FORM 10-K

REGENERX BIOPHARMACEUTICALS INC - RGRX

Filed: March 31, 2011 (period: December 31, 2010)

Annual report with a comprehensive overview of the company

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2010

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, Rockville, MD	20850
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 301-280-1992

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

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

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

Warrants to Purchase Common Stock, $0.001 par value

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☐	Smaller reporting company ☑

(Do not check if a smaller reporting company)

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, 2010, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $11.5 million. Such aggregate market value was computed by reference to the closing price of the Common Stock as reported on the

NYSE Amex on June 30, 2010.

The number of shares outstanding of the registrant's common stock, as of March 30, 2011, was 79,860,282.

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, Tß4, for tissue and organ protection, repair, and regeneration. We have formulated Tß4 into three distinct product candidates currently in clinical development:

- RGN-352, an injectable product candidate to treat cardiovascular diseases, central nervous system diseases, and other medical indications that may be treated by systemic administration, for which we began a Phase 2 clinical trial in the second half of 2010;
- RGN-259, a topical eye drop for ophthalmic indications for which we are supporting a physician-sponsored clinical trial in patients with dry eye; and
- RGN-137, a topically applied gel for chronic dermal wounds and reduction of scar tissue that is currently in a Phase 2 clinical trial for the treatment of the skin defect epidermolysis bullosa, or EB.

We have a fourth product candidate, RGN-457, in preclinical development. RGN-457 is an inhaled formulation of Tß4 targeting cystic fibrosis and other pulmonary diseases.

In addition to our four pharmaceutical product candidates, we are also pursuing the commercial development of peptide fragments and derivatives of Tß4 for cosmeceutical use. Cosmeceuticals are cosmetic products with biologically active ingredients. We believe the biological activities of these fragments may be useful, for example, in developing novel cosmeceutical products for the anti-aging market.

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 is a complex process, most companies working to develop new drugs in this area have focused primarily on the development of growth factors to stimulate healing 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 normal fetal animal heart development.

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.

- ***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, human endothelial cells, and progenitor cells. 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 NFκB pathway, which is involved in DNA activation of inflammatory mediators, thereby modulating inflammation in the body. This anti-inflammatory activity may explain, in part, the mechanism by which Tß4 appeared to improve functional outcome in the mouse multiple sclerosis model described above, as well as promoting repair in the heart and skin. Identifying a factor such as Tß4 that blocks activation of NFκB suggests that Tß4 could have additional important therapeutic applications for inflammation-related diseases, such as cancer, osteoarthritis, rheumatic diseases, autoimmune diseases, inflammatory pulmonary disease and pancreatitis.

- ***Collagen and Laminin-5 Stimulation.*** Tß4 has a number of additional biological activities shown to reduce inflammation, stimulate the formation of collagen, and up-regulate the expression of laminin-5, a subepithelial basement membrane protein. Both collagen and laminin-5 are central to healthy tissue 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, and in the heart muscle of ischemic animal models, such as in mice and pigs, cell death was prevented by the systemic administration of Tß4.

In combination, we believe that these various biological activities work together 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, manufactured as a synthetic copy of the naturally occurring peptide and formulated for various routes of administration and applications.

Our Product Candidates

RGN-352

Our product candidate RGN-352 is an injectable formulation of Tß4 for systemic administration. We have initially targeted RGN-352 for patients who have suffered an AMI. Preclinical research published in the scientific journal *Nature* has indicated that Tß4 can guide specific types of stem cells from the outer layer of the heart to generate new myocardial blood vessels and tissue at injured sites.

Clinical Development. In 2009, we completed a Phase 1 clinical trial evaluating the safety, tolerability and the pharmacokinetics of the intravenous administration of RGN-352. We also designed this trial to explore the use of RGN-352 in other indications in which acute administration of Tß4 may be warranted. We conducted the Phase 1 trial in two consecutive parts, referred to as Phase 1A and Phase 1B, both of which were double-blind, placebo-controlled, and dose-escalating over four doses. We enrolled a total of 60 healthy subjects in the trial, consisting of 40 subjects in each phase, of which 20 subjects participated in both phases. In Phase 1A, we evaluated a single administration of RGN-352, and in Phase 1B we evaluated once daily administration for 14 consecutive days.

In September 2008, we reported the results of Phase 1A. The single intravenous injection of RGN-352 was well-tolerated at all four dose levels. In December 2009, we reported the results of Phase 1B. A daily intravenous injection of RGN-352 for 14 consecutive days was also observed to be well-tolerated at all four dose levels. There were no reported dose-limiting adverse events in either Phase 1A or Phase 1B.

In May 2010, we were awarded a $3 million grant from the NIH's Heart, Lung and Blood Institute to support the further development of RGN-352.

Future Plans. Based on data from animals treated with RGN-352 post-myocardial infarction and the results of our Phase 1 trial, we began a Phase 2 clinical trial in the second half of 2010 to evaluate RGN-352 in patients who have suffered an AMI and were scheduled to begin enrolling patients near the end of the first quarter of 2011. We designed this trial to evaluate RGN-352's cardioprotective effects and its ability to salvage and regenerate damaged cardiac tissue and improve cardiac function after a heart attack. However, in March 2011, we were notified by the U.S. Food and Drug Administration, or FDA that the trial had been placed on clinical hold pending the resolution of compliance issues at one of our contract manufacturers. Based on available information, we are unable to estimate how long the trial will be on clinical hold. The clinical hold is limited to Good Manufacturing Practice compliance issues at our contract manufacturer and is not related to the manufacture of Tß4 peptide, safety of RGN-352, the trial protocol or our clinical development plan, nor does it affect any of our other clinical trials or drug candidates.

Of significance, our Phase 2 AMI trial allows for an interim review of patient data from an initial group of evaluated patients. Because of our limited capital resources, we will need to raise additional capital to complete this trial. Depending on our capital resources, we may conduct the AMI trial while continuing strategic partnership discussions with biotechnology and pharmaceutical companies to further clinical development of RGN-352.

Recent preclinical research published in the scientific journals *Neuroscience* and *Journal of Neurosurgery* also indicates that RGN-352 may prove beneficial 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 and improvement of neurological function. Based on this research, we intend to support a proposed Phase 1/2 clinical trial to be conducted at a major U.S. medical center under a physician-sponsored investigational new drug application, or IND, in order to evaluate the therapeutic potential of RGN-352 in patients with MS. This trial is estimated to commence in early 2012.

RGN-259

Our product candidate RGN-259 is a sterile topical eye drop formulation of Tß4 for ophthalmic indications.

Clinical Development. Emerging human clinical data from two compassionate use studies have demonstrated the ability of RGN-259 to repair and regenerate corneal tissue. In the first compassionate study, a middle-aged diabetic woman had undergone corneal epithelial debridement during surgery. The resultant corneal defect had not healed for 23 days prior to treatment with RGN-259. Typically, these wounds heal within a few days after surgery. Following treatment with RGN-259, the patient experienced reduced ocular irritation and the wound fully healed within 11 days.

In the second compassionate use study, a corneal specialist treated nine patients divided into two groups. The first group consisted of six patients with a single non-healing eye ulcer resulting from neurotrophic keratitis, or NK, a rare degenerative corneal disease commonly caused by the herpes zoster virus and induced by a nerve impairment resulting in painful corneal lesions that can lead to blindness. The NK patients evaluated had defects that had not healed for at least six weeks and in some cases for several years. The second group consisted of three patients with diffuse punctate erosions, corneal defects that appear as numerous small pinhole-sized lesions.

All nine patients were treated with RGN-259 for periods of up to 49 days. The six NK patients with single non-healing ulcers showed clinically significant improvement during the treatment with RGN-259 and the follow-up period, with four of the six patients healing completely. The completely healed ulcers remained healed during the follow-up period, and those that had demonstrated significant improvement continued to improve after completion of treatment with RGN-259. The three patients with diffuse punctate erosions demonstrated no significant improvement, although they did report reduced ocular irritation.

We had previously initiated a Phase 2 clinical trial to evaluate RGN-259 in diabetic patients undergoing corneal epithelial debridement, or removal of the outer transparent tissue layer of the front part of the eye, during vitrectomy surgery. In this randomized, double-blind, placebo-controlled, dose-response trial conducted at several U.S. clinical sites, we originally intended to evaluate the safety, tolerability, and healing efficacy of three different concentrations of RGN-259 compared to placebo, applied as eye drops, four times daily for up to 14 consecutive days.

While we did not view this particular ophthalmic indication as a significant commercial opportunity, we believed that it represented a "proof-of-concept" clinical model to evaluate the safety and efficacy of RGN-259 for the treatment of corneal indications. We intended to obtain initial data that could be used to address other ophthalmic indications with larger market potential. Patient enrollment in the trial was significantly slower than anticipated due to newer surgical techniques and equipment that reduced the need for corneal epithelial debridement required for the trial. We closed the trial in January 2009, after completion of the first low-dose cohort of 12 patients, in order to focus our research on other commercial opportunities. The encouraging compassionate use data described above, which we received during the course of the trial, also influenced our decision to close the trial earlier than originally intended.

In the 12 patients evaluated in the trial, there were no reported drug-related adverse events associated with RGN-259. We observed increased corneal epithelial thickening and reduced cell flare and inflammation in the low-dose patients treated with RGN-259 as compared to patients receiving placebo, which we believe to be indicative of corneal re-epithelialization and healing. None of the results from the trial are considered to be statistically significant.

In all patients treated to date, RGN-259 has been well-tolerated, and there have been no drug-related adverse events. Based on these preliminary findings, we believe that RGN-259 may provide a novel approach to the treatment of patients with corneal defects.

Future Plans. We are supporting a physician-sponsored clinical trial in patients with dry eye in order to gain further insight into RGN-259's ability to repair and regenerate ophthalmic tissues. Our support includes manufacturing and supplying RGN-259 for the trial and providing regulatory and clinical guidance. We are continuing to collaborate with the U.S. military to evaluate the potential of RGN-259 to prevent or reduce eye damage caused by chemical warfare agents. We are also engaged in discussions with potential partners regarding the clinical development of this product candidate. Once enough human data is generated, we intend to seek strategic partnerships with one or more ophthalmic specialty companies.

RGN-137

Our product candidate RGN-137 is a topical gel formulation of Tß4 intended to promote dermal wound healing and tissue regeneration. Preclinical research has demonstrated that Tß4 can accelerate dermal regeneration after a wound, while more recent research indicates that Tß4 can reduce scarring after injury in the skin and heart. Based on research conducted at the NIH, we initiated a series of Phase 2 clinical trials to evaluate RGN-137 for the treatment of three different types of skin wounds.

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 epidermal tissues that can blister 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 are enrolling a total of 36 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. We estimate the prevalence of EB in the United States to be between 20,000 and 30,000 patients, with a subpopulation of approximately 5,000 patients in the group eligible for inclusion in our Phase 2 clinical trial. We received a grant of $681,000 from the FDA's Office of Orphan Products Development to partially fund this trial. While enrollment has been difficult due to the small addressable patient population, we currently expect to complete this trial in 2011.

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. 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.

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, and it 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 the 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.

Future Plans. Once we complete our Phase 2 EB trial, we will analyze the data in conjunction with our two other completed Phase 2 trials of RGN-137, along with preclinical data indicating Tß4's ability to reduce scarring, at which time we will 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 an inhaled therapeutic agent. We have completed a substantial amount of preclinical work necessary for an 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. 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.

For example, in 2004, we 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.

Manufacturing

We use a contract manufacturer to produce bulk Tß4 by an established and proven manufacturing process known as solid-phase peptide synthesis, and we are in the early stages of qualifying backup manufacturers. 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 drug substance in accordance with current Good Manufacturing Practice requirements of the FDA, and ability to meet our established specifications.

We also use a number of outside contract manufacturers to formulate bulk Tß4 into our product candidates. All of these formulations may require modifications along with additional studies as we move through our clinical development programs. As described elsewhere in this report, our contract manufacturer for RGN-352 recently underwent a manufacturing inspection by the FDA and was alleged not to be in compliance with the FDA's Good Manufacturing Practices. In March 2011, we were notified of this matter by the FDA, and our Phase 2 AMI clinical trial was placed on clinical hold pending resolution of the issues with the manufacturer. If we are unable to use the RGN-352 previously produced by this manufacturer in our clinical trial, in order to continue the trial we would need to have new material prepared by the current manufacturer if it has remediated the compliance issues to the FDA's satisfaction or we would need to obtain an alternate manufacturer of RGN-352 for the trial.

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-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. However, many pharmaceutical companies and research organizations are developing products 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 multiple sclerosis patients. 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 multiple sclerosis.

- ***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 to help eye healing and function, many of which are sold without prescriptions. Companies also market steroids to treat certain severe conditions within our area of interest. Allergan, Inc. has marketed Restasis ™, a relatively new approved eye drop to treat dry eye. Dry eye is a condition related to a number of diseases and one that we believe could benefit from the use of RGN-259.

- ***RGN-137.*** Johnson & Johnson has marketed Regranex™ 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 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' TOBI®, an inhaled version of tobramycin, 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 currently launched by major international cosmetic enterprises 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, 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 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 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 contract manufacturers has recently been alleged by the FDA to have not complied with current Good Manufacturing Practices, which could impair our ability to timely conduct our pending Phase 2 AMI trial with RGN-352.

In June 2004, we 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 of approximately $681,000 in the aggregate for our ongoing 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, a patent was issued in Europe and the U.S. related to the original NIH patent application, which patent expires 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, 2010, 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.

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 2010. 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 as well as the treatment of heart attacks. The license excludes the use of Tß4 in ophthalmic indications and other indications that are disease-based and not the result of a wound. Under the agreement, Sigma-Tau will 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. As described elsewhere in this report, in 2009, we 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, have not triggered the milestone obligation described above.

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.

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

To balance costs and optimize control, we utilize an outsourcing business strategy, whereby our management oversees the outsourced activities for many of our research and development and administrative functions. We currently have nine full-time employees and one part-time employee, and we retain several independent contractors on an as-needed basis. 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 will only be sufficient to fund our operations into the second half of 2011, or into 2012 if our Phase 2 AMI trial is delayed.

We intend to use our existing capital resources to fund our ongoing research and development activities; however, we may not be able to complete all of our active trials and those we intend to initiate and support in 2011 and 2012 without additional funding. We project that our existing capital resources will support our operations into the second half of 2011, without giving effect to any other financing activities, including any purchases under a committed equity facility that we recently entered into with Lincoln Park Capital, as described below. Our research initiatives include support for a Phase 1/2 clinical trial of RGN-352 in patients with multiple sclerosis and a physician-sponsored clinical trial in patients with dry eye using RGN-259, and completing our ongoing Phase 2 trial of RGN-137 in patients with EB. We also intend to conduct a portion of a Phase 2 clinical trial of RGN-352 in patients who have suffered an acute myocardial infarction or AMI, although, as described elsewhere in this report, this trial is currently on clinical hold pending resolution of issues at our contract manufacturer relating to compliance with FDA good manufacturing practices. If the Phase 2 AMI trial remains on hold, or if we are required to have new batches of RGN-352 re-manufactured for the trial, we would need to delay patient enrollment in this trial until additional funding is available. If we do not resume the trial, we project that our current cash resources would support our operations into 2012.

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 over a 30-month period. If we make sales of our common stock under the facility, we would be able to fund our operations for a longer period of time. 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.

We have registered the resale of 15,000,000 shares by LPC. In the event we elect to issue more than 15,000,000 shares, we would be required to file a new registration statement and have it declared effective by the SEC. If obtaining sufficient funding from LPC does not occur or is prohibitively dilutive, we will need to secure another source of funding in order to satisfy our 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.

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 prospectus. 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 access the full amounts available under the LPC committed equity facility.

Under the facility with LPC, we may direct LPC to purchase up to $11,000,000 worth of shares of our common stock over a 30-month period, generally in amounts of up to 200,000 shares every two business days. LPC does not have the right or the obligation to purchase any shares of our common stock on any business day that the market price of our common stock is less than $0.15. 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.

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. If the market price of our common stock is less than $0.35 per share, our sales will be limited to 200,000 shares on each purchase date. 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, or $9,000,000 over the 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.

In addition, we have only registered 15,000,000 shares of our common stock for sale to LPC. Assuming a purchase price of $0.22 per share, the closing sale price of our common stock on March 25, 2011, and the issuance to LPC of 15,000,000 shares, which would be comprised of 14,717,909 shares purchased at $0.22 per share and 282,091 shares issued as additional pro rata commitment shares for no additional consideration, the proceeds to us would only be $3.2 million. In the event we elect to issue more than 15,000,000 shares, we would be required to file a new registration statement and have it declared effective by the SEC.

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;
- 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 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, 2010, our accumulated deficit totaled approximately $89.5 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 additional 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 has been delisted from the NYSE Amex stock exchange, which subjects us to the SEC's penny stock rules and will further decrease the liquidity of our common stock.

We were previously operating under a compliance plan intended to allow us to regain compliance with the NYSE Amex stock exchange's, or the Exchange's stockholders' equity requirement by October 25, 2010. On October 26, 2010, we were notified by the Exchange that we had not timely regained compliance with the Exchange's continued listing standards. As a result, the notice indicated that our securities were subject to delisting from the Exchange. We were initially granted a hearing before the Exchange's Listing Qualifications Panel that was scheduled for December 17, 2010. On December 15, 2010, we withdrew our request for a hearing, and our common stock was suspended from trading on the Exchange as of the commencement of trading on December 23, 2010 and was delisted.

As of December 23, 2010, our common stock began trading 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, now that our stock is not traded on an exchange, we are no longer eligible 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, 2010 contains explanatory language that substantial doubt exists about our ability to continue as a going concern, without raising additional capital. We estimate that our existing capital resources, without giving effect to any proceeds that we may receive from sales of our shares to LPC, will only be sufficient to fund our operations into the second half of 2011, or into early 2012 if our Phase 2 AMI trial is delayed, as described above. 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 recently placed on clinical hold by the FDA and we are unsure when, if ever, we will be able to resume this trial.

In the second half of 2010, we began a 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 has been placed on clinical hold as a result of our contract manufacturer's alleged failure to comply with Good Manufacturing Practices. Ultimately, the FDA could prohibit us from using any of the active drug or placebo manufactured by our manufacturer, which would require us to either have new material manufactured by the manufacturer, in the event that the FDA's concerns are addressed, or we would be required to identify a new manufacturer. In the event a new manufacturer is needed, significant preparatory time and procedures would be required before the new manufacturer would be able to manufacture RGN-352 for the AMI trial. We are unable to estimate the length of time that the trial will be on clinical hold, or if a new manufacturer will ultimately be needed. If the FDA clinical hold remains in effect or if we need to re-manufacture RGN-352 we will need to delay the commencement of this trial until additional funding is available. 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 that has yet to be proven effective in human subjects.

Our current primary business focus is the development of Tß4, and its analogues, derivatives and fragments, for the improvement of cardiac function, the acceleration of corneal healing, the treatment of non-healing wounds and other conditions. 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, we cannot assure you that our product candidates will exhibit activity or importance in humans. 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 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 recent clinical hold with respect to our pending 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 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.

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 other cardiovascular indications. With respect to our product candidate RGN-259 for corneal defects, 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. 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 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. 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 risks of relying solely on single suppliers for each of our product candidates include:

- the possibility that they may not be able to ensure quality and compliance with regulations relating to the manufacture of pharmaceuticals, as illustrated by the FDA's recent determination that our contract manufacturer for RGN-352 was in non-compliance with current Good Manufacturing Practices;
- 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, or our chief executive officer, J.J. Finkelstein, could prevent or significantly delay the achievement of our goals. We have employment agreements with Dr. Goldstein and Mr. Finkelstein. We cannot assure you that they, or other key employees, will not elect to terminate their employment. In addition, we do not maintain a key man life insurance policy with respect to Dr. Goldstein or Mr. Finkelstein. In the future, we anticipate that we may 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, a relationship 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 in the treatment of pressure ulcers and venous stasis ulcers. However, due to the lack of statistical significance of the reported efficacy results, these trials were not sufficient to trigger the milestone obligation described above. 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.

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 Tβ4 in wound healing and tissue repair. The intellectual property rights from this license form the basis for our current commercial development focus with Tβ4. 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 Tβ4-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 Tβ4 in the treatment of non-healing wounds. While patents covering our use of Tβ4 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 Tβ4. 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 Tβ4 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, 2009 through December 31, 2010, the closing price of our common stock has ranged from $0.21 to $1.75, with an average daily trading volume of approximately 117,000 shares. We expect the trading volume of our common stock to decline further in light of our recent delisting from the NYSE Amex exchange. 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, may have a significant impact on the market price of our common stock, some of which are beyond our control:

- the recent delisting of our common stock from the NYSE Amex exchange;
- 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 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.

Following the investment transactions that were consummated on January 7, 2011, our officers, directors and principal stockholders together controlled approximately 43% of our outstanding common stock. Included in this group is Sigma-Tau and its affiliates, which together held outstanding shares representing approximately 38% 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 the date of this report, there are outstanding options to purchase an aggregate of 5,348,863 shares of our common stock at exercise prices ranging from $0.27 per share to $3.82 per share and outstanding warrants to purchase 16,136,900 shares of our common stock at a weighted average exercise price of $0.89 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 over approximately 30 months. 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.

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.

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 none 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. Reserved.

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 $0.22 on March 25, 2011. 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.

	2010		2009	
	High	Low	High	Low
First Quarter	$ 0.65	$ 0.53	$ 1.75	$ 0.42
Second Quarter	$ 0.68	$ 0.26	$ 0.85	$ 0.45
Third Quarter	$ 0.35	$ 0.24	$ 1.12	$ 0.52
Fourth Quarter	$ 0.30	$ 0.21	$ 0.83	$ 0.55

As of December 31, 2010, we had 832 holders of record of our common stock and over 4,100 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.

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-352, an injectable product candidate to treat cardiovascular diseases, central nervous system diseases, and other medical indications that may be treated by systemic administration;
- RGN-259, a topical eye drop for regeneration of corneal tissues damaged by injury, disease or other pathology; and
- RGN-137, a topically applied gel for dermal wounds and reduction of scar tissue.

We have a fourth product candidate, RGN-457, in preclinical development. RGN-457 is an inhaled 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.

During 2009, we completed a Phase 1 clinical trial evaluating the safety 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, we began a Phase 2 clinical trial in the second half of 2010 to evaluate RGN-352's ability to salvage and regenerate damaged cardiac tissue and improve cardiac function after an acute myocardial infarction, or AMI, commonly known as a heart attack. We were scheduled 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 pending the resolution of certain compliance issues at the contract manufacturer supplying RGN-352. Based on available information, we are unable to estimate the length of time that the trial will be on clinical hold. The clinical hold is limited to Good Manufacturing Practices at the contract manufacturer and is not related to the manufacture of Tß4 peptide, safety of RGN-352, the trial protocol or our clinical development plan, nor does it affect any of our other clinical trials or drug candidates.

Additionally, recent preclinical research published in the scientific journals *Neuroscience* and the *Journal of Neurosurgery* indicate that RGN-352 may 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 and improvement of neurological function. Based on this preclinical research, we intend to support a proposed Phase 1/2 clinical trial to be conducted at a major U.S. medical center under a physician-sponsored investigational new drug application, or IND, in order to evaluate the therapeutic potential of RGN-352 in patients with MS. Depending on the status of our operations and our ability to procure RGN-352, either from our current contract manufacturer, if it resolves its compliance issues with the FDA, or from an alternate manufacturer, we are planning to supply RGN-352 and provide clinical and regulatory guidance for the trial, which we currently estimate will commence in early 2012.

We are supporting a physician-sponsored clinical trial in patients with dry eye, in order to evaluate RGN-259's ability to repair and regenerate damaged ophthalmic tissues. Our support includes manufacturing and supplying RGN-259 for the trial and providing regulatory and clinical guidance. We are continuing to collaborate with the U.S. military to evaluate the potential of RGN-259 to prevent or reduce eye damage caused by chemical warfare agents.

We are evaluating the use of RGN-137 in the treatment of patients with epidermolysis bullosa, or EB, which is a genetic defect that results in fragile skin and other epithelial tissues that can blister at the slightest trauma or friction, creating a wound that at times does not heal or heals poorly. A portion of this trial was funded by a grant from the U.S. Food and Drug Administration, or FDA. Despite the small patient population with EB, we continue to enroll patients in this Phase 2 trial and expect to complete the trial in 2011. Once we complete our Phase 2 EB trial, we will analyze the data in conjunction with our two other completed Phase 2 trials of RGN-137, along with preclinical data indicating Tß4's ability to reduce scarring, at which time we will further evaluate our strategy for the clinical development of RGN-137.

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 enter into a collaboration with another company to develop cosmeceutical formulations based on these peptides.

We intend to use our existing capital resources to fund our ongoing research and development activities; however, we may not be able to complete all of our active trials and those we intend to initiate or support in 2011 and 2012 without additional funding. We project that our existing capital resources will be sufficient to support our operations into the second half of 2011, without giving effect to any other financing activities, including any sales of our common stock to LPC under our committed equity facility described below. Our research initiatives include support for a Phase 1/2 clinical trial of RGN-352 in patients with multiple sclerosis and a physician-sponsored clinical trial in patients with dry eye using RGN-259, and completing our ongoing Phase 2 trial of RGN-137 in patients with EB. We also intend to conduct a portion of a Phase 2 clinical trial of RGN-352 in patients who have suffered an acute myocardial infarction or AMI, although, as described elsewhere in this report, this trial is currently on clinical hold pending resolution of certain Good Manufacturing Practices by our contract manufacturer for RGN-352. If the Phase 2 AMI trial remains on hold or if new batches of RGN-352 are required to be manufactured, we would need to delay patient enrollment in this trial until additional funding is available. If we do not resume the trial, we project that our current cash resources would support our operations into early 2012. Of significance, the Phase 2 trial design allows for an interim review of patient data, which, if positive, we believe will facilitate discussions with potential strategic partners when it becomes available. In any event, we will need substantial additional funds in order to initiate and complete further clinical trials beyond those currently contemplated and to continue to fund our operations.

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, seven 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 National Institutes of Health, or 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. 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.

Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board issued Accounting Standards Update, or ASU, No. 2010-17, "Revenue Recognition—Milestone Method," which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Research or development arrangements frequently include payment provisions whereby all or a portion of the consideration is contingent upon milestone events such as successful completion of phases in a study or achieving a specific result from the research or development efforts. The amendments in this ASU provide guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. The ASU is effective for fiscal years and interim periods within those years beginning on or after June 15, 2010, with early adoption permitted. The adoption of ASU No. 2010-17 is not expected to have a material impact on our financial position, results of operations or cash flows.

In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act was signed into law. This legislation includes an exemption for companies with less than $75 million in market capitalization from the requirement set forth in Section 404(b) of the Sarbanes-Oxley Act of 2002 to include an external auditor's report on the effectiveness of a registrant's internal control over financial reporting. As a result of the new legislation, our independent registered public accounting firm will not be required to issue an attestation report with respect to our internal control over financial reporting. However, we will continue to be subject to the requirement of Section 404 of the Sarbanes-Oxley Act of 2002 for our management to make an annual assessment of the effectiveness of our internal control over financial reporting.

Results of Operations

Comparison of years ended December 31, 2010 and 2009

Revenues. For the year ended December 31, 2010, grant revenue was approximately $850,000 compared to $0 for the year ended December 31, 2009. 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. During the year ended December 31, 2010, we recognized approximately $117,000 based on costs incurred related to this grant. In addition, in October 2010 we were awarded approximately $733,000 under the Patient Protection and Affordable Care Act as part of an incentive for biotechnology companies. There were no revenue-generating grants or other sources of revenue during 2009.

Expenses — Research and development. For the year ended December 31, 2010, our R&D expenditures decreased by approximately $1.0 million, or 27%, to approximately $2.7 million, from approximately $3.7 million in 2009.

Our outsourced R&D costs, which are costs paid directly to contract research organizations and outside consultants, decreased by approximately $1.0 million, or 47%, to approximately $1.1 million, from approximately $2.1 million. This net decrease is directly related to the conclusion of several clinical trials in early 2009.

In early 2009 we concluded the data evaluation of our Phase 2 trials of RGN-137 to treat patients with pressure ulcers and venous stasis ulcers. We also terminated our Phase 2 trial of RGN-259 to treat patients with corneal defects related to vitrectomy surgery, and we concluded the last cohort of healthy volunteers in our Phase 1 trial of RGN-352 evaluating safety. During the remaining portion of 2009 we were actively enrolling patients in our Phase 2 trial of RGN-137 to treat patients with EB. In contrast, during 2010, we continued our efforts to enroll 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.

Our internal R&D costs remained relatively unchanged at approximately $1.6 million.

Expenses — General and administrative. For the year ended December 31, 2010, our G&A expenses increased by approximately $0.4 million, or 14%, to approximately $3.2 million, from approximately $2.8 million in 2009. This increase is the result of an increase of approximately $0.4 million in legal fees incurred for the prosecution of our increasing patent portfolio.

Interest Income. For the year ended December 31, 2010, our interest income decreased by approximately $4,000, or 33%, to approximately $8,000, from approximately $12,000 in 2009. The decrease was due to lower average interest-bearing cash balances during 2010.

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 recently 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, 2010 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 $5.0 million for the year ended December 31, 2010. We had cash and cash equivalents totaling $3.8 million at December 31, 2010. Based on our current operations, we believe our existing cash resources will be adequate to fund our operations into the second half of 2011, without considering any potential sales of our common stock to LPC or any other sources of capital. If our Phase 2 AMI trial remains on hold or if new drug product (RGN-352) requires re-manufacture, as described elsewhere in this report, we will need to delay the commencement of this trial until additional funding is available. In that event, we project that our current cash resources would support our operations into 2012. 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 approximately $5.0 million and $6.2 million for the years ended December 31, 2010 and 2009, respectively. While our reported net loss for the year ended December 31, 2010 was approximately $5.0 million, it included approximately $0.5 million in non-cash expenses, primarily non-cash share-based compensation, which was offset by approximately $0.5 million of cash used for working capital purposes during 2010. During 2009, approximately $0.7 million in non-cash share based compensation expenses was offset by approximately $0.4 million of cash used for working capital purposes, the net of which reduced the reported net loss for the year of approximately $6.5 million to approximately $6.2 million of cash used in operating activities.

Net Cash Used in Investing Activities. Net cash used in investing activities was approximately $26,000 and $0 for the years ended December 31, 2010 and 2009, respectively. During 2010 we purchased office equipment and furnishings in connection with the relocation of our corporate headquarters, which was our only investing activity during the year.

Net Cash Provided by Financing Activities. Net cash provided by financing activities totaled approximately $4.5 million and $4.9 million for the years ended December 31, 2010 and 2009, 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. During 2009, we completed two Phase 2 clinical trials, closed one additional Phase 2 clinical trial and completed a Phase 1 clinical trial. Currently, we are actively enrolling patients in only a Phase 2 trial, for RGN-137 in EB patients, and we are supporting a physician-sponsored Phase 2 clinical trial of RGN-259 in patients with dry eye. 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 recently been placed on clinical hold by the FDA pending resolution of certain manufacturing compliance issues at our contract manufacturer. We are unable to estimate when this trial will resume, whether our manufactured RGN-352 will be available for use in that trial or whether it will need to be re-manufactured and at an alternate site.

We project that we currently have sufficient capital resources to continue clinical development, as originally planned, into the second half of 2011, without giving effect any sales of our securities. If our Phase 2 AMI trial remains on hold or if new batches of RGN-352 are required to be manufactured, as described elsewhere in this report, we will need to delay patient enrollment in this trial until additional funding is available. In that event, we project that our current cash resources would support our operations into 2012. In any event, we will require substantial capital resources to continue operations beyond that time.

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 potential product candidates in numerous pre-clinical studies to identify indications for which they may be product candidates. 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 pre-clinical 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 31, 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. During the first half of 2010, we raised approximately $4.5 million from an underwritten public offering of our securities, and during 2009, we raised approximately $3.7 million from a registered direct offering of our securities.

In January 2011, we also entered into a committed equity facility with LPC. We have an effective registration statement for the resale by LPC of the common stock issuable under the facility. If and when we being making draws under the facility, over approximately 30 months thereafter, we will have 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. We may sell up to $11,000,000 worth of shares under the facility. 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.

We are also party to 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 are also aggressively pursuing government funding and in May 2010 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 in parallel with our pending Phase 2 clinical trial 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 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.

Additionally, the U.S. government is evaluating RGN-259, our sterile eye drop formulation, in animals exposed to chemical warfare agents. We believe our other formulations may also be of interest in healing damaged tissues for indications that result from battlefield or homeland security situations. As such, we have engaged a consulting firm to help us identify other sources of funding from U.S. government agencies. There can be no assurance, however, that we will be able to secure additional funds from the U.S. government or other governmental 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, 2010, these cash equivalents were $3.8 million. Due to the short-term nature of these investments, if market interest rates differed by 10% from their levels as of December 31, 2010, 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 49 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 (our principal executive officer) and our Chief Financial Officer (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 principal executive officer and our principal financial 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, 2010, the end of the period covered by this report. Based upon that evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2010 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 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, 2010 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, 2010, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth as of March 15, 2011 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	59	President, Chief Executive Officer and Director
Mr. C. Neil Lyons	54	Chief Financial Officer
Mr. David R. Crockford	65	Vice President, Clinical and Regulatory Affairs
Directors:		
Dr. Allan L. Goldstein	73	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	57	Senior Vice President Finance & Administration and Chief Financial Officer of Emergent BioSolutions, Inc.
Mr. Joseph C. McNay	77	Chairman, Chief Investment Officer and Managing Principal, Essex Investment Management Company
Mr. Mauro Bove	56	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.	79	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. Lyons has served as our Chief Financial Officer and Treasurer since 2005. With more than 25 years of experience, Mr. Lyons has developed expertise related to operations, finance, SEC compliance, complex transactions, strategy, information systems and corporate governance. From 1979 to 1990, Mr. Lyons practiced with Deloitte, providing assurance and advisory services to several public companies in the Washington, D.C. metro area. Following that, Mr. Lyons served as a senior financial executive with HFS, Inc. (a major Department of Defense contractor) from 1990 to 1996, with Bell Atlantic from 1996 to 1998, with SkyBridge LP (an international satellite broadband start-up affiliated with Alcatel) from 1998 to 2003, and consulted with area businesses regarding financial management, including the initial implementations of the Sarbanes-Oxley Act from 2003 to 2005. Mr. Lyons is a certified public accountant and received a Bachelor of Science degree in accounting, magna cum laude, from Florida Southern College.

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 α 1, 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 25 years of business and management experience within the pharmaceutical industry. Mr. Bove is currently the Head of Corporate & Business Development and serves on the board 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 brings 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, 2010, 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, 2010 and 2009, compensation awarded to or paid to, or earned by, our chief executive officer and our two other most highly compensated executive officers during 2010 who were serving as executive officers at December 31, 2010. 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 in effect at December 31, 2010 and 2009 remain the same. However, given our limited cash resources during 2009, the named executive officers other than Mr. Crockford had their annual base salaries reduced by 35% for the period from April 1 to September 30, 2009. Consequently, the salary amounts set forth in the following table may differ from the disclosed annual base salaries then in effect.

In return for the 35% salary reduction, Mr. Finkelstein and Mr. Lyons received options to purchase shares of our common stock at an exercise price of $0.57 per share. Effective October 1, 2009, their salaries were restored to the levels in effect at December 31, 2008 and, therefore, the options ceased vesting as of September 30, 2009 but remain exercisable in accordance with the terms of our stock option plan. The number of shares vested and outstanding from these option grants are set forth in the table within the "Outstanding Equity Awards at December 31, 2010" section below.

Name and Principal Position	Year	Salary(1) ($)	Bonus(2) ($)	Option Awards(3) ($)	All Other Compensation(4) ($)	Total ($)
J.J. Finkelstein, President and Chief Executive Officer	2010	299,520	—	19,396	18,425	337,341
	2009	244,608	18,720	116,198	13,005	392,531
C. Neil Lyons, Chief Financial Officer	2010	202,537	2,000	15,284	6,886	226,707
	2009	167,093	11,140	74,395	4,999	257,627
David R. Crockford, Vice President, Clinical and Regulatory Affairs	2010	210,223	2,000	15,284	10,321	237,828
	2009	210,223	5,781	—	6,818	222,822

(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.

Employment Agreements; Potential Payments Upon Termination or Change in Control

We are party to written employment agreements with our named executive officers. These employment agreements contain severance and other provisions that may provide for payments to the named executive officers following termination of employment with us in specified circumstances. The following is a summary of the material terms of these employment agreements with our named 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 is automatically renewed for additional one-year periods unless either we or Mr. Finkelstein elect not to renew it. This agreement was amended and restated during 2008 and again in 2009. Mr. Finkelstein's annual base salary is $299,520. Mr. Finkelstein's salary may not be adjusted downward without his written consent, except in a circumstance which is part of a general reduction or other concessionary arrangement affecting all employees or affecting senior executive officers. Mr. Finkelstein is also eligible to receive an annual bonus in an amount established by the board of directors and is entitled to participate in and receive all standard employee benefits and to participate in all of our applicable incentive plans, including stock option, stock, bonus, savings and retirement plans. We also provide him with $5 million in life and disability insurance.

Mr. Finkelstein is eligible to receive options to purchase common stock under our equity incentive plans. The decision to grant any such options and the terms of such options are within the discretion of our board 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.

In the event that Mr. Finkelstein's employment is terminated by us without "cause" or by Mr. Finkelstein for "good reason," each as defined in his employment agreement, or if Mr. Finkelstein voluntarily terminates his employment within 12 months following a "change in control," as defined in his employment agreement, then in each case, subject to Mr. Finkelstein's entering into and not revoking a release of claims in a form acceptable to us, Mr. Finkelstein will be entitled to receive (i) a lump sum severance payment equal to his annual base salary then in effect (or if his base salary is less than the amount in effect as of March 31, 2009, the base salary in effect as of March 31, 2009), plus (ii) any earned bonus, and (iii) if he timely elects and remains eligible for continuation of healthcare benefits, that portion of the continued healthcare premiums that we were paying prior to the date of termination for a period of 12 months, in each case less applicable taxes and withholdings. If Mr. Finkelstein's employment had been terminated for any of the reasons described in this paragraph as of December 31, 2010, he would have been entitled to receive a lump sum payment of $299,520, less taxes and withholdings, plus continuation of healthcare benefits with a value of $9,204.

In addition, if Mr. Finkelstein's employment is terminated without "cause," or if there is a "change in control" event, in each case as defined in either the applicable benefit plan or in Mr. Finkelstein's employment agreement, then the unvested portion of Mr. Finkelstein's options outstanding as of December 31, 2010 would accelerate in full.

C. Neil Lyons. We entered into an employment agreement with Mr. Lyons in April 2007 for him to serve as our chief financial officer. Mr. Lyons' employment agreement had an initial one-year term, which is automatically renewed for additional one-year periods unless either we or Mr. Lyons elect not to renew it. The agreement was amended and restated during 2008 and again in 2009. Under the employment agreement, as amended to date, Mr. Lyons' base salary is $202,537. Mr. Lyons is also eligible to receive an annual bonus in an amount established by the board of directors and chief executive officer and is entitled to participate in and receive all standard employee benefits and to participate in all of our applicable incentive plans, including stock option, stock, bonus, savings and retirement plans. We also reimburse Mr. Lyons for two-thirds of his annual term life insurance premium, for term life insurance coverage not to exceed two times his annual base salary.

Mr. Lyons 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. Lyons' employment as may be set forth in the applicable benefit plan or in any option agreement between Mr. Lyons and us.

In the event that Mr. Lyons' employment is terminated by us without "cause" as defined in his employment agreement, or if Mr. Lyons voluntarily terminates his employment within 12 months following a "change in control," as defined in his employment agreement, then in each case, subject to Mr. Lyons' entering into and not revoking a release of claims in a form acceptable to us, Mr. Lyons will be entitled to receive (i) severance payments equal to his annual base salary then in effect, plus (ii) any earned bonus, and (iii) if he timely elects and remains eligible for continuation of healthcare benefits, that portion of the continued healthcare premiums that we were paying prior to the date of termination for a period of 12 months, in each case less applicable taxes and withholdings. If Mr. Lyons's employment had been terminated for any of the reasons described in this paragraph as of December 31, 2010, he would have been entitled to receive severance payments of $202,537, less taxes and withholdings, plus continuation of healthcare benefits with a value of $17,844.

In addition, if Mr. Lyons' employment is terminated without "cause," or if there is a "change in control" event, in each case as defined in either the applicable benefit plan or in Mr. Lyons' employment agreement, then the unvested portion of Mr. Lyons' options to purchase 350,000 shares of common stock outstanding as of December 31, 2010 would accelerate in full.

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 is automatically renewed for additional one-year periods unless either we or Mr. Crockford elect not to renew it. The agreement was amended and restated during 2008 and again in 2009. Under the employment agreement, as amended to date, Mr. Crockford's base salary is $210,223. Mr. Crockford is also eligible to receive an annual bonus in an amount established by the board of directors and chief executive officer and is entitled to participate in and receive all standard employee benefits and to participate in all of our applicable incentive plans, including stock option, stock, bonus, savings and retirement plans. We also reimburse Mr. Crockford for two-thirds of his annual term life insurance premium, for term life insurance coverage not to exceed two times his annual base salary.

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.

In the event that Mr. Crockford's employment is terminated by us without "cause" as defined in his employment agreement, or if Mr. Crockford voluntarily terminates his employment within 12 months following a "change in control," as defined in his employment agreement, then in each case, subject to Mr. Crockford's entering into and not revoking a release of claims in a form acceptable to us, Mr. Crockford will be entitled to receive (i) severance payments equal to his annual base salary then in effect, plus (ii) any earned bonus, and (iii) if he timely elects and remains eligible for continuation of healthcare benefits, that portion of the continued healthcare premiums that we were paying prior to the date of termination for a period of 12 months, in each case less applicable taxes and withholdings. If Mr. Crockford's employment had been terminated for any of the reasons described in this paragraph as of December 31, 2010, he would have been entitled to receive severance payments of $210,223, less taxes and withholdings, plus continuation of healthcare benefits with a value of $15,324. In addition, upon a "change in control," all of Mr. Crockford's unvested options will accelerate in full, but there is no such acceleration upon a termination without cause.

Outstanding Equity Awards at December 31, 2010

The following table shows certain information regarding outstanding equity awards at December 31, 2010 for the named executive officers, all of which were stock options.

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	
	93,750	31,250	2.34	3/15/2014	(1)
	62,500	62,500	1.15	4/15/2015	(1)
	114,748	—	0.57	4/10/2019	
	31,250	93,750	0.76	10/11/2016	(1)
	—	125,000	0.27	07/14/2017	(1)
Mr. Lyons	166,667	33,333	3.10	4/7/2015	(2)
	56,250	18,750	2.34	3/15/2014	(1)
	37,500	37,500	1.50	6/15/2015	(1)
	77,728	—	0.57	4/10/2019	
	18,750	56,250	0.76	10/11/2016	(1)
	—	98,500	0.27	07/14/2017	(1)
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	
	37,500	12,500	2.15	1/16/2014	(1)
	56,250	18,750	2.34	3/15/2014	(1)
	37,500	37,500	1.15	4/15/2015	(1)
	—	98,500	0.27	07/14/2017	(1)

(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) This option vests in equal installments on the first six anniversaries of the grant date which was April 7, 2005.

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, 2010 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.

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 also 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.

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.

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 2010

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Allan Goldstein, Ph.D.	—	15,284	187,460(2)	202,744
R. Don Elsey	7,726	6,403	—	14,129
L. Thompson Bowles M.D., Ph.D.	28,017	3,103	—	31,120
Joseph McNay	25,028	3,103	—	28,131
Mauro Bove	17,303	3,103	—	20,406
Richard Hindin (3)	21,836	—	—	21,836

(1) These amounts reflect the aggregate total grant date fair values (computed in accordance with FASB ASC Topic 718) of options granted to directors during 2010. Options held by each Board member as of December 31, 2010, are as follows:

Allan Goldstein, Ph.D.	795,442
R. Don Elsey	40,000
L. Thompson Bowles M.D., Ph.D.	174,843
Joseph McNay	248,024
Mauro Bove	247,155

(2) 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 $187,460 for 2010. Under Dr. Goldstein's employment agreement, in the event that his employment is terminated by us without "cause," as defined in his employment agreement, or if he voluntarily terminates his employment within 12 months following a "change in control," as defined in his employment agreement, then in each case, subject to Dr. Goldstein's entering into and not revoking a release of claims in a form acceptable to us, Dr. Goldstein will be entitled to receive a lump sum severance payment equal to his annual base salary then in effect, plus any earned bonus as of the date of termination, in each case less applicable taxes and withholdings. Dr. Goldstein is not entitled to receive any continuing health and welfare benefits as part of our severance obligation to him. If Dr. Goldstein's employment had been terminated for any of the reasons described in this paragraph as of December 31, 2010, he would have been entitled to receive a lump sum payment of $187,460, less taxes and withholdings. Dr. Goldstein is eligible to receive options to purchase common stock under our equity incentive plans. The decision to grant any such options and the terms of such options are within the discretion of our board of directors or the compensation committee. In addition, if Dr. Goldstein's employment is terminated without "cause," or if there is a "change in control" event, in each case as defined in either the applicable benefit plan or in Dr. Goldstein's employment agreement, then the unvested portion of Dr. Goldstein's options would accelerate in full. All vested options are exercisable for a period of time following any termination of Dr. Goldstein's employment as may be set forth in the applicable benefit plan or in any option agreement between Dr. Goldstein and us.

(3) Mr. Hindin's term as a director ended in July 2010.

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, 2011 by (i) each director; (ii) each of the named executive officers; (iii) all executive officers and directors as a group; and (iv) all those known by us to be beneficial owners of more than five percent of our common stock. The address for all directors and executive officers is c/o RegeneRx Biopharmaceuticals, Inc., 15245 Shady Grove Road, Suite 470, Rockville, MD 20850.

	Beneficial Ownership(1)	
Beneficial Owner	**Number of Shares**	**Percent of Total**
5% Stockholders:		
Entities affiliated with Sigma-Tau Finanziaria, S.p.A. Via Sudafrica, 20, Rome, Italy 00144	33,997,378(2)	40.5%
Named Executive Officers and Other Directors:		
J.J. Finkelstein	2,393,386(3)	3.0%
Allan L. Goldstein	1,958,788(4)	2.4%
R. Don Elsey	—	*
Joseph C. McNay	1,548,385(5)	1.9%
Mauro Bove	208,405(6)	*
L. Thompson Bowles	136,093(7)	*
C. Neil Lyons	438,978(8)	*
David R. Crockford	446,250(7)	*
All directors and executive officers as a group (8 persons)	7,130,285(9)	8.6%

* 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 79,860,282 shares of common stock outstanding on March 15, 2010, 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 589,481 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, 2011; 6,348,878 shares of common stock held of record and 1,228,486 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 Claudio Cavazza, who directly and indirectly owns 57% of Sigma-Tau, that are exercisable within 60 days of March 15, 2011; and 9,711,407 shares of common stock held of record and 2,197,400 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, 2011. 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 964,748 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2011.

(4) Consists of 1,336,846 shares of common stock held of record by Dr. Goldstein and 621,942 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2011.

(5) Consists of 1,339,111 shares of common stock held of record by Mr. McNay and 209,274 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2011.

(6) Consists of shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2011. 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, 2011.

(8) Consists of 30,000 shares of common stock held of record by Mr. Lyons and 408,978 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2011.

(9) Consists of 4,134,595 shares of common stock held of record and 2,995,690 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2011.

Equity Compensation Plan Information

The following table provides information as of December 31, 2010 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	5,348,863	$ 1.37	4,327,500
Equity compensation plans not approved by security holders	—	—	—
Total	5,348,863	$ 1.37	4,327,500

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, 2010 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."

Since January 1, 2010, we have entered into three financing transactions in which Sigma-Tau and its affiliates have participated, as described below. Mauro Bove, one of our directors, is an officer of Sigma-Tau. Each of these transactions was approved by our Board of Directors and our audit committee, following disclosure of Mr. Bove's potential interests in these transactions.

On May 21, 2010, we completed a public offering of units, consisting of shares of our common stock and warrants to purchase common stock. Sinaf S.A. or Sinaf, which participated in the offering, 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 own 38% of Sigma Tau. Sinaf purchased 240,000 units, consisting of 240,000 shares of common stock and warrants to purchase 96,000 shares of our common stock, for a purchase price of $0.41 per unit, in the public offering on the same terms and conditions as other investors participating in the public offering.

On June 29, 2010, Inverlochy-Consultadoria e Servicos (S.U.) LDA, or Inverlochy, an entity wholly owned by Claudio Cavazza, who directly and indirectly owns 57% of Sigma-Tau, merged with and into Taufin International S.A., or Taufin. Taufin is a direct wholly-owned subsidiary of Taufin SPA. Taufin SPA is owned directly by Claudio Cavazza. As a result of the merger, Taufin became the direct beneficial owner of the warrants and shares of common stock owned by Inverlochy immediately prior to the merger. Also on June 29, 2010, Chaumiere-Consultadoria e Servicos SDC Unipessoal LDA, or Chaumiere, which was an indirect wholly-owned subsidiary of an entity owned by Paolo Cavazza and members of his family, merged with and into Sinaf, and Sinaf thereby became the direct beneficial owner of the warrants and shares of Common Stock owned by Chaumiere immediately prior to the merger.

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 and 1,296,297 shares to 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 will be exercisable on July 7, 2011 and thereafter 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.

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, 2010 and 2009 by Reznick Group, P.C., our independent registered public accounting firm. All such fees described below were approved by the audit committee.

	2010	2009
Audit fees	$ 77,453	$ 76,000
Tax fees (1)	22,053	25,000
Total Fees	$ 99,506	$ 101,000

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

Our audit committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm, 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 form 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)

Exhibit No.	Description of Exhibit	Reference*
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	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)

Exhibit No.	Description of Exhibit	Reference*
10.11	Stock Purchase Agreement, dated June 23, 2005	Exhibit 99.2 to Current Report on Form 8-K (File No. 001-15070) (filed June 23, 2005)
10.12	Form of Warrant to Purchase Common Stock, dated March 17, 2006	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed March 7, 2006)
10.13	Registration Rights Agreement, dated December 15, 2006	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed December 18, 2006)
10.14	Form of Warrant to Purchase Common Stock, dated December 18, 2006	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed December 18, 2006)
10.15	Form of Securities Purchase Agreement, dated February 27, 2008	Exhibit 99.1 to Current Report on Form 8-K (File No. 001-15070) (filed February 27, 2008)
10.16	Form of Warrant to Purchase Common Stock, dated February 29, 2008	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed February 27, 2008)
10.17	Form of Securities Purchase Agreement, dated December 10, 2008	Exhibit 99.1 to Current Report on Form 8-K (File No. 001-15070) (filed December 12, 2008)
10.18	Form of Warrant to Purchase Common Stock, dated December 10, 2008	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed December 12, 2008)
10.19	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)
10.20	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)
10.21	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)
10.22	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)
10.23	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)

Exhibit No.	Description of Exhibit	Reference*
10.24	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)
10.25	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)
10.26	Purchase Agreement, dated January 4, 2011	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.27	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)
10.28	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)
10.29	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)
10.30	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)
10.31	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)
10.32	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)
10.33	Form of Warrant to Purchase Common Stock, dated January 7, 2011, issued to the Sigma-Tau Purchasers	Exhibit 4.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.34	Omnibus Warrant Amendment Agreement, dated January 5, 2011	Exhibit 4.3 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)

Exhibit No.	Description of Exhibit	Reference*
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 pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith***
32.2	Certification of 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.

*** These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are 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: March 31, 2011

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

By: /s/ C. Neil Lyons
C. Neil Lyons
Chief Financial 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 and C. Neil Lyons, and each of them, as his true and lawful attorneys-in-fact and agents, each 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 attorneys-in-fact and agents, and each of them, 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 attorneys-in-fact and agents, or their 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	March 31, 2011
/s/ J.J. Finkelstein J.J. Finkelstein	President, Chief Executive Officer, and Director (Principal Executive Officer)	March 31, 2011
/s/ C. Neil Lyons C. Neil Lyons	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2011
/s/ R. Don Elsey R. Don Elsey	Director	March 31, 2011
/s/ Joseph C. McNay Joseph C. McNay	Director	March 31, 2011
/s/ Mauro Bove Mauro Bove	Director	March 31, 2011
/s/ L. Thompson Bowles L. Thompson Bowles	Director	March 31, 2011

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, 2010 and 2009, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2010. 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, 2010 and 2009, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2010 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
March 31, 2011

RegeneRx Biopharmaceuticals, Inc.
Balance Sheets

	December 31, 2010	December 31, 2009
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,790,352	$ 4,355,768
Grant receivable	10,703	—
Prepaid expenses and other current assets	384,806	196,546
Total current assets	4,185,861	4,552,314
Property and equipment, net of accumulated depreciation of $107,907 and $98,171	24,940	8,492
Other assets	17,255	22,948
Total assets	$ 4,228,056	$ 4,583,754
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 185,643	$ 140,206
Accrued expenses	430,996	740,198
Total current liabilities	616,639	880,404
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, 73,531,578 shares issued and outstanding as of December 31, 2010; 100,000,000 shares authorized, 60,406,828 shares issued and outstanding as of December 31, 2009	73,532	60,407
Additional paid-in capital	93,063,201	88,144,347
Accumulated deficit	(89,525,316)	(84,501,404)
Total stockholders' equity	3,611,417	3,703,350
Total liabilities and stockholders' equity	$ 4,228,056	$ 4,583,754

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Operations

	Years ended December 31,	
	2010	2009
Sponsored research revenue	$ 849,539	$ —
Operating expenses		
Research and development	2,707,909	3,724,514
General and administrative	3,173,729	2,781,790
Total operating expenses	5,881,638	6,506,304
Loss from operations	(5,032,099)	(6,506,304)
Interest income	8,187	12,444
Net loss	$ (5,023,912)	$ (6,493,860)
Basic and diluted net loss per common share	$ (0.07)	$ (0.12)
Weighted average number of common shares outstanding	68,444,011	55,680,525

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Changes in Stockholders' Equity
Years ended December 31, 2010 and 2009

	Common stock		Additional	Accumulated	Accumulated other comprehensive	Total stockholders'
	Shares	Amount	paid-in capital	deficit	income/(loss)	equity
Balance, December 31, 2008	53,622,491	$ 53,623	$ 82,550,585	$(78,007,544)	$ —	$ 4,596,664
Issuance of common stock, net of offering costs of $447,933	6,784,337	6,784	4,845,282	—	—	4,852,066
Share-based compensation expense	—	—	748,480	—	—	748,480
Net loss	—	—	—	(6,493,860)	—	(6,493,860)
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

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Cash Flows

	Years ended December 31,	
	2010	2009
Operating activities:		
Net loss	$ (5,023,912)	$ (6,493,860)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,736	16,547
Non-cash share-based compensation	474,355	748,480
Gain on settlement of accrued expenses	(141,016)	(100,000)
Changes in operating assets and liabilities:		
Grant receivable	(10,703)	—
Prepaid expenses and other current assets	(188,260)	39,931
Other assets	5,693	(17,255)
Accounts payable	45,437	69,652
Accrued expenses	(168,186)	(415,160)
Net cash used in operating activities	(4,996,856)	(6,151,665)
Investing activities:		
Purchase of property and equipment	(26,184)	—
Net cash used in investing activities	(26,184)	—
Financing activities:		
Net proceeds from issuance of common stock	4,457,624	4,852,066
Net cash provided by financing activities	4,457,624	4,852,066
Net decrease in cash and cash equivalents	(565,416)	(1,299,599)
Cash and cash equivalents at beginning of year	4,355,768	5,655,367
Cash and cash equivalents at end of year	$ 3,790,352	$ 4,355,768

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 ("Tβ4"), an amino acid peptide.

Management Plans to Address Operating Conditions. We have incurred net losses of $5.0 million and $6.5 million for the years ended December 31, 2010 and 2009, respectively. Since inception, and through December 31, 2010, we have an accumulated deficit of $89.5 million and we had cash and cash equivalents of $3.8 million as of December 31, 2010. On January 5, 2011 and January 7, 2011, we raised aggregate net proceeds of $1.4 million from the sale of our securities (See Note 10, Subsequent Events). Based on our current operating plan which includes a Phase 2 trial to evaluate RGN-352 in patients suffering from an acute myocardial infarction (heart attack) or AMI, support of a physician sponsored Phase 2 trial to evaluate RGN-259 in patients suffering from dry eye, and a Phase 2 trial to evaluate RGN-137 in patients suffering from epidermolysis bullosa or EB, we project that our existing capital resources would fund our operations into the second half of 2011, without giving effect to any other financing activities, including any purchases under our recent committed equity facility with Lincoln Park Capital (See Note 10, Subsequent Events). However, in March 2011, we were notified by the U.S. Food and Drug Administration, or FDA, that the Phase 2 AMI trial had been placed on clinical hold pending the resolution of issues at our contract manufacturer relating to compliance with FDA good manufacturing practices. Based on the information available as of the date of these financial statements, we are unable to estimate how long the trial will be on clinical hold. The clinical hold is limited to Good Manufacturing Practice compliance issues at our contract manufacturer and is not related to the manufacture of Tß4 peptide, safety of RGN-352, the trial protocol or our clinical development plan, nor does it affect any of our other clinical trials or drug candidates. If the Phase 2 AMI trial remains on hold or if we are required to have new batches of RGN-352 manufactured for the trial, we would need to delay patient enrollment in this trial until additional funding is available. If we do not resume the trial, we project that our current cash resources would support our operations into early 2012.

We anticipate incurring additional losses in the future as we continue to explore the potential clinical benefits of Tβ4-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 the second half of 2011. Accordingly, we will have a 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 or 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 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 $9,736 and $16,547 for the years ended December 31, 2010 and 2009, 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, 2010 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, 2010, all of our revenues were received from multiple grants.

Research and Development. Research and development ("R&D") costs are expensed as incurred and include all of the wholly-allocable costs associated with our various clinical programs passed through to us by our outsourced vendors. Those costs include: manufacturing Tβ4; formulation of Tβ4 into the various product candidates; stability for both Tβ4 and the various formulations; pre-clinical toxicology; safety and pharmacokinetic studies; clinical trial management; medical oversight; laboratory evaluations; statistical data analysis; regulatory compliance; quality assurance; and other related activities. R&D includes cash and non-cash compensation, employee benefits, travel and other miscellaneous costs of our internal R&D personnel, six 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. The Company's policy for recording interest and penalties associated with audits is that penalties and interest expense are recorded in "Income taxes" in the Company's 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, 2010 and 2009. 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, 2010 and 2009, 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 19,337,615 shares and 12,847,964 shares in 2010 and 2009, 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 $474,355 and $748,480 in share-based compensation expense for the years ended December 31, 2010 and 2009, 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. In April 2010, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2010-17, "Revenue Recognition—Milestone Method (Topic 605) — Milestone Method of Revenue Recognition — a consensus of the FASB Emerging Issues Task Force." ASU 2010-17 provides guidance to vendors on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This guidance is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. We have not yet begun to generate revenues that contain milestone payments. ASU 2010-17 will be reviewed and implemented, if applicable to our revenue arrangements, in the fiscal year in which we begin to generate revenues under such arrangements.

In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act was signed into law. This legislation includes an exemption for companies with less than $75 million in market capitalization from the requirement set forth in Section 404(b) of the Sarbanes-Oxley Act of 2002 to include an external auditor's report on the effectiveness of a registrant's internal control over financial reporting. As a result of the new legislation, our independent registered public accounting firm will not be required to issue an attestation report with respect to our internal control over financial reporting. However, we will continue to be subject to the requirement of Section 404 of the Sarbanes-Oxley Act of 2002 for our management to make an annual assessment of the effectiveness of our internal control over financial reporting.

Other new pronouncements issued but not effective until after December 31, 2010 are 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, 2010 and 2009, 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 $3.8 million and $4.4 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 Tβ4 within their broadly-defined patent application. In exchange for this exclusive worldwide license, we must make certain royalty and milestone payments to the NIH. Through December 31, 2010 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, 2010 and 2009 were $25,000, and are expected to amount to approximately $25,000 annually in 2011 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, provides for the payment of license fees and/or minimum payments, which are generally creditable against future royalties. Fees paid by the Company amounted to $25,000 for the year ended December 31, 2010. Future minimum annual fees are expected to amount to approximately $25,000. 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 Tβ4 to conduct research and development activities in Europe. Under the Agreement, we will receive fees and royalty payments based on a percentage of specified sales of Tβ4-related products by Defiante. The term of the Agreement continues until the later of the expiration of any patents developed under the Agreement, the expiration of marketing rights, or December 31, 2016.

In furtherance of the licensed rights, Sigma-Tau Group funded and managed the RegeneRx-sponsored Phase II dermal wound healing clinical trials in venous stasis ulcers conducted in Italy and Poland that concluded in the first quarter of 2009.

5. COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

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

	December 31,	
	2010	2009
Prepaid research and development	$ 245,498	$ —
Legal retainer	100,000	100,000
Prepaid compensation	24,960	24,960
Prepaid insurance	8,596	55,063
Other	5,753	16,523
	$ 384,806	$ 196,546

Accrued expenses are comprised of the following:

	December 31,	
	2010	2009
Accrued clinical research	$ 208,515	$ 496,997
Accrued professional fees	128,847	122,590
Accrued vacation	48,096	35,300
Other	43,538	26,316
Accrued compensation	2,000	28,995
Accrued license fees	—	30,000
	$ 430,996	$ 740,198

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 $43,280 and $18,269 for the years ended December 31, 2010 and 2009, respectively. In order to conserve cash, the Company discontinued the matching contribution effective June 5, 2009 and reinstated it on March 1, 2010.

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. On April 30, 2009 we issued 1,052,631 shares of common stock at a price of $0.57 per share, and warrants to purchase 263,158 shares of our common stock at $0.91 per share, to Sigma-Tau Group for gross proceeds of $600,000. The warrants, which have a term of three years and an exercise price of $0.91 per share, were valued using the Black-Scholes option-pricing model as of the closing date and accounted for in permanent equity. The estimated fair market value of the warrants at the date of issuance was $0.1 million.

On October 5, 2009, we issued 4,512,194 shares of common stock and warrants to purchase 2,256,097 shares of our common stock in a registered direct offering to new institutional investors, for proceeds of approximately $3.3 million, net of approximately $400,000 of offering costs. The warrants, which have a term of five years and an exercise price of $1.12 per share, were valued using the Black-Scholes option-pricing model as of the closing date and accounted for in permanent equity. The estimated fair market value of the warrants at the date of issuance was $1.0 million.

On October 15, 2009, we issued 1,219,512 shares of common stock and warrants to purchase 609,756 shares of our common stock to Sigma-Tau Group for gross proceeds of $1.0 million. The warrants, which become exercisable on April 15, 2010 and have a term through September 30, 2014, and an exercise price of $1.12 per share, were valued using the Black-Scholes option-pricing model as of the closing date and accounted for in permanent equity. The estimated fair market value of the warrants at the date of issuance was $0.2 million.

During the quarter ended June 30, 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 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 beginning on November 17, 2010 and continuing 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.

Share-Based Compensation. We recognized $474,355 and $748,480 in stock-based compensation expense for the years ended December 31, 2010 and 2009, respectively. Given our current estimates of future forfeitures, we expect to recognize the compensation cost related to non-vested options as of December 31, 2010 of $334,000 over the weighted average remaining recognition period of 1.25 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, 2010 and 2009, which was allocated as follows:

	December 31,	
	2010	2009
Research and development	$ 206,427	$ 369,814
General and administrative	267,928	378,666
	$ 474,355	$ 748,480

The following summarizes stock option activity for the years ended December 31, 2010 and 2009:

		Options outstanding		
	Shares available for grant	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2008	2,347,500	4,117,500	$ 0.27 – 3.82	$ 1.72
Grants	(1,192,939)	1,192,939	0.57 – 0.76	0.64
Exercises	—	—	—	—
Cancellations	396,327	(396,327)	0.57 – 2.59	0.82
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
Vested and expected to vest at December 31, 2010		5,075,220		
Exercisable at December 31, 2010		3,716,153		

The following summarizes information about stock options outstanding at December 31, 2010:

	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
$0.27 – $0.86	2,691,363	4.3	$ 0.44	1,709,488	3.2	$ 0.45
$1.07 – $1.93	812,500	4.0	$ 1.32	558,750	3.8	$ 1.36
$2.02 – $2.68	845,000	3.3	$ 2.26	481,250	3.4	$ 2.30
$3.00 – $3.82	1,000,000	4.4	$ 3.19	966,665	4.4	$ 3.19
	5,348,863	4.1	$ 1.37	3,716,153	3.6	$ 1.54
Intrinsic value of in-the-money options, using the December 31, 2010 closing price of $0.22	$ —			$ —		

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, 2010 and 2009:

	2010	2009
Dividend yield	0.0%	0.0%
Risk free rate of return	1.47 – 1.76%	1.9 – 2.3%
Expected life in years	4.75	4.75 – 5.38
Volatility	70%	71 – 72%
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 $0.16 for the year ended December 31, 2010 and $0.39 for the year ended December 31, 2009.

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 2010 and 2009:

	Warrants outstanding		
	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2008	5,249,091	$ 1.60 – $4.06	$ 2.80
Grants	3,129,011	0.91 – 1.12	1.10
Exercises	—	—	—
Cancellations	(444,250)	4.06	4.06
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

8. INCOME TAXES

Significant components of the Company's deferred tax assets at December 31, 2010 and 2009 and related valuation reserves are presented below:

	December 31, 2010	December 31, 2009
Deferred tax assets:		
Net operating loss carryforwards	$ 15,890,000	$ 16,988,000
Research and development tax credit carryforward	1,836,000	1,710,000
Charitable contribution carryforward	37.000	37,000
Accrued vacation	17,000	8,000
Accrued expenses	83.000	163,000
Amortization	4,000	5,000
Depreciation	—	1,000
Non-cash share based compensation	980,000	975,000
	18,847,000	19,887,000
Less — valuation allowance	(18,847,000)	(19,887,000)
Net deferred tax asset	$ —	$ —

A full valuation allowance has been provided at December 31, 2010 and 2009 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, 2010, we had net operating loss carryforwards for income tax purposes of approximately $40.3 million, which are available to offset future federal and state taxable income, if any, and, research and development tax credit carryforwards of approximately $1.8 million. The carryforwards, if not utilized, will expire in increments through 2030.

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, 2010 and 2009. While the Company has not formally updated the study conducted during 2009, it has less formally reviewed the equity transactions executed during 2009 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, 2010 and 2009, due to the following:

	December 31, 2010	December 31, 2009
Tax benefit at statutory rate	$ (1,700,000)	$ (2,213,000)
State taxes	(274,000)	(354,000)
Permanent M-1s	259,000	339,000
Limited/expired net operating loss carryforwards	2,881,000	3,546,000
Limited/expired research and development tax credit carryforward	59,000	120,000
Research and development tax credit carryforward	(185,000)	(202,000)
Change in valuation allowance	(1,040,000)	(1,236,000)
	$ —	$ —

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, 2010 and 2009, 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, 2010 and 2009.

The 2001 through 2010 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 2007.

9. COMMITMENTS

Lease. Our rent expense, related solely to office space, for 2010 and 2009 was $102,838 and $91,183, respectively. We are committed under an office space lease that expires on January 31, 2013 that requires the following approximate annual lease payments: $94,000, $98,000 and $8,000 for the years ending December 31, 2011 through 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, 2010 these obligations, if triggered, could amount to a maximum of approximately $900,000 in the aggregate.

10. SUBSEQUENT EVENTS

On January 4, 2011 and January 5, 2011, we, entered into two purchase agreements and a registration rights agreement with Lincoln Park Capital Fund, LLC, an Illinois limited liability company ("LPC"). In addition to the agreements entered into with LPC, on January 5, 2011, we entered into securities purchase agreements for a private placement with affiliates of Sigma-Tau Group, our largest stockholder.

Purchase Agreements with Lincoln Park Capital Fund, LLC

On January 5, 2011, we entered into a securities purchase agreement with LPC, 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 will be exercisable beginning on July 7, 2011 and will expire on 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 are payable in connection with the Registered Offering, and the Company expects to use 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 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 over a 30-month period (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, 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.

Purchase Agreements with Affiliates of Sigma-Tau Group

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 are payable in connection with the Private Placement, and we intend to use 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 will be exercisable beginning on July 7, 2011 and will expire on 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.

Warrant Amendment Agreement with Affiliates of Sigma-Tau Group

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.

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)

Exhibit No.	Description of Exhibit	Reference*
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)

Exhibit No.	Description of Exhibit	Reference*
10.10	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)
10.11	Stock Purchase Agreement, dated June 23, 2005	Exhibit 99.2 to Current Report on Form 8-K (File No. 001-15070) (filed June 23, 2005)
10.12	Form of Warrant to Purchase Common Stock, dated March 17, 2006	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed March 7, 2006)
10.13	Registration Rights Agreement, dated December 15, 2006	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed December 18, 2006)
10.14	Form of Warrant to Purchase Common Stock, dated December 18, 2006	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed December 18, 2006)
10.15	Form of Securities Purchase Agreement, dated February 27, 2008	Exhibit 99.1 to Current Report on Form 8-K (File No. 001-15070) (filed February 27, 2008)
10.16	Form of Warrant to Purchase Common Stock, dated February 29, 2008	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed February 27, 2008)
10.17	Form of Securities Purchase Agreement, dated December 10, 2008	Exhibit 99.1 to Current Report on Form 8-K (File No. 001-15070) (filed December 12, 2008)
10.18	Form of Warrant to Purchase Common Stock, dated December 10, 2008	Exhibit 4.1 to Current Report on Form 8-K (File No. 001-15070) (filed December 12, 2008)
10.19	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)
10.20	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)
10.21	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)
10.22	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)

Exhibit No.	Description of Exhibit	Reference*
10.23	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)
10.24	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)
10.25	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)
10.26	Purchase Agreement, dated January 4, 2011	Exhibit 10.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.27	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)
10.28	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)
10.29	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)
10.30	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)
10.31	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)
10.32	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)
10.33	Form of Warrant to Purchase Common Stock, dated January 7, 2011, issued to the Sigma-Tau Purchasers	Exhibit 4.2 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)
10.34	Omnibus Warrant Amendment Agreement, dated January 5, 2011	Exhibit 4.3 to Current Report on Form 8-K (File No. 001-15070) (filed January 7, 2011)

Exhibit No.	Description of Exhibit	Reference*
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 pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith***
32.2	Certification of 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.

*** These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are 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-3 and related prospectuses (Registration Nos. 333-150675, 333-140415, 333-125861 and 333-122386) and on Form S-8 (Registration Nos. 333-168252, 333-152250 and 333-111386) of RegeneRx Biopharmaceuticals, Inc. of our report dated March 31, 2011, with respect to the financial statements of RegeneRx Biopharmaceuticals, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2010.

/s/ Reznick Group, P.C.

Vienna, Virginia

March 31, 2011

EXHIBIT 31.1

CERTIFICATION

I, J.J. Finkelstein, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: March 31, 2011

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

EXHIBIT 31.2

CERTIFICATION

I, C. Neil Lyons, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: March 31, 2011

/s/ C. Neil Lyons
C. Neil Lyons
Chief Financial Officer and Treasurer
(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, 2010, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, J.J. Finkelstein, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

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

Date: March 31, 2011

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

EXHIBIT 32.2

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, 2010, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, C. Neil Lyons, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

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

Date: March 31, 2011

/s/ C. Neil Lyons
C. Neil Lyons
Chief Financial Officer and Treasurer
(Principal Financial Officer and
Principal Accounting Officer)