affect the scope of our patent protection and our competitive situation.

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

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

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

The value of our patents depends in part on their duration. A shorter period of patent protection could lessen the value of our rights under any patents that may be obtained and may decrease revenues derived from its patents. For example, the U.S. patent laws were previously amended to change the term of patent protection from 17 years following patent issuance to 20 years from the earliest effective filing date of the application. Because the time from filing to issuance of biotechnology applications may be more than three years depending on the subject matter, a 20-year patent term from the filing date may result in substantially shorter patent protection. Future changes to patent laws could shorten our period of patent exclusivity and may decrease the revenues that we might derive from the patents and the value of our patent portfolio.

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

In addition to our patents, we 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, 2011through December 31, 2011, the closing price of our common stock has ranged from $0.08 to $0.32, with an average daily trading volume of approximately 103,000 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;
- future sales of our common stock, including to LPC under our committed equity facility;
- 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 46% of our outstanding common stock. Included in this group is Sigma-Tau and its affiliates, which together hold outstanding shares representing approximately 39% of our outstanding common stock. A portion of the shares of common stock currently held by Sigma-Tau and its affiliates are subject to voting agreements under which our Board controls the voting power of such stock. We cannot assure you that such voting agreements would prevent Sigma-Tau and its affiliates from taking actions not in your best interests and effectively exercising control over us. These voting agreements expire periodically through September 2012. After their expiration, we will have no control over the voting of these shares controlled by Sigma-Tau, including with respect to the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock, and therefore may not be in the best interest of our other stockholders.

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

The trading market for our common stock and other securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If securities or industry analysts do not commence or maintain coverage of us, the trading price for our common stock and other securities would be negatively affected. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our securities, the price of our securities would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our securities could decrease, which could cause the price of our common stock and other securities and their trading volume to decline.

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

As of March 31, 2012, there are outstanding options to purchase an aggregate of 5,524,599 shares of our common stock at exercise prices ranging from $0.14 per share to $3.82 per share and outstanding warrants to purchase 11,332,059 shares of our common stock at a weighted average exercise price of $0.67 per share. The exercise of options and warrants 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, including our committed equity facility with LPC.

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

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

The sale of shares of our common stock to LPC may cause substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

Under our committed equity facility with LPC, we may sell to LPC, under certain circumstances, up to $11,000,000 of our common stock through October 2013. Generally, we have the right, but no obligation, to direct LPC to periodically purchase up to $11,000,000 of our common stock in specific amounts under certain conditions, which periodic purchase amounts can be increased under specified circumstances. Through the date of this report, we have sold approximately 1,500,000 shares to LPC for net proceeds of $348,200.

We have also agreed to issue to LPC up to an aggregate of 1,916,666 shares of common stock as a fee for LPC's commitment to purchase our shares. Of these commitment shares, we issued one-half, or 958,333 shares, upon entering into the facility with LPC. The remaining commitment shares are issuable to LPC on a pro rata basis as purchases are made under the facility. In connection with the purchases made to date, we have issued 30,336 of the remaining commitment shares.

Depending upon market liquidity at the time, sales of shares of our common stock to LPC may cause the trading price of our common stock to decline. LPC may ultimately purchase all, some or no additional portion of the $11,000,000 of common stock, and after it has acquired shares, LPC may sell all, some or none of those shares. Therefore, sales to LPC by us could result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock to LPC, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to LPC, and we may terminate the facility at any time, in our discretion, without any cost to us.

Our certificate of incorporation, our stockholder rights plan 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, under our stockholder rights plan, our Board has the discretion to issue certain rights to purchase our capital stock when a person acquires in excess of 25% of our outstanding common shares. Our Board has exempted purchases by Sigma-Tau to date and purchases that may be made by LPC under the committed equity facility from the operation of our stockholder rights plan. The stockholder rights plan may make it more difficult for stockholders to take corporate actions and may have the effect of delaying or preventing a change in control, even if such actions or change in control would be in your best interests. 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. 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 with a term through January 31, 2013. 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 $0.18 on April 2, 2012. Prior to December 23, 2010, our stock traded on the NYSE Amex stock exchange under the symbol "RGN." The following table provides the high and low closing prices for our common stock for each quarterly period within the two most recent fiscal years as quoted on the NYSE Amex or reported by the OTC Bulletin Board, as appropriate. The quotation reported by the OTC Bulletin Board reflects inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

The following table sets forth the high and low bid prices for our common stock for the periods indicated.

	2011		2010	
	High	Low	High	Low
First Quarter	$0.27	$ 0.20	$0.65	$ 0.53
Second Quarter	$ 0.23	$ 0.18	$ 0.68	$0.26
Third Quarter	$ 0.32	$0.19	$ 0.35	$ 0.24
Fourth Quarter	$ 0.30	$ 0.08	$ 0.30	$ 0.21

As of December 31, 2011, we had 835 holders of record of our common stock and over 3,700 beneficial holders of our common stock.

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.

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 consolidated 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 currently in clinical development:

- RGN-259, a 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 have a fourth formulation, RGN-457, in preclinical development. RGN-457 is a liquid aerosol formulation of Tß4 targeting cystic fibrosis and other pulmonary diseases.

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 four pharmaceutical product candidates, we are also pursuing the commercial development of peptide fragments and derivatives of Tß4 for potential cosmeceutical use. These fragments are 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

Due to our current financial condition, beginning in late 2011, we began implementing significant cost-saving measures to conserve capital resources and maintain a minimal level of operations, while seeking to receive additional funding and/or complete a strategic transaction. To that end, we have greatly reduced salaries and work schedules of our employees and have increasingly relied on reimbursements under a grant that we received from the NIH to fund employee salaries. We have also engaged investment bankers to help us explore financing alternatives, including a possible equity financing or licensing transaction, in order to continue the development of our product candidates, as well as the exploration of other strategic alternatives, including a possible asset out-licensing, asset sale or sale of our company.

In March 2012, we entered into a term sheet with Lee's Pharmaceutical (HK) for the development of Tß4 in any pharmaceutical formulation in China, Hong Kong and Macau. At the time of the signing of the term sheet, we received a $200,000 payment from Lee's, and we project that our existing capital resources will fund our planned, minimal operating activities into May 2012. Upon execution of the definitive license agreement, we expect to receive an additional $200,000 payment from Lee's. While we expect that these funds will allow us to continue our minimal level of operations through June 2012, we will continue to have insufficient resources to complete any of our active trials or to initiate any additional trials that we have planned. As a result, we will still need to complete a financing or strategic transaction by the end of the second quarter of 2012 to continue as a going concern or we may be forced to cease operations, seek protection under the provisions of the U.S. Bankruptcy Code or liquidate and dissolve our company.

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. Subject to the availability of financing, we expect to invest increasingly significant amounts in the furtherance of our current clinical programs and may add additional nonclinical studies and new clinical trials as we explore the potential of our current product candidates in other indications and explore new formulations of Tß4-based product candidates. As we expand our clinical development initiatives, we expect to incur substantial and increasing losses. Accordingly, we will need to generate significant product revenues in order to ultimately achieve and then maintain profitability. Also, we expect that we will need to raise substantial additional capital in order to meet product development requirements. We cannot assure investors that such capital will be available when needed, on acceptable terms, or at all.

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, employee benefits, travel and other miscellaneous costs of our internal R&D personnel, five persons in total, who are wholly dedicated either on a full or part-time basis to R&D efforts. R&D also includes a proration of our common infrastructure costs for office space and communications. We expense our R&D costs as they are incurred.

R&D expenditures are subject to the risks and uncertainties associated with clinical trials and the FDA review and approval process. As a result, these expenses could exceed our expectations, possibly materially. We are uncertain as to what we will incur in future research and development costs for our clinical studies, as these amounts are subject to the outcome of current studies, management's continuing assessment of the economics of each individual research and development project and the internal competition for project funding. As described below under "Sources of Liquidity," in May 2010 we were awarded a grant from the NIH to support the development of RGN-352. Subject to our compliance with the terms and conditions of the grant, we are eligible to receive up to $3.0 million over a three-year period in cost reimbursements related to the purposes set forth in the grant. We intend to use proceeds from the grant for the payment of research and development staff in connection with our grant related research and development activities and, as described above, we have increasingly relied on this grant for purposes of funding our R&D employees' reduced salaries. Proceeds from the grant have been used for animal studies supporting our clinical work to develop RGN-352 for myocardial infarction, as well as to manufacture additional quantities of T β4.

G&A costs include outside professional fees for legal, business development, audit and accounting services. G&A also includes cash and non-cash compensation, employee benefits, travel and other miscellaneous costs of our internal G&A personnel, three 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. We have expanded our patent prosecution activities and have been reviewing our pending patent applications in the United States, Europe and other countries with the advice of outside legal counsel. 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 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 will abandon these patent applications in order to reduce our costs of prosecution.

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:

Share-based payment

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

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

The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period. See Notes 2 and 7 to the Financial Statements for a further discussion on stock-based compensation and the relative ranges of our historical, underlying assumptions.

Costs of pre-clinical studies and clinical trials

We accrue estimated costs for pre-clinical studies and clinical trials conducted by contract research organizations and participating hospitals. These costs are a significant component of research and development expenses. We accrue costs for pre-clinical studies and clinical trials performed by contract research organizations based on estimates of work performed under the contracts. Costs of setting up hospital sites for participation in trials are accrued immediately. Hospital costs related to patient enrollment are accrued as patients are entered in the trial.

Results of Operations

Comparison of years ended December 31, 2011 and 2010

Revenues. For the year ended December 31, 2011, grant revenue was $1.5 million compared to $850,000 for the year ended December 31, 2010. In May 2010, we were awarded a grant from NIH's National Heart Lung & Blood Institute ("NHLBI"). This grant was for $1 million per year for three years. All of the revenue recognized in 2011 was from the NIH grant to offset costs incurred. During the year ended December 31, 2010, we recognized $117,000 based on costs incurred related to this grant. In addition, in October 2010 we were awarded $733,000 under the Patient Protection and Affordable Care Act as part of an incentive for biotechnology companies.

Expenses—Research and development. For the year ended December 31, 2011, our R&D expenditures increased by $2.4 million, or 87%, to $5.1 million, from $2.7 million in 2010.

Our outsourced R&D costs, which are costs paid directly to contract research organizations and outside consultants, increased by $2.6 million, or 245%, to $3.7 million, from $1.1 million. This increase was related to 2011 costs associated with the Phase 2 dry eye trial for RGN-259, pre-dosing clinical trial costs for the anticipated AMI trial with RGN-352 and additional costs resulting from the acquisition of unformulatedTß4.

During 2011 we engaged a contract research organization to execute a preclinical dry eye study and to conduct a Phase 2 trial in dry eye patients and incurred $1.48 million in CRO costs associated with this trial. We also commissioned a manufacturing run of additional Tß4 for $840,000 and incurred costs of $715,000 associated with our Phase 2 trial of RGN-352 that has been placed on clinical hold. In contrast, during 2010, we focused our efforts on enrolling EB patients and commenced work on our Phase 2 trials with RGN-259 to treat patients with dry eye and our Phase 2 trial to treat AMI patients, resulting in an overall lower level of clinical activity.

Our internal R&D costs decreased by $200,000 to $1.4 million from the 2010 amount of $1.6 million. The decrease reflects reduced staffing levels and employee compensation, coupled with lower non-cash stock option expense.

Expenses—General and administrative. For the year ended December 31, 2011, our G&A expenses decreased by $718,000, or 23%, to $2.5 million, from $3.2 million in 2010. This decrease is the result of a reduction of $350,000 in legal fees incurred for the prosecution of our patent portfolio and a $250,000 decrease in personnel-related expenses, including non-cash stock option compensation.

Interest Income. For the year ended December 31, 2011, our interest income decreased by approximately $6,600, or 80%, to approximately $1,600, from approximately $8,200 in 2010. The decrease was due to lower average interest-bearing cash balances during 2011.

Liquidity and Capital Resources

We have not commercialized any of our product candidates to date and have incurred significant losses since inception. We have primarily financed our operations through the issuance of common stock and common stock warrants in private and public financings, although as discussed below we have been awarded government grants and will continue to pursue other governmental funding sources. The report of our independent registered public accounting firm regarding our financial statements for the year ended December 31, 2011 contains an explanatory paragraph regarding our ability to continue as a going concern based upon our history of net losses and dependence on future financing in order to meet our planned operating activities.

We incurred a net loss of $6.0 million for the year ended December 31, 2011. We only had cash and cash equivalents of $116,000 at December 31, 2011. Based on our current operations, we believe our existing cash resources, coupled with the payments associated with the Lee's licensing agreement will be adequate to fund our operations through June 2012, without considering any potential other sources of capital. In any event, we will continue to have a need for financing, which we may not be able to complete either on favorable terms or at all.

Net Cash Used in Operating Activities. Net cash used in operating activities was $5.4 million and $5.0 million for the years ended December 31, 2011 and 2010, respectively. Our reported net loss for the year ended December 31, 2011 was $6.0 million, which included $222,000 in non-cash share-based compensation, an increase of $204,000 in grants receivable, a decrease of $360,000 in prepaid expenses and other current assets and an increase in current liabilities of $194,000. During 2010, $474,000 in non-cash share based compensation expenses was offset by $316,000 of cash used for working capital purposes resulting in net cash used in operating activities approximating the net loss reported for the year.

Net Cash Used in Investing Activities. Net cash used in investing activities was approximately $1,000 and $26,000 for the years ended December 31, 2011 and 2010, respectively. Our only such activities during these periods were purchases of office equipment and furnishings.

Net Cash Provided by Financing Activities. Net cash provided by financing activities totaled approximately $1.7 million and $4.5 million for the years ended December 31, 2011 and 2010, respectively. In both periods, these net proceeds result from the issuance of common stock and warrants to purchase common stock as more fully described in Note 7 to our financial statements included in this report.

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. We are not currently enrolling patients in any clinical trials. We had intended to commence patient enrollment in a Phase 2 clinical trial of RGN-352 for AMI patients near the end of the first quarter of 2011, but this trial has been placed on clinical hold by the FDA pending resolution of certain manufacturing compliance issues at our original contract manufacturer, which was responsible for formulating, filling and finishing RGN-352. We have put the AMI trial on hold pending access to sufficient capital resources to enable us to retain a cGMP-compliant drug product manufacturer and are focusing our current efforts on the development of RGN-259 for ophthalmic indications.

Even with this change in our clinical development priorities, we currently do not have sufficient capital resources to continue product development beyond May 2012 without additional capital. While we expect to receive an additional $200,000 payment from Lee's by the end of May 2012, we expect that these funds will allow us to continue our minimal level of operations through June 2012, and we will continue to have insufficient resources to initiate any additional trials that we have planned. As described below, we have established a committed equity facility with LPC, but we are currently unable to draw on the facility and our ability to draw on the facility in the future is subject to a number of limitations, including our stock price, as described in "Risk Factors —Risks Related to Our Liquidity and Need for Financing—We are not currently able to access the LPC committed equity facility and, if we are able to do so in the future, we may not be able to access the full amounts available under the LPC committed equity facility." Therefore, even if we were able to sell shares of our common stock under the LPC facility, based on our recent stock price, the amount of proceeds we would be able to raise would likely not extend our capital resources significantly beyond the second quarter of 2012.

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.

In addition, 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 also 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 addition to our obligations under clinical trials, we are committed under an office space lease through January 2013 that requires average base rental payments of approximately $7,300 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. Our largest stockholder group, which we refer to as Sigma-Tau, has historically provided significant equity capital to us, including private placements of $950,000 in January 2011 and $1.6 million in October 2009. In January 2011, we also raised $500,000 from a registered direct offering of our securities to LPC and an additional $348,200 in sales of common stock to LPC under an equity line facility discussed below. During 2010 we raised approximately $4.5 million from an underwritten public offering of our securities.

Committed Equity Line with LPC

In January 2011, we also entered into an $11 million committed equity facility with LPC. We have an effective registration statement for the resale by LPC of 15 million shares of common stock issuable under the facility through October 2013. The facility provides us with the right but not the obligation to direct LPC to purchase up to 200,000 shares of common stock every two business days at a purchase price calculated by reference to the prevailing market price of our common stock without any fixed discount, subject to the floor price of $0.15 per share. While we may sell up to $11,000,000 worth of shares under the facility, we currently are not able to access the facility given our current stock price. Additionally, because the registration statement related to those shares has ceased to be effective under the Securities Act, we would need to prepare and file a post-effective amendment to the registration statement and have that post-effective amendment declared effective by the SEC before we can sell any of these shares to LPC.

There are no trading volume requirements or restrictions under the facility, and we will control the timing and amount of any sales of our common stock to LPC. Our ability to sell our shares to LPC is also subject to our obtaining all necessary consents, amendments or waivers as may be required, and subject to the shares to be sold having been registered for resale. LPC has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the facility. We can also accelerate the amount of common stock to be purchased under certain circumstances. There are no limitations on use of proceeds, financial or business covenants, restrictions on future funding, rights of first refusal, participation rights, penalties or liquidated damages. We may terminate the facility at any time, in our discretion, without any penalty or cost to us. To date, we have issued an aggregate of 1,530,336 shares of common stock to LPC under this facility for net proceeds of $348,200.

Licensing Agreements

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

We also have entered into a term sheet with Lee's Pharmaceuticals that provides for a definitive license agreement with 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 and Macau. However, we have not yet executed the definitive license agreement with Lee's, and we cannot assure you that we will be able to do so, nor can we assure you that we will be able to attain any such milestones or generate any such royalty payments under the agreement.

Government Grants

We are also aggressively pursuing government funding. In May 2010, we were awarded a grant from the NIH's National Heart, Lung and Blood Institute to support the requisite nonclinical development of RGN-352 for patients who have suffered a heart attack. These nonclinical activities are being conducted even though our pending Phase 2 clinical trial of RGN-352 is on clinical hold. Subject to our compliance with the terms and conditions of the grant, we are eligible to receive up to $3.0 million over a three-year period in cost reimbursements for our associated costs incurred for the purposes set forth in the grant. Revenue from the grant will be recorded during the same periods when we incur eligible expenses.

The Patient Protection and Affordable Care Act enacted in 2010 included a new incentive for biotechnology companies like ours, known as the Qualifying Therapeutic Discovery Project grant program. Under this program, small businesses were able to apply for a federal grant in an amount equal to 50% of their eligible investment in qualifying therapeutic discovery projects for 2009 and 2010. Qualifying therapeutic discovery projects included those designed to treat or prevent diseases or conditions by conducting pre-clinical or clinical activities for the purpose of securing FDA approval of a product. We submitted three applications, covering each of our clinical-stage product candidates, and in October 2010 were awarded an aggregate of $733,438 under this program.

Other Financing Sources

Other potential sources of outside capital include entering into 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 ongoing liquidity requirements would 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.

Our cash equivalents, which are generally comprised of Federally-insured bank deposits and short-term U.S. government debt securities, are subject to default, changes in credit rating and changes in market value. These investments are also subject to interest rate risk and will decrease in value if market interest rates increase. As of December 31, 2011, we had $116,000 of cash and cash equivalents. Due to the short-term nature of these investments, if market interest rates differed by 10% from their levels as of December 31, 2011, the change in fair value of our financial instruments would not have been material.

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 current 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, 2011, the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer, in his capacity of principal executive officer and principal financial officer, concluded that our disclosure controls and procedures were effective as of December 31, 2011 at the reasonable assurance level.

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 consolidated 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 of 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, 2011 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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 31, 2011 that have materially affected, or which are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

As reported on a Current Report on Form 8-K filed on January 6, 2012, the Company previously entered into letter agreements with each of J.J. Finkelstein, the Company's President and Chief Executive Officer, David Crockford, the Company's vice president of clinical and regulatory affairs, and Allan Goldstein, the Company's chief scientific advisor and a member of the Company's board of directors, relating to their employment with the Company. In addition, the Company entered into change of control agreements with each of Mr. Finkelstein, Mr. Crockford and Dr. Goldstein, providing for the payment of severance obligations upon specified terminations of employment.

The employment letter agreements and change in control agreements each had a term that was scheduled to expire on March 31, 2012. On April 3, 2012, the Board of Directors of the Company approved, and the Company and each officer entered into, amendments to each of the letter agreements to extend their terms through June 30, 2012. On that date, the Board of Directors of the Company also approved, and the Company and each officer entered into, amended and restated change in control agreements to: (i) provide that, upon the occurrence of a change in control of the Company, all outstanding stock options held by the officers will become fully vested and exercisable upon the effectiveness of the change in control transaction; (ii) clarify the definition of "net proceeds" under the agreements in the event of a reverse merger transaction; and (iii) extend their respective terms through June 30, 2012.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth as of March 15, 2012 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	60	President, Chief Executive Officer and Director
Mr. David R. Crockford	66	Vice President, Clinical and Regulatory Affairs
Directors:		
Dr. Allan L. Goldstein	74	Former Chairman, Department of Biochemistry and Molecular Biology, The George Washington University School of Medicine and Health Sciences; Founder, Chairman of the Board and Chief Scientific Advisor
Mr. R. Don Elsey	58	Senior Vice President Finance & Administration and Chief Financial Officer of Emergent BioSolutions, Inc.
Mr. Joseph C. McNay	78	Chairman, Chief Investment Officer and Managing Principal, Essex Investment Management Company
Mr. Mauro Bove	57	Head of Corporate and Business Development and Director, Sigma-Tau Finanziaria S.p.A and certain of its affiliates
Dr. L. Thompson Bowles, M.D.	80	Retired, former thoracic surgeon and former Dean of Medicine and Professor of Surgery, The George Washington University School of Medicine and Health Sciences

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 30 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 served on the executive committee of the Board of Directors of the Technology Council of Maryland since 2006, MdBio, Inc. since 1998 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.

Mr. Crockford has served as our Vice President of Clinical and Regulatory Affairs since March 2005 and was a consultant to the Company from 2000 until his appointment as Vice President. He has more than 25 years of experience in the biotechnology and pharmaceutical industries. During his career as a clinical and regulatory affairs professional, Mr. Crockford has established strategic plans, implemented and obtained marketing approval for 18 drug products, including one of the first human growth hormone preparations sold in the U.S., 17 in vitro diagnostic tests, and an intraoperative medical device to detect and treat cancer. Mr. Crockford's other clinical and regulatory achievements include the cost-effective and timely development of a number of innovative investigational drugs. Mr. Crockford is the author of a number of publications, including *Development of Thymosin ß4 for Treatment of Patients with Ischemic Heart Disease*, and is an inventor or co-inventor on approximately two dozen patents related to drug development. Mr. Crockford has a B.A. degree in biology and chemistry from Boston University. He also completed biochemistry and clinical chemistry course studies in Princeton, New Jersey, and seminars in reproductive medicine at medical schools at Wayne State University and UCLA.

Dr. Goldstein has served as the Chairman of our Board of Directors and our Chief Scientific Advisor since he founded our company in 1982. Dr. Goldstein has been a Professor of Biochemistry since 1978 and served as Chairman of the Department of Biochemistry and Molecular Biology at the George Washington University School of Medicine and Health Sciences until 2009. Dr. Goldstein is a recognized expert in the field of immunology and protein chemistry, having authored over 430 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 T α1, which is marketed worldwide, and Tβ4, which is the basis for RegeneRx's clinical program. Dr. Goldstein has served on the Board of Trustees of the Sabin Vaccine Institute since 2000 and on the Board of Directors of the Richard B. and Lynne V. Cheney Cardiovascular Institute since 2006. Dr. Goldstein has also done pioneering work in the area of medical education, developing distance learning programs offered through "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. He has served as senior vice president and chief financial officer of Emergent BioSolutions Inc., a publicly held biopharmaceutical company, since May 2007, and as its chief financial officer since March 2006 and Treasurer since June 2005. Mr. Elsey previously served as vice president, finance of Emergent BioSolutions from June 2005 to May 2007. He served as the director of finance and administration at IGEN International, Inc., a publicly held biotechnology company, and its successor BioVeris Corporation, from April 2000 to June 2005. Prior to joining IGEN, Mr. Elsey served as director of finance at Applera, a genomics and sequencing company, and in several finance positions at International Business Machines, Inc. He received an M.B.A. in finance and a B.A. in economics from Michigan State University. Mr. Elsey is a certified management accountant. The Board believes that Mr. Elsey's experience as chief financial officer of a public company is particularly valuable to our business in that it positions him to contribute to our board's and audit committee's understanding of financial matters.

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

Mr. Bove has served as a member of our Board of Directors since 2004 and has more than 30 years of business and management experience within the pharmaceutical industry. Mr. Bove is currently the Head of Corporate & Business Development of Sigma-Tau Finanziaria S.p.A., the holding company of Sigma-Tau Group, a leading international pharmaceutical company, and certain Sigma-Tau affiliates, positions he has held since 1993. Sigma-Tau Finanziaria S.p.A. and its affiliates are collectively our largest stockholder. Mr. Bove has also held a number of senior positions in business, licensing and corporate development within Sigma-Tau Group, which has subsidiaries in most European countries and the United States. Mr. Bove obtained his law degree at the University of Parma, Italy, in 1980. In 1985, he attended the Academy of American and International Laws at the International and Comparative Law Center, Dallas, Texas. The Board believes that Mr. Bove's extensive business and management experience within the pharmaceutical industry allows him to recognize and advise the Board with respect to recent industry developments.

Dr. Bowles has served as a member of our Board of Directors since 2006. He retired from his career as a thoracic surgeon in 1988. Dr. Bowles served as Dean of Medicine and Professor of Surgery at The George Washington University ("GWU") School of Medicine and Health Sciences from 1976 to 1988 and as Vice President for Medical Affairs and Executive Dean of the GWU Medical Center from 1988 to 1992. Dr. Bowles previously served as President of the National Board of Medical Examiners, a medical accrediting organization, from 1992 to 2000. He has also been a member of the National Academy of Sciences Institute of Medicine since 1988 and currently serves as a member of several other national medical societies including: The American College of Surgeons, The American Association for Thoracic Surgery, The Society of Thoracic Surgeons, The American College of Chest Physicians, The American Gerontological Society, The Society of Medical Administrators, The College of Physicians of Philadelphia, and The Washington Academy of Surgeons. Dr. Bowles has served on the editorial board of a number of medical journals, including the Journal of Medical Education and continued on as chairman of its newly revised updated version, Academic Medicine. Dr. Bowles has been President of the District of Columbia's medical licensing board called the Healing Arts Commission (1977-1979), and was a member of the National Library of Medicine's Board of Regents (1982-1986), chairman (1984-1986), member of the Special Medical Advisory Group of Veterans Administration (now Dept. of Veterans Affairs) 1984-1992, chairman 1992-1994. Dr. Bowles was also chairman of the National Committee on Foreign Medical Education and Accreditation, 1994-1996. Dr. Bowles received his medical degree from Duke University and his Ph.D. in higher education from New York University. The Board believes that Dr. Bowles' distinguished medical career positions him to bring extensive medical and clinical trial experience to the Board. The Board expects that this experience will permit Dr. Bowles to provide leadership and insight as we translate our laboratory discoveries into human clinical trials and advance our product candidates through clinical development toward commercialization.

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 that no other reports were required, during the fiscal year ended December 31, 2011, 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, and Dr. Bowles. 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, 2011 and 2010, compensation awarded to or paid to, or earned by, our chief executive officer and our other executive officer who was serving at December 31, 2011, as well as our former chief financial officer who terminated his employment prior to December 31, 2011. For purposes of this report, we refer to these officers as the named executive officers.

Of note, our annual rates of compensation for our named executive officers and all employees were reduced effective December 1, 2011. Until that time the compensation rates in effect for our named executive officers were the same as at December 31, 2010. For the month of December 2011, each executive officer received a cash salary of $2,800 and options to purchase shares of our common stock at an exercise price of $0.16 per share. Consequently, the salary amounts set forth in the following table may differ from the disclosed annual base salaries then in effect. These options vested in full on December 31, 2011 and remain outstanding and are set forth in the table within the “Outstanding Equity Awards at December 31, 2011” section below.

Name and Principal Position	Year	Salary(1) ($)	Bonus(2) ($)	Option Awards(3) ($)	All Other Compensation(4) ($)	Total ($)
J.J. Finkelstein,	2011	252,400	—	22,432	17,476	292,308
President and Chief Executive Officer	2010	299,520	—	19,396	18,425	337,341
David R. Crockford,	2011	195,505	—	20,107	11,234	226,846
Vice President, Clinical and Regulatory Affairs	2010	210,223	2,000	15,284	10,321	237,828
C. Neil Lyons,	2011	135,025	—	—	5,401	140,426
Former Chief Financial Officer (5)	2010	202,537	2,000	15,284	6,886	226,707

(1) Reflects base salary before pretax contributions and therefore includes compensation deferred under our 401(k) plan.
(2) Reflects the payment of discretionary bonus.
(3) These amounts reflect the aggregate total grant date fair values (computed in accordance with FASB ASC Topic 718) of options granted to executives during the respective fiscal years.
(4) Primarily reflects our match of executive compensation deferrals into our 401(k) plan, along with supplemental life and disability insurance premiums. None of the individual items exceeded $10,000.
(5) Mr. Lyons terminated his employment with us effective August 31, 2011.

Employment Agreements; Potential Payments Upon Termination or Change in Control

We are party to written agreements with our currently serving executive officers. These agreements contain severance and other provisions that may provide for payments to the currently serving executive officers following termination of employment with us in specified circumstances. The following is a summary of the material terms of these agreements with our currently serving executive officers.

J.J. Finkelstein. We entered into an employment agreement with Mr. Finkelstein in January 2002 for him to serve as our president and chief executive officer. Mr. Finkelstein's employment agreement had an initial three-year term, which was automatically renewed for additional one-year periods. This agreement was amended and restated during 2008 and again in 2009. Immediately prior to November 30, 2011, Mr. Finkelstein's annual base salary was $299,520.

On November 30, 2011, the Company and Mr. Finkelstein amended the employment agreement to reduce Mr. Finkelstein's salary, effective as of December 1, 2011. Pursuant to the amendment, Mr. Finkelstein's annual base salary was reduced from $299,520 to $33,600 effective as of December 1, 2011. In consideration for the salary reduction, on December 2, 2011, the Company granted to Mr. Finkelstein an option to purchase 80,135 shares of the Company's common stock. This option vested in full on December 31, 2011.

In addition to the change in salary, Mr. Finkelstein's amended employment agreement also changed the Company's severance obligations. Pursuant to the revised severance obligations, Mr. Finkelstein's severance was reduced from one year's salary to two weeks' salary, and he was not entitled to severance in the event that his employment was terminated by the Company because the Company ceased operations as a result of financial losses, lack of funding, legal decisions, administrative rulings, declaration of war, dissolution, national or local economic depression or crisis or any reasons beyond the control of the Company.

Effective as of January 1, 2012, the Company and Mr. Finkelstein entered into a letter agreement for temporary employment and terminated the previous employment agreement, changing Mr. Finkelstein's status to that of a part-time temporary employee. In connection with this conversion, the Company paid Mr. Finkelstein two weeks of severance based on his December 2011 salary (payment equal to $1,400) plus accrued vacation. Pursuant to his letter agreement, Mr. Finkelstein receives a salary at a rate of $50.00 per hour, subject to deductions and withholdings. Mr. Finkelstein's typical work schedule is up to 100 hours per month, with no guaranteed minimum number of hours. In accordance with the letter agreement, the employment termination date for Mr. Finkelstein was originally March 31, 2012, unless terminated prior to March 31, 2012 by Mr. Finkelstein or the Company. As a result of the receipt of funding in connection with the Lee's term sheet, the Company and Mr. Finkelstein extended the term of the letter agreement to June 30, 2012. Mr. Finkelstein was also granted an option to purchase 35,000 shares of the Company's common stock at an exercise price of $0.16 per share, which option will vest in full on June 30, 2012 subject to Mr. Finkelstein's continued service.

In addition to the letter agreement, the Company and Mr. Finkelstein also entered into a change in control agreement effective January 1, 2012, which was amended on April 3, 2012. Pursuant to the change in control agreement, as amended, if a change in control of the Company is consummated and the employment of Mr. Finkelstein is (i) within twelve months following such change in control (a) terminated by the Company for any reason, other than for cause or due to death or disability of Mr. Finkelstein or (b) terminated by Mr. Finkelstein by resignation for good reason, or (ii) terminated by the Company for any reason (other than for cause or due to death or disability of Mr. Finkelstein) in connection with or in anticipation of such change in control, then Mr. Finkelstein may be eligible to receive severance. The amount of severance due to Mr. Finkelstein is determined according to his base salary as of November 30, 2011, not including bonuses or any other compensation, or Base Salary, and the amount of Net Proceeds, as defined in the change in control agreement, received in connection with the change in control. The amount of the severance may not exceed six months of Mr. Finkelstein's Base Salary. Mr. Finkelstein will be required to execute a general release and waiver of all legal claims prior to receiving severance. Additionally, under the terms of the amended change in control agreement, upon the occurrence of a change in control of the Company, all outstanding stock options will become fully vested and exercisable upon the effectiveness of the change in control transaction. The compensation provided pursuant to the change in control agreement will be the only severance benefits to which Mr. Finkelstein may be entitled upon termination of his employment with the Company.

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 of directors 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.

David R. Crockford. We entered into an employment agreement with Mr. Crockford in March 2005 for him to serve as our vice president of clinical and regulatory affairs. Mr. Crockford's employment agreement had an initial one-year term, which was automatically renewed for additional one-year periods. The agreement was amended and restated during 2008 and again in 2009. Immediately prior to November 30, 2011, Mr. Crockford's base salary was $210,223.

On November 30, 2011, the Company and Mr. Crockford amended his employment agreement to reduce Mr. Crockford's salary effective as of December 1, 2011. Pursuant to the amendment, Mr. Crockford's annual base salary was reduced from $210,223 to $33,600 effective as of December 1, 2011. In consideration for the salary reduction, on December 2, 2011, the Company granted to Mr. Crockford an option to purchase 91,991 shares of the Company's common stock. This option vested in full on December 31, 2011.

In addition to the change in salary, Mr. Crockford's amended employment agreement also changed the Company's severance obligations. Pursuant to the revised severance obligations, Mr. Crockford's severance was reduced from one year's salary to two weeks' salary, and he was not entitled to severance in the event that his employment was terminated by the Company because the Company ceased operations as a result of financial losses, lack of funding, legal decisions, administrative rulings, declaration of war, dissolution, national or local economic depression or crisis or any reasons beyond the control of the Company.

Effective as of January 1, 2012, the Company and Mr. Crockford entered into a letter agreement for temporary employment and terminated the previous employment agreement, changing his status to that of a part-time temporary employee. In connection with this conversion, the Company paid Mr. Crockford two weeks of severance based on his December 2011 salary (payment equal to $1,400) plus accrued vacation.

Pursuant to his letter agreement, Mr. Crockford receives a salary at a rate of $96.01 per hour for work related to the May 2010 grant from the National Institutes of Health's National Heart Lung & Blood Institute, or the NIH Grant, all of which is expected to be funded from proceeds of the NIH Grant, and at a rate of $50.00 per hour for all other work, subject to deductions and withholdings. Mr. Crockford's typical work schedule is up to 20 hours per month for non-grant work, with no guaranteed minimum number of hours. In accordance with the letter agreement, the employment termination date for Mr. Crockford was originally March 31, 2012, unless terminated prior to March 31, 2012 by Mr. Crockford or the Company. As a result of the receipt of funding in connection with the Lee's term sheet, the Company and Mr. Crockford extended the term of the letter agreement to June 30, 2012. Mr. Crockford was also granted an option to purchase 35,000 shares of the Company's common stock at an exercise price of $0.16 per share, which option will vest in full on June 30, 2012 subject to Mr. Crockford's continued service.

In addition to the letter agreement, the Company and Mr. Crockford also entered into a change in control agreement effective January 1, 2012, which was amended on April 3, 2012. Pursuant to the change in control agreement, as amended, if a change in control of the Company is consummated and the employment of Mr. Crockford is (i) within twelve months following such change in control (a) terminated by the Company for any reason, other than for cause or due to death or disability of Mr. Crockford or (b) terminated by Mr. Crockford by resignation for good reason, or (ii) terminated by the Company for any reason (other than for cause or due to death or disability of Mr. Crockford) in connection with or in anticipation of such change in control, then Mr. Crockford may be eligible to receive severance. The amount of severance due to Mr. Crockford is determined according to his Base Salary and the amount of Net Proceeds, as defined in the change in control agreement, received in connection with the change in control. The amount of the severance may not exceed six months of Mr. Crockford's Base Salary. Mr. Crockford will be required to execute a general release and waiver of all legal claims prior to receiving severance. Additionally, under the terms of the amended change in control agreement, upon the occurrence of a change in control of the Company, all outstanding stock options will become fully vested and exercisable upon the effectiveness of the change in control transaction. The compensation provided pursuant to the change in control agreement will be the only severance benefits to which Mr. Crockford may be entitled upon termination of his employment with the Company.

Mr. Crockford 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 of directors or the compensation committee thereof. All vested options are exercisable for a period of time following any termination of Mr. Crockford's employment as may be set forth in the applicable benefit plan or in any option agreement between Mr. Crockford and us.

Outstanding Equity Awards at December 31, 2011

The following table shows certain information regarding outstanding equity awards at December 31, 2011 for the named executive officers, 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	500,000	—	0.33	1/1/2012	
	100,000	—	3.21	4/1/2015	
	125,000	—	2.34	3/15/2014	(1)
	93,750	31,250	1.15	4/15/2015	(1)
	114,748	—	0.57	4/10/2019	
	62,500	62,500	0.76	10/11/2016	(1)
	31,250	93,750	0.27	07/14/2017	(1)
	—	125,000	0.22	8/3/2018	(1)
	80,135	—	0.16	12/2/2018	
Mr. Crockford	15,000	—	1.07	7/1/2013	
	125,000	—	0.86	1/1/2014	
	100,000	—	3.21	4/1/2015	
	25,000	—	3.82	5/25/2015	
	50,000	—	2.15	1/16/2014	(1)
	75,000	—	2.34	3/15/2014	(1)
	56,250	18,750	1.15	4/15/2015	(1)
	24,625	73,875	0.27	07/14/2017	(1)
	—	98,500	0.22	08/3/2018	(1)
	91,991	—	0.16	12/2/2018	
Mr. Lyons	—	—	—	—	(2)

(1) This option vests in equal installments on the first four anniversaries of the grant date. In each case these options were granted seven years prior to the listed expiration dates.

(2) Mr. Lyons terminated his employment with us as of August 31, 2011 and, as of December 31, 2011, all unexercised stock options previously held by Mr. Lyons had terminated.

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 made available to all employees. 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, 2011 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.

Under our non-employee director compensation policy, as in effect during 2011, each non-employee director is eligible to receive an annual cash retainer of $13,905. The chairman of each of our audit committee and compensation committee is eligible to receive a supplemental annual cash retainer of $10,300. Mr. McNay currently serves as the chairman of the audit committee and Dr. Bowles currently serves as the chairman of the Compensation Committee. Directors are also eligible to receive $1,288 for each board meeting attended in person and $412 for each Board meeting attended by telephone. Additionally, members of each committee of the board of directors are eligible to receive $515 for each committee meeting attended, whether in person or by telephone. However, during November 2011, our Board of Directors elected to suspend the payment of cash retainers to non-employee directors to help the company preserve capital.

Additionally, non-employee directors receive a nonqualified stock option under our equity incentive plan to purchase 20,000 shares of common stock upon their re-election as a director at each annual meeting of stockholders. Newly elected or appointed non-employee directors receive a nonqualified stock option to purchase 40,000 shares of common stock. All options granted to directors under this policy vest over four years, with 25% of the shares underlying the option vesting on the first through fourth anniversaries of the date of grant.

In April 2012, in view of the Board's November 2011 decision to temporarily cease paying cash compensation to non-employee directors for Board and committee service, the Board elected to make a one-time option grant to each the non-employee directors to compensate them for serving during the first half of 2012. Each non-employee director was granted a stock option to purchase 50,000 shares of common stock at an exercise price of $0.16 per share, which option will vest in full on June 30, 2012 subject to the director's continued service.

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 2011

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)(2)	All Other Compensation ($)	Total ($)
Allan Goldstein, Ph.D.	—	19,108	174,638(3)	193,746
R. Don Elsey	19,982	2,509	—	22,491
L. Thompson Bowles M.D., Ph.D.	30,282	2,509	—	32,791
Joseph McNay	28,530	2,509	—	31,039
Mauro Bove	15,655	2,509	—	18,164

(1) These amounts reflect the cash earned during 2011. As described above, during 2011, our Board of Directors elected to cease paying cash compensation to non-employee directors to help the company preserve capital. The amounts in the table above include the following amounts of accrued and unpaid compensation as of December 31, 2011: $10,712 for Mr. Elsey; $15,862 for Dr. Bowles; $14,986 for Mr. McNay; and $8,291 for Mr. Bove. Each director elected to forfeit such amounts in March 2012.

(2) These amounts reflect the aggregate total grant date fair values (computed in accordance with FASB ASC Topic 718) of options granted to directors during 2011. Options held by each Board member as of December 31, 2011, are as follows:

Allan Goldstein, Ph.D.	974,077
R. Don Elsey	60,000
L. Thompson Bowles M.D., Ph.D.	194,843
Joseph McNay	168,024
Mauro Bove	267,155

(3) In addition to being Chairman of our Board of Directors, Dr. Goldstein also serves as our Chief Scientific Advisor. In this capacity, Dr. Goldstein received a base salary of $174,638 for 2011 which reflects one month of a reduced salary. As of December 1, 2011, Dr. Goldstein's annual salary has been reduced from $187,460 to $33,600. In consideration for this salary reduction, on December 2, 2011, the Company granted to Dr. Goldstein an option to purchase 80,135 shares of the Company's common stock. These options vested in full on December 31, 2011.

In addition to the changes in salary, Dr. Goldstein's amended employment agreement also changed the Company's severance obligations. Pursuant to the revised severance obligations, Dr. Goldstein's severance was reduced from one year's salary to two weeks' salary, and Dr. Goldstein was not entitled to severance in the event that his employment was terminated by the Company because the Company ceased operations as a result of financial losses, lack of funding, legal decisions, administrative rulings, declaration of war, dissolution, national or local economic depression or crisis or any reasons beyond the control of the Company.

Effective January 1, 2012, the Company and Dr. Goldstein entered into a letter agreement for temporary employment and terminated Dr. Goldstein's previous employment agreement, changing his status to that of part-time temporary employee. In connection with this conversion, the Company paid Dr. Goldstein two weeks of severance based on his December 2011 salary (payment equal to $1,400).

Pursuant to this letter agreement, Dr. Goldstein receives a salary at a rate of $50.00 per hour, subject to deductions and withholdings. Dr. Goldstein's typical work schedule is up to 32 hours per month, with no guaranteed minimum number of hours. In accordance with the letter agreement, Dr. Goldstein's employment termination date was originally March 31, 2012, unless terminated prior to March 31, 2012 by Dr. Goldstein or the Company. As a result of the receipt of funding in connection with the Lee's term sheet, the Company and Dr. Goldstein extended the term of the letter agreement to June 30, 2012. Dr. Goldstein was also granted an option to purchase 35,000 shares of the Company's common stock at an exercise price of $0.16 per share, which option will vest in full on June 30, 2012 subject to Dr. Goldstein's continued service.

In addition to the letter agreement, the Company and Dr. Goldstein also entered into a change in control agreement effective January 1, 2012, which was amended on April 3, 2012. Pursuant to his change in control agreement, as amended, if a change in control of the Company is consummated and either the employment of Dr. Goldstein is (i) within twelve months following such change in control (a) terminated by the Company for any reason, other than for cause or due to death or disability of Dr. Goldstein, or (b) terminated by Dr. Goldstein by resignation for good reason, or (ii) terminated by the Company for any reason (other than for cause or due to death or disability of Dr. Goldstein) in connection with or in anticipation of such change in control, then Dr. Goldstein may be eligible to receive severance. The amount of severance due to Dr. Goldstein will be determined according to his Base Salary and the amount of Net Proceeds, as defined in the change in control agreement, received in connection with the change in control. The amount of the severance may not exceed six months of his Base Salary. Dr. Goldstein will be required to execute a general release and waiver of all legal claims prior to receiving severance. Additionally, under the terms of the amended change in control agreement, upon the occurrence of a change in control of the Company, all outstanding stock options will become fully vested and exercisable upon the effectiveness of the change in control transaction. The compensation provided pursuant to the change in control agreement will be the only severance benefits to which Dr. Goldstein may be entitled upon termination of his employment with the Company.

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, 2012 by (i) each director; (ii) each of the named executive officers; (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 Owner	Beneficial Ownership(1) Number of Shares	Percent of Total
5% Stockholders:		
Entities affiliated with Sigma-Tau Finanziaria, S.p.A. Via Sudafrica, 20, Rome, Italy 00144	32,358,332(2)	38.6%
Named Executive Officers and Other Directors:		
J.J. Finkelstein	2,067,271(3)	2.5%
Allan L. Goldstein	1,771,048(4)	2.2%
R. Don Elsey	10,000(7)	*
Joseph C. McNay	1,460,885(5)	1.8%
Mauro Bove	220,905(6)	*
L. Thompson Bowles	148,593(7)	*
David R. Crockford	581,616(7)	*
C. Neil Lyons	30,000	*
All directors and currently serving executive officers as a group (7 persons)	6,260,318(8)	7.5%

* Less than one percent.

(1) This table is based upon information supplied by officers, directors and principal stockholders. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believes 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 81,390,618 shares of common stock outstanding on March 15, 2012, adjusted as required by rules promulgated by the Securities and Exchange Commission (the "SEC").

(2) Consists of 984,615 shares of common stock held of record held by Sigma-Tau Finanziaria, S.p.A. ("Sigma-Tau"); 12,937,111 shares of common stock held of record and 370,370 shares of common stock issuable upon exercise of warrants held by Defiante Farmaceutica S.A. ("Defiante"), a subsidiary of Sigma-Tau, that are exercisable within 60 days of March 15, 2012; 6,348,878 shares of common stock held of record and 518,518 shares of common stock issuable upon exercise of warrants held by Taufin International S.A. ("Taufin"), an entity wholly owned by Taufin SPA, which is owned directly by the estate of Claudio Cavazza, who directly and indirectly owns 57% of Sigma-Tau, that are exercisable within 60 days of March 15, 2012; and 9,711,407 shares of common stock held of record and 1,487,433 shares of common stock issuable upon exercise of warrants held by Sinaf S.A. ("Sinaf"), an indirect wholly-owned subsidiary of Aptafin S.p.A., which is owned by Paolo Cavazza and members of his family, that are exercisable within 60 days of March 15, 2012. Paolo Cavazza directly and indirectly owns 38% of Sigma-Tau.

(3) Consists of 1,377,638 shares of common stock held of record by Mr. Finkelstein and 51,000 shares of common stock held of record by Mr. Finkelstein's daughter over which Mr. Finkelstein shares voting and dispositive power. Also includes 638,633 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2012.

(4) Consists of 1,306,846 shares of common stock held of record by Dr. Goldstein and 464,202 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2012.

(5) Consists of 1,339,111 shares of common stock held of record by Mr. McNay and 121,774 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2012.

(6) Consists of shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2012. Mr. Bove is an officer of Sigma-Tau, but he has no beneficial ownership over the reported securities as he has no voting or dispositive power with respect to the securities held by Sigma-Tau and its affiliates described in Note 2 above.

(7) Consists of shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2012.

(8) Consists of 4,074,595 shares of common stock held of record and 2,185,723 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2012.

Equity Compensation Plan Information

The following table provides information as of December 31, 2011 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	5,374,599	$ 1.16	3,489,036
Equity compensation plans not approved by security holders	—	—	—
Total	5,374,599	$ 1.16	3,489,036

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

Related Party Transactions

The following is a summary of transactions, and series of related transactions, since January 1, 2011 to which we have been or will be a participant, in which the amount involved exceeded or will exceed one percent of the average of our total assets at year end for the last two completed fiscal years and in which any of our executive officers, directors or beneficial holders of more than five percent of our capital stock had or will have a direct or indirect material interest, or any immediate family member of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest, other than executive and director compensation arrangements, including the employment, termination of employment and change of control arrangements, which are described in the section of this report entitled “Executive Compensation.”

Sigma-Tau

On January 7, 2011, we issued 925,926 shares of common stock to Defiante Farmaceutica S.A., or Defiante, a subsidiary of Sigma-Tau, as well as 1,296,296 shares to Taufin International S.A., or Taufin and 1,296,297 shares to Sinaf S.A. or Sinaf, all at a purchase price of $0.27 per share in a private placement. We also issued warrants to each of Defiante, Taufin and Sinaf to purchase 370,370 shares, 518,518 shares and 518,519 shares of our common stock, respectively, at an exercise price of $0.38 per share. The warrants are exercisable until January 7, 2016. We also entered into an agreement with Defiante, Taufin and Sinaf to amend the terms of certain warrants held by them. Under the warrant amendment, all outstanding warrants held by Defiante, Taufin and Sinaf that were issued between March 2006 and December 2008, exercisable for an aggregate of 3,046,453 shares of common stock and with exercise prices between $1.60 per share and $4.06 per share, were amended to reduce their exercise prices to $0.38 per share and to extend their expiration dates to December 31, 2011, as of which date the warrants expired unexercised. Taufin is a direct wholly-owned subsidiary of Taufin SPA. Taufin SPA is owned directly by the estate of Claudio Cavazza, which directly and indirectly owns 57% of Sigma-Tau. Sinaf 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.

Lee’s Pharmaceuticals

In March 2012, we entered into a term sheet with Lee’s Pharmaceutical (HK) for the development of Tß4 in any pharmaceutical formulation in China, Hong Kong and Macau. At the time of the signing of the term sheet, we received a $200,000 payment from Lee’s. Upon execution of the definitive license agreement, we will receive an additional $200,000 payment from Lee’s. In accordance with the terms of the term sheet, we expect that the definitive license agreement will 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. Lee’s will pay for all developmental costs associated with each product candidate. RegeneRx will provide T β4 to Lee’s at no charge for a Phase 2 ophthalmic clinical trial and will provide T β4 to Lee’s for all other developmental and clinical work at a price equal to RegeneRx’s cost. The two companies will create a joint development committee to discuss and agree on 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. Lee’s is an affiliate of Sigma Tau, which collectively with its affiliates is our largest stockholder, and Mr. Bove is a non-executive director of Lee’s.

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 four directors are independent directors within the meaning of the applicable NYSE Amex listing standards: Mr. Elsey, Mr. Bove, Mr. McNay and Dr. Bowles. In making this determination, the board found that none of the 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 Advisor, 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. The board of directors does not believe that any of the transactions with 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, 2011 and 2010 by Reznick Group, P.C., our independent registered public accounting firm. All such fees described below were approved by the audit committee.

	2011	2010
Audit fees	$67,000	$ 77,453
Tax fees [1]	11,000	22,053
Total Fees	$ 78,000	$99,506

[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, Reznick Group, P.C. 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 form 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 Reznick Group P.C. is compatible with maintaining that firm's independence.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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 10.1 to Annual Report on Form 10-KSB for the year ended December 31, 2000 (File No. 001-15070) (filed April 2, 2001)**
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 ^	Second Amended and Restated Employment Agreement, dated March 11, 2009, between the Company and Allan L. Goldstein, as amended	Exhibit 10.4 to Amendment No. 1 to Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 001-15070) (filed April 30, 2009)
10.7 ^	Second Amended and Restated Employment Agreement, dated March 12, 2009, between the Company and J.J. Finkelstein, as amended	Exhibit 10.5 to Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 001-15070) (filed April 15, 2009)
10.8 ^	Second Amended and Restated Employment Agreement, dated March 31, 2009, between the Company and C. Neil Lyons, as amended	Exhibit 10.6 to Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 001-15070) (filed April 15, 2009)
10.9 ^	Second Amended and Restated Employment Agreement, dated March 31, 2009, between the Company and David Crockford	Exhibit 10.7 to Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 001-15070) (filed April 15, 2009)

10.10 ^	Second Amendment to the Amended and Restated Employment Agreement between the Company and J.J. Finkelstein, dated December 1, 2011.	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed December 6, 2011)
10.11 ^	First Amendment to the Amended and Restated Employment Agreement between the Company and David Crockford, dated December 1, 2011.	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed December 6, 2011)
10.12 ^	Second Amendment to the Amended and Restated Employment Agreement between the Company and Allan L. Goldstein, dated December 1, 2011.	Exhibit 10.3 to Current Report on Form 8-K (File No. 001-15070) (filed December 6, 2011)
10.13 ^	Letter Agreement between the Company and J.J. Finkelstein, dated January 1, 2012.	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.14 ^	Letter Agreement between the Company and David Crockford, dated January 1, 2012.	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.15 ^	Letter Agreement between the Company and Allan L. Goldstein, dated January 1, 2012.	Exhibit 10.5 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.16 ^	Change in Control Agreement between the Company and J.J. Finkelstein, dated January 1, 2012.	Exhibit 10.3 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.17 ^	Change in Control Agreement between the Company and David Crockford, dated January 1, 2012.	Exhibit 10.4 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.18 ^	Change in Control Agreement between the Company and Allan L. Goldstein, dated January 1, 2012.	Exhibit 10.6 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.19	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)
10.20	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)
10.21	Securities Purchase Agreement, dated April 13, 2009	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed April 16, 2009)
10.22	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)

10.23	Securities Purchase Agreement, dated September 30, 2009	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed September 30, 2009)
10.24	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)
10.25	Securities Purchase Agreement, dated September 30, 2009	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed October 5, 2009)
10.26	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)
10.27	Purchase Agreement, dated January 4, 2011	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.28	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)
10.29	Securities Purchase Agreement, dated January 5, 2011	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.30	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)
10.31	Securities Purchase Agreement, dated January 5, 2011, by and between the Company and Defiante Farmaceutica S.A.	Exhibit 10.4 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.32	Securities Purchase Agreement, dated January 5, 2011, by and between the Company and Taufin International S.A.	Exhibit 10.5 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.33	Securities Purchase Agreement, dated January 5, 2011, by and between the Company and Sinaf S.A.	Exhibit 10.6 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.34	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)
23.1	Consent of Reznick Group, P.C.	Filed herewith
24.1	Powers of Attorney	Included on signature page

31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934	Filed herewith
31.2	Certification of 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***

* 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.

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: April 4, 2012

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 Advisor, and Director	April 4, 2012
/s/ J.J. Finkelstein J.J. Finkelstein	President, Chief Executive Officer, and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	April 4, 2012
/s/ R. Don Elsey R. Don Elsey	Director	April 4, 2012
/s/ Joseph C. McNay Joseph C. McNay	Director	April 4, 2012
/s/ Mauro Bove Mauro Bove	Director	April 4, 2012
/s/ L. Thompson Bowles L. Thompson Bowles	Director	April 4, 2012

RegeneRx Biopharmaceuticals, Inc.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
RegeneRx Biopharmaceuticals, Inc.

We have audited the accompanying balance sheets of RegeneRx Biopharmaceuticals, Inc. (the "Company") as of December 31, 2011 and 2010, and the related statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of RegeneRx Biopharmaceuticals, Inc. as of December 31, 2011 and 2010, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

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

/s/ REZNICK GROUP, P.C.

Vienna, Virginia
April 4, 2012

RegeneRx Biopharmaceuticals, Inc.
Balance Sheets

	December 31, 2011	2010
ASSETS		
Current assets		
Cash and cash equivalents	$ 116,092	$ 3,790,352
Grant receivable	214,450	10,703
Prepaid expenses and other current assets	24,603	384,806
Total current assets	355,145	4,185,861
Property and equipment, net of accumulated depreciation of $116,985 and $107,907	16,946	24,940
Other assets	11,503	17,255
Total assets	$ 383,594	$ 4,228,056
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 451,881	$ 185,643
Accrued expenses	358,778	430,996
Total current liabilities	810,659	616,639
Commitments	—	—
Stockholders' equity		
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, 81,390,618 and 73,531,578 issued and outstanding	81,391	73,532
Additional paid-in capital	95,023,912	93,063,201
Accumulated deficit	(95,532,368)	(89,525,316)
Total stockholders' equity (deficit)	(427,065)	3,611,417
Total liabilities and stockholders' equity (deficit)	$ 383,594	$ 4,228,056

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Operations

	Years ended December 31,	
	2011	2010
Sponsored research revenue	$ 1,511,572	$ 849,539
Operating expenses		
Research and development	5,067,085	2,707,909
General and administrative	2,456,028	3,173,729
Total operating expenses	7,523,113	5,881,638
Loss from operations	(6,011,541)	(5,032,099)
Interest and other income	4,489	8,187
Net loss	$ (6,007,052)	$(5,023,912)
Basic and diluted net loss per common share	$ (0.07)	$ (0.07)
Weighted average number of common shares outstanding	80,135,099	68,444,011

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Changes in Stockholders' Equity (Deficit)
Years ended December 31, 2011 and 2010

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount			
Balance, December 31, 2009	60,406,828	$ 60,407	$ 88,144,347	$ (84,501,404)	$ 3,703,350
Issuance of common stock, net of offering costs of $923,524	13,124,750	13,125	4,444,499	—	4,457,624
Share-based compensation expense	—	—	474,355	—	474,355
Net loss	—	—	—	(5,023,912)	(5,023,912)
Balance, December 31, 2010	73,531,578	73,532	93,063,201	(89,525,316)	3,611,417
Issuance of common stock, net of offering costs of $51,400	7,859,040	7,859	1,738,957	—	1,746,816
Share-based compensation expense	—	—	221,754	—	221,754
Net loss	—	—	—	(6,007,052)	(6,007,052)
Balance, December 31, 2011	81,390,618	$81,391	$95,023,912	$ (95,532,368)	$ (427,065)

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Cash Flows

	Years ended December 31, 2011	2010
Operating activities:		
Net loss	$ (6,007,052)	$ (5,023,912)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,078	9,736
Non-cash share-based compensation	221,754	474,355
Gain on settlement of accrued expenses	—	(141,016)
Changes in operating assets and liabilities:		
Grant receivable	(203,747)	(10,703)
Prepaid expenses and other current assets	360,203	(188,260)
Other assets	5,752	5,693
Accounts payable	266,238	45,437
Accrued expenses	(72,218)	(168,186)
Net cash used in operating activities	(5,419,992)	(4,996,856)
Investing activities:		
Purchase of property and equipment	(1,084)	(26,184)
Net cash used in investing activities	(1,084)	(26,184)
Financing activities:		
Net proceeds from issuance of common stock	1,746,816	4,457,624
Net cash provided by financing activities	1,746,816	4,457,624
Net decrease in cash and cash equivalents	(3,674,260)	(565,416)
Cash and cash equivalents at beginning of year	3,790,352	4,355,768
Cash and cash equivalents at end of year	$ 116,092	$ 3,790,352

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

1. ORGANIZATION AND BUSINESS

Organization and Nature of Operations. RegeneRx Biopharmaceuticals, Inc. ("RegeneRx", the "Company", "We", "Us", "Our"), a Delaware corporation, was incorporated in 1982. We are focused on the discovery and development of novel molecules to accelerate tissue and organ repair. Our operations are confined to one business segment: the development and marketing of product candidates based on Thymosin Beta 4 ("T β4"), an amino acid peptide.

Management Plans to Address Operating Conditions. On March 27, 2012, we entered into a term sheet with Lee's Pharmaceutical (HK) Limited ("Lee's") for the license of Tß4 in any pharmaceutical formulation, including our RGN-259, RGN-352 and RGN-137 product candidates, in China, Hong Kong and Macau. Lee's paid us $200,000 upon signing of the term sheet, and Lee's will pay us an additional $200,000 upon signing of the definitive license agreement, which we expect to occur by May 31, 2012. Sigma-Tau Finanziaria S.P.A., an international pharmaceutical company, which together with its subsidiaries and affiliates, collectively beneficially own approximately 39% of our common stock and represent our largest stockholder group, also collectively own approximately 28% of Lee's. The receipt of the initial $200,000 will support our operations for thirty to sixty days. Receipt of the additional $200,000 from the signing of the definitive license agreement will provide funding of planned operations through the second quarter of 2012. We continue to evaluate potential strategic options, including the licensing of additional territorial rights to our proprietary clinical programs. Additionally, beginning in late 2011, we began implementing significant cost-saving measures to conserve capital resources and maintain a minimal level of operations, while seeking additional funding and/or complete a strategic transaction. To that end, in December 2011 we reduced the salaries of all of our employees to approximately $2,800 per month, and we granted stock options to them (in lieu of a portion of the cash salary adjustment) that vested at the end of the year. Beginning in January 2012, all employees became part-time hourly employees with reduced work schedules. Additionally, in January 2012, we discontinued providing employee health benefits and company-sponsored 401(k) matching contributions. The majority of our research and development staff's efforts since this time have been directed to work under a grant that we received from the National Institutes of Health ("NIH").

We have incurred net losses of $6.0 million and $5.0 million for the years ended December 31, 2011 and 2010, respectively. Since inception, and through December 31, 2011, we have an accumulated deficit of $95.5 million and we had cash and cash equivalents of $116,000 as of December 31, 2011. Currently, we are not enrolling patients in any of our clinical trials. We had intended to commence patient enrollment in a Phase 2 clinical trial of RGN-352 for AMI patients near the end of the first quarter of 2011, but this trial has been placed on clinical hold by the FDA pending resolution of certain manufacturing compliance issues at our original contract manufacturer, which was responsible for formulating, filling and finishing RGN-352. We have put the AMI trial on hold pending access to sufficient capital resources to enable us to retain a new drug product manufacturer and are focusing our current efforts on the development of RGN-259 for ophthalmic indications.

We have stopped enrolling and have closed a Phase 2 trial to evaluate RGN-137 in patients suffering from epidermolysis bullosa, or EB. We plan to have the data analyzed once we have the financial resources. Given these objectives and as noted above, we project that our existing capital resources, coupled with the expected $200,000 payment from Lee's upon entry into the definitive license agreement, will fund our planned operating activities through the end of June 2012, without giving effect to any other financing sources, including any purchases under our committed equity facility with Lincoln Park Capital, which is subject to a number of conditions that limit our ability to draw against such facility (See Note 7).

We anticipate incurring additional losses in the future as we continue to explore the potential clinical benefits of T β4-based product candidates over multiple indications. We will need substantial additional funds in order to initiate any further preclinical studies or clinical trials, and to fund our operations beyond June 2012. Accordingly, we have an immediate need for financing 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 a strategic partner, 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 expect to continue to expend substantial funds to complete our planned product development efforts. Additionally, we continually refine our operating strategy and evaluate alternative clinical uses of T β4. 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 Stated 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 clinical trial accruals 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 $9,078 and $9,736 for the years ended December 31, 2011 and 2010, 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 two years ended December 31, 2011 we did not report qualifying long-lived assets and therefore no impairment losses were recorded.

Sponsored Research Revenues. We account for non-refundable grants as "Sponsored research revenues" in the accompanying statements of operations. Revenue from non-refundable grants is recognized when the following criteria are met; persuasive evidence of an arrangement exists, services have been rendered and the underlying costs incurred, the contract price is fixed or determinable, and collectability is reasonably assured. For the year ended December 31, 2011, all of our revenues were received from one NIH grant. For the year ended December 31, 2010, all revenues were received from this NIH grant and from awards under the Patient Protection and Affordable Care Act as part of an incentive for biotechnology companies.

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 T β4; formulation of Tβ4 into the various product candidates; stability for both T β4 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, five persons in total, who are wholly dedicated to R&D efforts. R&D also includes a pro-ration of our common infrastructure costs for office space and communications.

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

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

Income Taxes. Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. We recognize the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. Our policy for recording interest and penalties associated with audits is that penalties and interest expense are recorded in “Income taxes” in our statements of operations.

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making that assessment. We recorded a full valuation allowance against all estimated net deferred tax assets at December 31, 2011 and 2010. We have significant net operating loss carryforwards to potentially reduce future federal and state taxable income, and research and experimentation tax credit carryforwards available to potentially offset future federal and state income taxes. Use of our net operating loss and research and experimentation credit carryforwards may be limited due to changes in our ownership as defined within Section 382 of the Internal Revenue Code.

Net Loss Per Common Share. Net loss per common share for the years ended December 31, 2011 and 2010, respectively, is based on the weighted-average number of shares of common stock outstanding during the periods. Basic and diluted loss per share are identical for all periods presented as potentially dilutive securities have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive. The potentially dilutive securities include 16,706,658 shares and 19,337,615 shares in 2011 and 2010, respectively, reserved for the exercise of outstanding options and warrants.

Share-Based Compensation. We measure share-based compensation expense based on the grant date fair value of the awards which is then recognized over the period which service is required to be provided. We estimate the grant date fair value using the Black-Scholes option-pricing model (“Black-Scholes”). We recognized $221,754 and $474,355 in share-based compensation expense for the years ended December 31, 2011 and 2010, 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, and accounts payable.

Recent Accounting Pronouncements.

New pronouncements issued by the Financial Accounting Standards Board (“FASB”) or other authoritative accounting standards groups with future effective dates are either not applicable or not expected to have a significant effect on our financial position or results of operations.

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.

At December 31, 2011 and 2010, we held no qualifying liabilities, and our only qualifying assets that required measurement under the foregoing fair value hierarchy were money market funds and U.S. Treasury Bills included in Cash and Cash Equivalents valued at $116,000 and $3.8 million, respectively, using Level 1 inputs.

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 T β4 within their broadly-defined patent application. In exchange for this exclusive worldwide license, we must make certain royalty and milestone payments to the NIH. Through December 31, 2011 we have complied with these requirements. 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. Minimum annual maintenance fees for each of the years ended December 31, 2011 and 2010 were $25,000, and are expected to amount to approximately $25,000 annually in 2012 and thereafter.

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 expected to amount to approximately $5,000 annually. 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.

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

We have entered into a License and Supply Agreement (the "Agreement") with Defiante Farmaceutica S.A. ("Defiante") a Portuguese company that is a wholly owned subsidiary of Sigma-Tau, S.p.A., an international pharmaceutical company and an affiliate of Sigma-Tau Finanziaria S.p.A., who together with its affiliates comprise our largest stockholder group (the "Sigma-Tau Group"). This Agreement grants to Defiante the exclusive right to use T β4 to conduct research and development activities in Europe. Under the Agreement, we will receive fees and royalty payments based on a percentage of specified sales of Tβ4-related products by Defiante. The term of the Agreement continues until the later of the expiration of any patents developed under the Agreement, the expiration of marketing rights, or December 31, 2016.

5. COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

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

	December 31,	
	2011	2010
Prepaid research and development	$ —	$245,498
Legal retainer	—	100,000
Prepaid compensation	—	24,960
Prepaid insurance	14,133	8,596
Other	10,470	5,573
	$24,603	$ 384,806

Accrued expenses are comprised of the following:

	December 31,	
	2011	2010
Accrued clinical research	$167,595	$208,515
Accrued professional fees	48,543	128,847
Accrued vacation	46,579	48,096
Other	37,810	43,538
Accrued compensation	—	2,000
Accrued severance	8,400	—
Accrued board of directors' fees	49,851	—
	$ 358,778	$430,996

6. EMPLOYEE BENEFIT PLANS

We have a defined contribution retirement plan that complies with Section 401(k) of the Internal Revenue Code (the "Code"). All employees of the Company are eligible to participate in the plan. The Company matches 100% of each participant's voluntary contributions, subject to a maximum Company contribution of 4% of the participant's compensation. The Company's matching portion totaled $40,516 and $43,280 for the years ended December 31, 2011 and 2010, respectively. Pursuant to changes in the employment status of all employees, we discontinued the matching contribution effective January 1, 2012.

7. STOCKHOLDERS' EQUITY

Shareholders Rights Plan. Our Board of Directors adopted a Rights Agreement, dated April 29, 1994, as amended, that is intended to discourage an unsolicited change in control of the Company. In general, if an entity acquires more than a 25% ownership interest in the Company without the endorsement of our Board of Directors, then our current stockholders (other than the acquiring entity) will be issued a significant number of new shares, the effect of which would dilute the ownership of the acquiring entity and could delay or prevent the change in control.

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.

Common Stock. During 2010, we sold an aggregate of 13,124,750 shares of our common stock and warrants to purchase an additional 5,249,900 shares of our common stock in a public offering for net proceeds of approximately $4.5 million. These securities were sold as units, with each unit consisting of one share of common stock and a warrant to purchase 0.4 shares of our common stock. Each unit was sold at a public offering price of $0.41.

Each warrant has a term of five years and represents the right to purchase one share of common stock at an exercise price of $0.56 per share. In the event the closing sale price of our common stock is at least $1.78 per share for any 20 trading days within a period of 30 consecutive trading days, we may call these warrants for redemption, at a redemption price of $0.01 per warrant, by providing at least 30 days notice to each warrant holder. The warrants were valued using the Black-Scholes option-pricing model as of the closing date and accounted for in permanent equity. The estimated fair value of the warrants at the date of issuance was approximately $725,000.

In addition, the representative of the underwriters in the public offering was granted a warrant to purchase 805,000 shares of our common stock at an exercise price of $0.45 per share. This warrant is exercisable until May 17, 2015. The representative's warrant also provides for one demand registration until May 17, 2015. The representative's warrant was also valued using the Black-Scholes option-pricing model as of the closing date and accounted for as a cost of the offering. The estimated fair value of the representative's warrant at the date of issuance was approximately $112,000.

The public offering was made pursuant to a registration statement on Form S-1 (Registration No. 333-166146), which was declared effective by the SEC on May 17, 2010, and a final prospectus filed with the SEC on May 18, 2010.

On January 5, 2011, we entered into a securities purchase agreement with Lincoln Park Capital Fund, LLC ("LPC"), as previously described in footnote 10, Subsequent Events, to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2010, pursuant to which we sold in a registered direct offering 1,851,852 shares of our common stock to LPC at a price per share of $0.27, for gross proceeds of $500,000 before offering expenses (the "Registered Offering"). As part of the Registered Offering, we also issued to LPC, for no additional consideration, a warrant to purchase 740,741 shares of common stock at an exercise price of $0.38 per share (the "LPC Warrant"). Subject to certain ownership limitations, the LPC Warrant is exercisable until January 7, 2016. The exercise price of the LPC Warrant is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

The Registered Offering was made pursuant to an S-3 shelf registration statement on (SEC File No. 333-150675), which was declared effective by the SEC on May 16, 2008, pursuant to a prospectus supplement filed with the SEC on January 7, 2011.

The Registered Offering closed on January 7, 2011. No discounts or placement agent fees were payable in connection with the Registered Offering, and the Company used the proceeds from the Registered Offering for preclinical and clinical development of the Company's drug candidates and for general corporate purposes, including working capital.

On January 5, 2011, we entered into three separate securities purchase agreements (each, a "Sigma-Tau Purchase Agreement" and together, the "Sigma-Tau Purchase Agreements") with affiliates of Sigma-Tau Group, our largest stockholder (the "Sigma-Tau Purchasers"), with respect to the private placement (the "Private Placement") of an aggregate of 3,518,519 shares of common stock (the "Sigma-Tau Shares") at a price per share of $0.27, for gross proceeds of $950,000. No discounts or placement agent fees were payable in connection with the Private Placement, and we used the net proceeds of the Private Placement for working capital and other general corporate purposes.

In connection with the Private Placement, we also issued to the Sigma-Tau Purchasers warrants (the "Sigma-Tau Warrants") to purchase an aggregate of 1,407,407 additional shares of common stock at an exercise price of $0.38 per share. The Sigma-Tau Warrants are exercisable until January 7, 2016. The exercise price of the Sigma-Tau Warrants is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The Private Placement closed on January 7, 2011.

In connection with the Private Placement, on January 5, 2011, we and the Sigma-Tau Purchasers entered into an agreement (the "Warrant Amendment") to amend the terms of certain outstanding warrants held by the holders of such warrants (the "Holders"). Under the Warrant Amendment, all outstanding warrants held by the Holders that were issued between March 2006 and December 2008, exercisable for an aggregate of 3,046,453 shares of Common Stock and with exercise prices between $1.60 per share and $4.06 per share, were amended to reduce their exercise prices to $0.38 per share and to extend their expiration dates to December 31, 2011. The incremental fair value transferred to the Holders pursuant to the Warrant Amendment was not material. All of the amended warrants expired unexercised on December 31, 2011.

On January 4, 2011, we and LPC also entered into a committed equity facility (the "LPC Equity Facility"), together with a Registration Rights Agreement (the "Registration Rights Agreement"), whereby we have the right to sell to LPC up to $11,000,000 of our common stock through October 2013 (any such shares sold being referred to as the "Purchase Shares"). Under the Registration Rights Agreement, we filed a registration statement related to the transaction with the SEC covering the Purchase Shares and the Additional Commitment Shares (as defined below), which was declared by the SEC on February 11, 2011. We will generally have the right, but not the obligation, over a 30-month period that began in April 2011, to direct LPC to periodically purchase the Purchase Shares in specific amounts under certain conditions. The purchase price for the Purchase Shares will be the lower of (i) the lowest trading price on the date of sale or (ii) the arithmetic average of the three lowest closing sale prices for the common stock during the 12 consecutive business days ending on the business day immediately preceding the purchase date. In no event, however, will the Purchase Shares be sold to LPC at a price of less than $0.15 per share.

In consideration for entering into the LPC Equity Facility, we issued to LPC 958,333 shares of common stock as an initial commitment fee (the "Initial Commitment Shares") and are required to issue up to 958,333 shares of common stock as additional commitment shares on a pro rata basis (the "Additional Commitment Shares") as we direct LPC to purchase our shares under the Equity Facility over the term of the agreement. The LPC Equity Facility may be terminated by us at any time at our discretion without any cost to us. The proceeds that may be received by us under the LPC Equity Facility are expected to be used for preclinical and clinical development of our drug candidates and for general corporate purposes, including working capital.

Under the LPC Equity Facility, we have agreed that, subject to certain exceptions, we will not, during the term of the LPC Equity Facility, effect or enter into an agreement to effect any issuance of common stock or securities convertible into, exercisable for or exchangeable for common stock in a "Variable Rate Transaction," which means a transaction in which we:

- issue or sell any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional shares of common stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon and/or varies with the trading prices of or quotations for the shares of common stock at any time after the initial issuance of such debt or equity securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to our business or the market for the common stock; or
- enter into any agreement, including, but not limited to, an equity line of credit, whereby we may sell securities at a future determined price.

We have also agreed to indemnify LPC against certain losses resulting from our breach of any of our representations, warranties or covenants under the agreements with LPC.

During 2011, we sold 1,500,000 shares of common stock to LPC as Purchase Shares for $348,200 in net proceeds. We also issued 30,336 Additional Commitment Shares in connection with this purchase. At December 31, 2011 additional sales to LPC were not available as our share price was less than $0.15 per share.

Share-Based Compensation. We recognized $221,754 and $474,355 in stock-based compensation expense for the years ended December 31, 2011 and 2010, respectively. Given our current estimates of future forfeitures, we expect to recognize the compensation cost related to non-vested options as of December 31, 2011 of $210,000 over the weighted average remaining recognition period of 1.26 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.

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, 2011 and 2010, which was allocated as follows:

	December 31,	
	2011	2010
Research and development	$ 102,396	$ 206,427
General and administrative	119,358	267,928
	$ 221,754	$ 474,355

The following summarizes stock option activity for the years ended December 31, 2011 and 2010:

		Options outstanding		
	Shares available for grant	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2009	1,550,888	4,914,112	$ 0.28 – 3.82	$ 1.53
Grants	(672,500)	672,500	0.27 – 0.28	0.27
Exercises	—	—	—	—
Newly authorized	5,000,000	—	—	—
Cancellations	(1,550,888)	(237,749)	0.46 – 3.21	1.52
December 31, 2010	4,327,500	5,348,863	0.27 – 3.82	1.37
Grants	(1,002,964)	1,002,964	0.16 – 0.22	0.19
Exercises	—	—	—	—
Cancellations	164,500	(977,228)	0.22 – 3.10	1.31
December 31, 2011	3,489,036	5,374,599	$0.16 – 3.82	$ 1.16
Vested and expected to vest at December 31, 2011		5,113,498		
Exercisable at December 31, 2011		4,007,224		

The following summarizes information about stock options outstanding at December 31, 2011:

	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
$0.16 – $0.86	3,152,099	4.4	$ 0.37	2,086,599	3.6	$ 0.39
$1.07 – $1.93	712,500	2.9	1.30	610,625	2.8	1.32
$2.02 – $2.68	710,000	2.3	2.27	510,000	2.4	2.31
$3.00 – $3.82	800,000	3.4	3.21	800,000	3.4	3.21
	5,374,599	3.8	1.16	4,007,224	3.3	1.34
Intrinsic value of in-the-money options, using the December 31, 2011 closing price of $0.14	$ —			$ —		

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, 2011 and 2010:

	2011	2010
Dividend yield	0.0%	0.0%
Risk free rate of return	0.91 - 1.54%	1.47 - 1.76%
Expected life in years	3.5 - 4.75	4.75
Volatility	70%	70%
Forfeitures	2.61%	2.61%

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 107 ("SAB 107"), using a "simplified" method. The Company has used the simplified method and will continue to use the simplified method as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate an expected term. Our volatility assumption is based on reviews of the historical volatility of our common stock. We estimate forfeiture rates at the time of grant and adjust these estimates, if necessary, periodically based on the extent to which future actual forfeitures differ, or are expected to differ, from such estimates. Accordingly, we have estimated forfeiture percentages for the unvested portion of previously granted awards that remain outstanding at the date of adoption and for awards granted subsequent to the date of adoption. Forfeitures are estimated based on the demographics of current option holders and standard probabilities of employee turnover. Using Black-Scholes and these factors, the weighted average fair value of stock options granted to employees and directors was $0.11 for the year ended December 31, 2011 and $0.16 for the year ended December 31, 2010.

We do not record tax-related effects on stock-based compensation given our historical and anticipated operating experience and offsetting changes in our valuation allowance which fully reserves against potential deferred tax assets.

Warrants to Purchase Common Stock

The following table summarizes our warrant activity for 2011 and 2010:

	Warrants outstanding		
	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2009	7,933,852	$0.91 – 4.06	$2.01
Grants	6,054,900	0.45 – 0.56	0.55
Exercises	—	—	—
Cancellations	—	—	—
December 31, 2010	13,988,752	0.45 – 4.06	1.38
Grants	2,148,148	0.38	0.38
Exercises	—	—	—
Cancellations	(4,804,841)	0.38 – 4.06	1.41
December 31, 2011	11,332,059	$0.38 - $1.12	$0.67

8. INCOME TAXES

Significant components of the Company's deferred tax assets at December 31, 2011 and 2010 and related valuation reserves are presented below:

	December 31,	
	2011	2010
Deferred tax assets:		
Net operating loss carryforwards	$ 17,307,000	$ 15,890,000
Research and development tax credit carryforward	2,145,000	1,836,000
Charitable contribution carryforward	4,000	37,000
Accrued vacation	—	17,000
Accrued expenses	123,000	83,000
Amortization	13,000	4,000
Non-cash share based compensation	1,010,000	980,000
	20,602,000	18,847,000
Less — valuation allowance	(20,602,000)	(18,847,000)
Net deferred tax asset	$ —	$ —

A full valuation allowance has been provided at December 31, 2011 and 2010 to reserve for deferred tax assets, as it appears more likely than not that net deferred tax assets will not be realized.

At December 31, 2011, we had net operating loss carryforwards for income tax purposes of approximately $43.9 million, which are available to offset future federal and state taxable income, if any, and, research and development tax credit carryforwards of approximately $2.1 million. The carryforwards, if not utilized, will expire in increments through 2031.

The Code imposes substantial restrictions on the utilization of net operating losses and tax credits in the event of a corporation's ownership change, as defined in Section 382 of the Code. 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 sheet at December 31, 2011 and 2010. While the Company has not formally updated the study conducted during 2009, it has less formally reviewed the equity transactions executed during 2011 and 2010 and believes that the future utilization of net operating losses and tax credits presented above may be further compromised under the provisions of Section 382.

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2011 and 2010, due to the following:

	December 31,	
	2011	2010
Tax benefit at statutory rate	$ (2,042,000)	$ (1,700,000)
State taxes	(327,000)	(274,000)
Permanent M-1s	197,000	259,000
Limited/expired net operating loss carryforwards	726,000	2,881,000
Limited/expired research and development tax credit carryforward	34,000	59,000
Research and development tax credit carryforward	(343,000)	(185,000)
Change in valuation allowance	1,755,000	(1,040,000)
	$ —	$ —

As discussed in Note 2, we recognize the effect of income tax positions only if those positions more likely than not of being sustained. At December 31, 2011 and 2010, 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, 2011 and 2010.

The 2002 through 2011 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 2008.

9. COMMITMENTS

Lease. Our rent expense, related solely to office space, for 2011 and 2010 was $95,166 and $102,838, respectively. We are committed under an office space lease that expires on January 31, 2013 that requires the following approximate annual lease payments: $98,000 and $8,000 for the years ending December 31, 2012 and 2013, respectively.

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, 2011 these obligations, if triggered, could amount to a maximum of approximately $350,000 in the aggregate.

10. SUBSEQUENT EVENTS

Due to our current financial condition, beginning in late 2011, we began implementing significant cost-saving measures to conserve capital resources and maintain a minimal level of operations, while seeking additional funding and/or complete a strategic transaction. On January 1, 2012, all employees became part-time hourly employees with reduced work schedules. Additionally, in January 2012, we discontinued providing employee health benefits and company-sponsored 401(k) matching contributions. In addition, we have entered into change in control agreements with our executive officers that provide for severance if the executive is dismissed without cause or under certain circumstances after a change of control in our ownership.

On March 27, 2012, we entered into a term sheet with Lee's Pharmaceutical (HK) Limited ("Lee's"), for the license of Tß4 in any pharmaceutical formulation, including our RGN-259, RGN-352 and RGN-137 product candidates, in China, Hong Kong and Macau. Lee's paid us $200,000 upon signing of the term sheet, and Lee's will pay us an additional $200,000 upon signing of the definitive license agreement, which we expect to occur by May 31, 2012.

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 10.1 to Annual Report on Form 10-KSB for the year ended December 31, 2000 (File No. 001-15070) (filed April 2, 2001)**
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^	Second Amended and Restated Employment Agreement, dated March 11, 2009, between the Company and Allan L. Goldstein, as amended	Exhibit 10.4 to Amendment No. 1 to Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 001-15070) (filed April 30, 2009)
10.7^	Second Amended and Restated Employment Agreement, dated March 12, 2009, between the Company and J.J. Finkelstein, as amended	Exhibit 10.5 to Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 001-15070) (filed April 15, 2009)
10.8^	Second Amended and Restated Employment Agreement, dated March 31, 2009, between the Company and C. Neil Lyons, as amended	Exhibit 10.6 to Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 001-15070) (filed April 15, 2009)
10.9^	Second Amended and Restated Employment Agreement, dated March 31, 2009, between the Company and David Crockford	Exhibit 10.7 to Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 001-15070) (filed April 15, 2009)

10.10^	Second Amendment to the Amended and Restated Employment Agreement between the Company and J.J. Finkelstein, dated December 1, 2011.	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed December 6, 2011)
10.11^	First Amendment to the Amended and Restated Employment Agreement between the Company and David Crockford, dated December 1, 2011.	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed December 6, 2011)
10.12^	Second Amendment to the Amended and Restated Employment Agreement between the Company and Allan L. Goldstein, dated December 1, 2011.	Exhibit 10.3 to Current Report on Form 8-K (File No. 001-15070) (filed December 6, 2011)
10.13^	Letter Agreement between the Company and J.J. Finkelstein, dated January 1, 2012.	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.14^	Letter Agreement between the Company and David Crockford, dated January 1, 2012.	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.15^	Letter Agreement between the Company and Allan L. Goldstein, dated January 1, 2012.	Exhibit 10.5 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.16^	Change in Control Agreement between the Company and J.J. Finkelstein, dated January 1, 2012.	Exhibit 10.3 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.17^	Change in Control Agreement between the Company and David Crockford, dated January 1, 2012.	Exhibit 10.4 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.18^	Change in Control Agreement between the Company and Allan L. Goldstein, dated January 1, 2012.	Exhibit 10.6 to Current Report on Form 8-K (File No. 001-15070) (filed January 6, 2012)
10.19	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)
10.20	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)
10.21	Securities Purchase Agreement, dated April 13, 2009	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed April 16, 2009)
10.22	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)

10.23	Securities Purchase Agreement, dated September 30, 2009	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed September 30, 2009)
10.24	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)
10.25	Securities Purchase Agreement, dated September 30, 2009	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed October 5, 2009)
10.26	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)
10.27	Purchase Agreement, dated January 4, 2011	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.28	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)
10.29	Securities Purchase Agreement, dated January 5, 2011	Exhibit 10.1 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.30	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)
10.31	Securities Purchase Agreement, dated January 5, 2011, by and between the Company and Defiante Farmaceutica S.A.	Exhibit 10.4 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.32	Securities Purchase Agreement, dated January 5, 2011, by and between the Company and Taufin International S.A.	Exhibit 10.5 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.33	Securities Purchase Agreement, dated January 5, 2011, by and between the Company and Sinaf S.A.	Exhibit 10.6 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.34	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)
23.1	Consent of Reznick Group, P.C.	Filed herewith
24.1	Powers of Attorney	Included on signature page

31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934	Filed herewith
31.2	Certification of 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***

* 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 are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

^ Compensatory plan, contract or arrangement.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby 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 April 4, 2012, with respect to the financial statements of RegeneRx Biopharmaceuticals, Inc. (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the existence of substantial doubt about the Company's ability to continue as a going concern), included in this Annual Report (Form 10-K) for the year ended December 31, 2011.

/s/ Reznick Group, P.C.

Vienna, Virginia
April 4, 2012

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: April 4, 2012

/s/ J.J. Finkelstein

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

Exhibit 31.2

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: April 4, 2012

/s/ J.J. Finkelstein

J.J. Finkelstein
President and Chief 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, 2011, 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: April 4, 2012

/s/ J.J. Finkelstein

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