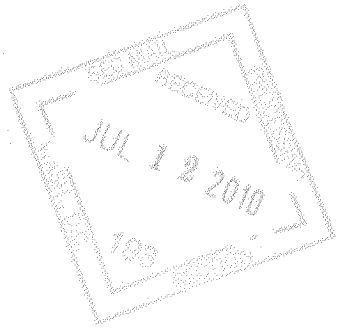
REGENERX



Annual Report to Shareholders
2009

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REGENERX

15245 Shady Grove Road
Suite 470
Rockville, MD 20850

June 2010

Dear Fellow Stockholders,

Clearly, 2009 was a difficult year for most industries and the biopharmaceutical industry was no exception. The financial markets were chaotic and product development in our industry was directly affected by the lack of available capital, in particular for small- and micro-cap companies. To help deal with these challenges, in April 2009 we asked our management, employees and directors to significantly reduce their cash compensation to help our cash flow at a critical time, until we raised additional working capital. We are pleased to report that virtually all agreed to do so, and we were able to restore compensation to their previous levels in October 2009, after having raised additional capital.

Despite the challenges we faced, during the past year we achieved a number of important goals and set in place a foundation for what we believe will be productive clinical research programs over the ensuing eighteen months. One of the most important milestones achieved in 2009 was the completion of our Phase 1 clinical trial evaluating the safety of the intravenous administration of our product candidate RGN-352, our systemic formulation of the peptide Thymosin beta 4, or Tβ4. The systemic administration of RGN-352 was well-tolerated at four escalating doses. We designed the trial to provide a platform from which we can explore the use of RGN-352 for other medical indications in which acute systemic administration may be warranted. In particular, we intend to initiate a Phase 2 clinical trial to evaluate RGN-352 as a treatment for heart attack patients to reduce cardiac damage and improve cardiac function. We expect to initiate this trial in the second half of 2010 with the first patient to be enrolled by the end of the year. We intend to conduct an interim analysis at the mid-point of the trial, which we expect will occur in the first half of 2011. We believe that the results of this interim analysis will be important for our ongoing strategic discussions with pharmaceutical companies for the further clinical development of RGN-352.

New preclinical research performed at the Henry Ford Hospital System in Detroit and published in *Neuroscience* and the *Journal of Neurosurgery* during 2009 and 2010 also indicates that RGN-352 was effective in regenerating damaged brain tissue and significantly improving neurological function in laboratory animals in three key areas: multiple sclerosis (MS), stroke, and traumatic brain injury. The results were similar in each model and we believe will support the further clinical development of RGN-352 for systemic injuries and tissue regeneration. We are collaborating with these researchers at Henry Ford Hospital to conduct a proposed Phase 1/2 clinical trial to evaluate the therapeutic potential of RGN-352 in patients with MS. We expect that the first patients will be enrolled in this trial in the second half of 2010.

During the past year, we reported human clinical data demonstrating the ability of, our sterile eye drop formulation of Tβ4, RGN-259, to repair chronic non-healing eye ulcers in patients with neurotrophic keratitis, a rare degenerative corneal disease. The data were recently published in the *Archives of Ophthalmology*, the first time any human clinical data with Tβ4 has been published in a peer-reviewed scientific journal. As we previously reported, four out of six patients treated with Tβ4 for 28 to 49 days, reported complete healing of their ulcers, while the other two patients experienced significant healing. Eligible corneal lesions for this study were limited to those that had remained unhealed for a minimum of six weeks, and in one case for nearly 14 months. Furthermore, the physicians involved with these patients intend to sponsor a placebo-controlled Phase 2 follow-on clinical trial in a group of 20 patients with "dry eye" associated with graft vs. host disease, or GvHD. This study is designed to provide additional insight into the ability of RGN-259 to repair and regenerate ophthalmic tissues. Dry eye is a common result of GvHD and can cause significant quality of life issues, including infections and blindness. We intend to support this study by manufacturing and supplying RGN-259 and providing regulatory and clinical guidance. We expect to initiate this trial in the second half of 2010 and that the trial will continue through at least the first half of 2011.

Our fourth development effort is focused on RGN-137, our topical gel formulation of Tβ4 to promote dermal wound healing and tissue regeneration in patients with epidermolysis bullosa or EB, a rare genetic defect. EB results in fragile epidermal tissues that can blister at the slightest trauma or friction, creating a wound that at times does not heal or heals poorly. Enrollment in this trial has been difficult due to the small addressable patient population. Consequently, we are evaluating ways in which to enroll foreign EB patients at U.S treatment sites in order to complete the trial later in 2010 or early in 2011.

In addition to our pharmaceutical product candidates, we have also been developing Tβ4 fragments and derivatives for the cosmeceutical market over the past several years and continue to work on these molecules by identifying their properties that may have an impact in this market. Researchers in this area recently published an article in the *FASEB* journal, identifying some of the properties of these molecules that we believe could have important applications. As part of our developmental efforts, we continue to be engaged in collaborative research and discussions with several large cosmetics companies who have expressed an interest in our Tβ4-based product candidates.

We believe we are unique in establishing a strategy that leverages our resources via collaborations with third-party, independent researchers interested in conducting research and development with our product candidates. We currently have 25 R&D collaborations with institutions throughout the world, including major academic and medical research centers in the U.S., the National Institutes of Health, and the U.S. military. In each case, data generated from these projects either support our current clinical programs or, in the event that new intellectual property is generated, we receive the rights to exclusively license the asset.

Like most biopharmaceutical companies, we have historically used the capital markets to finance our clinical development programs. While the economic environment during 2009 and the first half of 2010 has been challenging, we have been successful in raising almost $9 million in net proceeds through two private placement transactions with our largest stockholder group in April and October 2009, a registered direct offering to new institutional investors in October 2009 and a follow-on public offering in May 2010. In each case, these were the best financing options for our company in very challenging times. We have supplemented our recent financing activities with a $3 million grant from the National Institutes of Health. Federal grants are an excellent source of non-dilutive financing that provide funds without which we would otherwise need to deplete our capital resources. Consequently, we intend to pursue any and all other sources of federal funding that may be appropriate. Finally, we intend to apply for a cash grant as provided for under the recent healthcare reform legislation. We believe we are well positioned for this application, and that our qualifying costs will approximate $7.0 to $8.0 million. The legislation provides for a grant equal to 50% of qualifying costs, with a maximum award of $5.0 million per applicant. However, there can be no assurance as to the level of grant award that we will ultimately receive, if any.

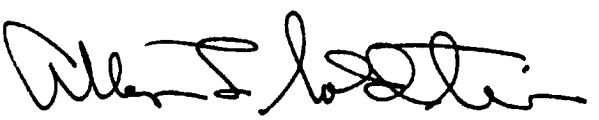
Finally, we continue active discussions with potential strategic partners for further development, regulatory approval and marketing of our product candidates. In some cases we have had discussions with specific companies for several years; in other cases we are engaged in initial discussions with prospective partners based on recent published scientific data. We will continue to seek and diligently pursue all commercialization opportunities that we believe are in the best interests of our stockholders.

We believe that the remainder of 2010 and 2011 will be a period of exciting opportunities for our company and should provide numerous important milestones, including the publication of new and important scientific papers, the initiation of three new clinical trials and the reporting of new clinical data. With success of our clinical program, we hope to complete one or more strategic partnerships.

On behalf of the RegeneRx Board of Directors and staff, thank you for your continued support!

Sincerely,

J.J. Finkelstein
President and CEO



Allan L. Goldstein, Ph.D.
Chairman and Chief Scientific Advisor

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, 2009

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:

Title of each class	Name of each exchange on which registered
Common Stock $0.001 par value, including associated Series A Participating Cumulative Preferred Stock Purchase Rights	NYSE Amex

Securities registered pursuant to section 12(g) of the Act: None.

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

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

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

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

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

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

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

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

As of June 30, 2009, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $14.5 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, 2009.

The number of shares outstanding of the registrant's common stock, as of March 15, 2010 was 60,406,828.

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 document speak only as of the date of this document, and we do not intend to update any such forward-looking statements to reflect events or circumstances that occur after that date.

Item 1. Business.

General

RegeneRx Biopharmaceuticals, Inc. (the "Company", "we", "us", "our" or "RegeneRx"), is a biopharmaceutical company focused on the discovery and development of novel molecules for tissue and organ protection, repair, and regeneration. Currently, we have formulated three product candidates based on Thymosin beta 4 ("Tβ4"), a naturally-occurring 43-amino acid peptide, that are in clinical development:

- RGN-137, a topically applied gel for chronic dermal wounds and reduction of scar tissue;
- RGN-259, a sterile, preservative-free topical eye drop for ophthalmic indications; and
- RGN-352, a parenteral (injectable) formulation for systemic delivery to treat cardiovascular diseases, central nervous system diseases, and other medical indications that require administration by injection. We are initially targeting RGN-352 for the treatment of patients who have suffered an acute myocardial infarction ("AMI") or heart attack. Recent animal research suggests that this formulation may also prove efficacious for patients with multiple sclerosis ("MS") and stroke.

A fourth product candidate, RGN-457, an inhaled formulation of Tβ4 targeting cystic fibrosis and other pulmonary diseases, is in pre-clinical development. We are seeking a development partner for this product candidate.

In the first quarter of 2009, we completed and reported results from two Phase 2 dermal wound healing trials of RGN-137 and closed a proof-of-concept Phase 2 ophthalmic wound healing trial with RGN-259. During the remainder of 2009 and into 2010, we have continued to enroll patients in a Phase 2 clinical trial evaluating RGN-137 for the treatment of patients with epidermolysis bullosa ("EB"), which we expect to complete later in 2010. Sigma-Tau Industrie Farmaceutiche Riunite 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"), conducted and funded the completed Phase 2 clinical trial in Italy and Poland to evaluate RGN-137 for the treatment of patients with venous stasis ulcers. In addition, we evaluated RGN-352 in a Phase 1 clinical trial in 60 healthy subjects (40 in each phase, 20 of whom participated in both phases) that was completed in 2009 and was designed to support our cardiovascular clinical program, as well as other indications in which acute administration of RGN-352 may be warranted. RGN-352 appeared to be safe and well-tolerated, and there were no reported dose-limiting adverse events.

Prospectively, we are supporting clinical development of RGN-259 in two ophthalmic indications under a compassionate use investigational new drug application ("IND"). We will also be supporting clinical development of RGN-259 under a physician-sponsored clinical trial in patients with dry eye secondary to graft versus host disease ("GvHD") in order to gain further insight into RGN-259's ability to repair and regenerate ophthalmic tissues. This support includes manufacturing and supplying RGN-259, and providing regulatory and clinical guidance. We are also collaborating with the U.S. military, under a Material Transfer Agreement, in evaluating RGN-259 for the prevention or reduction of eye damage caused by chemical warfare agents.

Based on the results of the RGN-352 Phase 1 trial, we intend to initiate a Phase 2 clinical trial in 2010 to evaluate patients who have suffered an AMI, subject to available funding. This year we are also planning to support a Phase 1 or 1/2 clinical trial under a physician-sponsored IND evaluating RGN-352 for the treatment of patients with MS. We currently plan on supplying study drug and may provide other assistance, depending on available financial resources.

In addition to the four pharmaceutical product candidates described above, we are pursuing the commercial development of peptide fragments of Tβ4 for potential cosmeceutical use. These fragments are amino acid sequences, and variations thereof, within the Tβ4 molecule that have demonstrated activity in several *in vitro* research studies sponsored by RegeneRx. We believe their biological activities may be useful in developing novel cosmeceutical products for the anti-aging market. To date, *in vitro* research has suggested that these fragments suppress inflammation, accelerate the deposition of certain types of collagen, promote the production of elastin, and inhibit apoptosis (programmed cell death), among other activities. We are currently holding discussions with several companies regarding the development of cosmeceutical formulations based on these peptides. Several worldwide patents related to this research are pending.

Going Concern

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. The report of our independent registered public accounting firm regarding our financial statements for the year ended December 31, 2009 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.

Mechanism of Action, Research Studies and Potential Commercial Applications

Tβ4 is a naturally-occurring 43-amino acid peptide that was originally isolated from bovine thymus glands. Subsequently, it was found in a majority of mammalian tissue types, with highest concentrations in blood platelets and white blood cells. Tβ4 is also found in blood, wound fluid and tears. 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 studies, published by independent researchers, have identified several important biological activities involving Tβ4 that we believe make it unique as a wound healing, repair and tissue regenerating agent. All of our drug candidates contain Tβ4, manufactured as a synthetic copy of the naturally-occurring peptide formulated for various routes of administration and applications.

Progenitor (stem) cell differentiation — Research published in Nature in November 2006 featured the discovery that Tβ4 is the key signaling molecule that triggers adult epicardial progenitor cells ("EPCs") to differentiate into coronary blood vessels. Confirmatory research published in 2009 in the Journal of Molecular and Cellular Cardiology concluded that Tβ4 is responsible for the initiation of the embryonic coronary developmental program and EPC differentiation in adult mice. EPCs are partially differentiated stem cells lying-in-wait to further differentiate into specific cell types when needed. These publications confirm Tβ4's interaction with EPCs is requisite for the maintenance of a healthy adult heart, as well as normal fetal heart development. The 2006 Nature publication concluded that Tβ4's interaction with EPCs resulted in the formation of cardiomyocytes that repaired damaged myocardium, or heart tissue, in mice after an induced AMI. Research published in the journal Circulation in April 2008 showed Tβ4'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, given that pigs are larger mammals, the anatomy of the pig heart is similar to the human, and due to the fact that vascular response processes run five to six times faster in pigs than in humans, long-term results can be obtained in a relatively short period of time. Again, this research identified Tβ4's interaction with EPCs as the underlying basis of cardioprotection through the differentiation of EPCs into cardiomyocytes, yielding statistically-significant cardiac functional recovery as compared to placebo. Similar science in brain tissue was published in Neuroscience in September 2009. The Neuroscience publication concluded that Tβ4, in a similar fashion, triggered the differentiation of oligodendrocyte progenitor cells to form myelin-producing oligodendrocytes which led to the remyelination of axons in the brain of experimental autoimmune encephalomyelitis ("EAE") mice, an accepted small animal model for multiple sclerosis.

Actin regulation — Tβ4 regulates actin, which comprises up to 10% of the protein of non-muscle cells and plays a central role in cell structure and in the movement of cells throughout the body. Research studies from the National Institutes of Health ("NIH") and other institutions indicate that Tβ4 stimulates the migration of human keratinocytes (skin cells), the migration of human endothelial cells, and the migration of progenitor cells. Endothelial cells are the major cell type responsible for the formation of new blood vessels, a process known as angiogenesis. The NIH studies were the first to document the important role of Tβ4 in wound healing. The data from these studies encouraged us to license the rights to Tβ4 from the NIH in 2001, a license discussed in more detail under "Proprietary Rights" below, and to launch an initial clinical development program that targeted promising medical indications, all of which were related to chronic dermal wounds.

Reduction of inflammation — Uncontrolled inflammation is the underlying basis of many pathologies and injuries. Research has shown that Tβ4 is a potent anti-inflammatory agent in a dermal model and in corneal epithelial cells. Tβ4 has also been shown to decrease the levels of inflammatory mediators and significantly reduce the influx of inflammatory cells in the reperfused heart of animals. More recent preclinical research suggests that Tβ4 blocks activation of the NFκB pathway, which is involved in DNA activation of inflammatory mediators, thus modulating inflammation in the body. This anti-inflammatory activity may explain, in part, the mechanism by which Tβ4 improves functional outcome in the mouse multiple sclerosis EAE model and promotes repair in the heart and skin. Identifying a factor, such as Tβ4, which blocks activation of NFκB, suggests that it 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 — Tβ4 has a number of additional biological activities shown to reduce inflammation, stimulate the formation of collagen, and up-regulate the expression of a subepithelial basement membrane protein — laminin-5. Both collagen and laminin-5 are central to healthy tissue and the prevention of disease.

Apoptosis — Tβ4 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 in the cornea through topical administration of Tβ4 and heart muscle of ischemic animal models (mice and pig), cell death was prevented by the systemic administration of Tβ4.

In combination, these various biological activities work together to play a vital role in the healing and repair of injured or damaged tissue and suggest that Tβ4 is an essential component of the tissue protection and regeneration process that may lead to many potential medical applications. Tβ4, therefore, serves as the key component of our various product candidates and the basis of our clinical development programs.

Clinical Development

The collaborative and independent research efforts described above have guided our current clinical development program for the treatment of chronic dermal wounds, ophthalmic indications and acute cardiovascular damage. In 2002, we filed our first IND and were cleared by the U.S. Food and Drug Administration ("FDA") to begin a Phase 1 human dermal clinical trial with RGN-137 that was successfully completed in 2003.

RGN-137 Clinical Trials

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 Tβ4 concentrations compared to placebo. The drug candidate was applied topically, once daily for up to 84 consecutive days. Trial subjects were 19 to 85 years of age 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 deemed safe and well-tolerated at all three dose levels studied, with no dose-limiting adverse events, thus meeting the primary objective of the study. Regarding the secondary efficacy objective, all Tβ4 doses performed similarly compared to placebo; however, patients treated with the mid-dose showed a 17% rate of wound healing which was the highest rate among the three active doses evaluated. Improved healing in the mid-dose group, as observed in the first 9 weeks of treatment, was equal to the placebo at week 12, the end of treatment. None of these efficacy results were deemed to be statistically significant.

Venous stasis ulcers. In mid-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 Tβ4 concentrations compared to placebo. RGN-137 was applied topically, once daily for up to 84 consecutive days. Trial subjects were 18 to 79 years of age and had at least one venous stasis ulcer with a surface area between 3 and 30 cm^2. This trial was sponsored by RegeneRx and funded by Sigma-Tau Group.

In March 2009, we reported final data from the trial. RGN-137 was deemed safe and well-tolerated at all three dose levels, with no dose-limiting adverse events, which met the primary objective of the study. In terms of efficacy, secondary endpoints included the percentage of patients with complete wound healing, as well as time to complete healing. Thirty-three percent (33%) of the patients in the mid-dose group had complete healing compared to 24% in the placebo group, 16% in the low-dose group, and 17% in the high dose group. Of those patients in the mid-dose group with complete healing, it was observed that RGN-137 decreased the median time to complete healing by approximately 45% compared to 37% in the placebo-treated group. None of these efficacy results were deemed to be statistically significant.

Epidermolysis bullosa ("EB"). 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, a genetic defect manifested by the presence of fragile skin and other epidermal tissues that can blister at the slightest trauma or friction, creating a wound that at times does not heal. In this randomized, double-blind, placebo-controlled, dose-response trial, nine clinical sites in the United States are enrolling a total of 36 patients to evaluate the safety, tolerability, and wound healing effectiveness of three different Tβ4 concentrations, compared to placebo, applied topically, once daily for up to 56 consecutive days.

EB has been designated as an "orphan" indication due to prevalence in the U.S. of less than 200,000 patients. In the case of EB, the U.S. patient population is estimated to be between 20,000 and 30,000 with a subpopulation of approximately 5,000 patients in the group under study by the Company. RegeneRx was awarded and has received $681,000 in grant funding from the Office of Orphan Drug Products at the FDA to support the EB clinical trial. While it has been difficult to estimate the time required for patient enrollment due to the small patient population, we expect to complete this trial by the end of 2010.

Future Plans with RGN-137. Once we complete our Phase 2 EB trial and evaluate the results, we will evaluate its potential value for acceleration of dermal wound healing and whether to continue clinical development of this product candidate. Subject to available funding, we also plan to continue research and development on the ability of RGN-137 to reduce scar tissue, as observed in preclinical studies. We believe these data to be consistent with other published data indicating the ability of Tβ4 to reduce scarring in the heart in mice after an induced heart attack.

RGN-259 Clinical Trials

In 2005, based on published results of pre-clinical animal studies indicating Tβ4's ability to accelerate corneal healing in the eye, we expanded our clinical development program to include indications related to corneal injuries. In 2007, we opened a Phase 2 clinical trial targeting 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 clinical sites in the United States, we intended to enroll a total of 36 patients to evaluate the safety, tolerability, and healing efficacy of three different Tβ4 concentrations compared to placebo, applied as eye drops, four times daily for up to 14 consecutive days. We did not view this medical indication as a significant commercial opportunity; rather, we believed that it represented a good "proof-of-concept" clinical model to evaluate the safety and efficacy of RGN-259 for the treatment of corneal indications. Our strategy was to obtain proof-of-concept data and then to address other ophthalmic indications with larger market potential.

Patient enrollment in this 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. Following the encouraging compassionate-use results discussed below, and given the slow enrollment in the Phase 2 diabetic vitrectomy trial, we closed the trial in January 2009, after completion of the first cohort of 12 patients in order to focus our research on other commercial opportunities. There were no reported drug-related adverse events associated with RGN-259. Results from the trial showed increased corneal epithelial thickening and reduced inflammation (cell and flare) in the Tβ4-treated patients compared to patients on placebo, indicative of corneal re-epithelialization and healing. We expect to report final results this year following the submission of the clinical study report to the FDA.

While the Phase 2 clinical trial was enrolling patients, Dr. Steven Dunn, an ophthalmologist and corneal specialist, applied for and received a "Compassionate-Use" IND from the FDA to treat ten patients with neurotrophic keratitis ("NK"), caused primarily by the herpes zoster virus, who had non-healing neurotrophic corneal epithelial defects of 6 weeks to greater than 10 years in duration. To date, nine of ten patients have been enrolled and treated in an open label protocol for periods of 28 or 49 days. Patients were divided into two groups. The first group consisted of 6 patients who had a single non-healing measurable eye ulcer. The second group consisted of 3 patients with diffuse punctate erosions, a corneal defect that appears as numerous small pinhole-sized lesions. All 6 patients with single lesions showed clinically significant improvement during the treatment and follow-up period with 4 of the 6 patients healing completely. The results indicated that completely healed ulcers remained healed and those that had demonstrated significant improvement continued to improve after completion of treatment with RGN-259. Patients with diffuse punctate erosions demonstrated no significant improvement, although they did report reduced ocular irritation.

In all nine cases, RGN-259 was well-tolerated and there were no drug-related adverse events. Dr. Dunn determined that there were no clinically significant adverse findings. A tenth patient with a single lesion has recently been enrolled in the study and we expect to report final results later in 2010. These findings suggest that RGN-259 may provide a novel approach to the treatment of patients with non-healing neurotrophic corneal ulcers.

Future Plans with RGN-259. We continue to support the use of RGN-259 by investigators treating patients unresponsive to current standards of care. Based on the results of the terminated Phase 2 vitrectomy trial, and data from Dr. Dunn's compassionate use study, we are manufacturing RGN-259, and providing regulatory and clinical guidance for a clinical trial under a physician-sponsored IND in 2010 in patients with dry eye secondary to GvHD in order to gain further insight into RGN-259's ability to repair and regenerate ophthalmic tissues. We are also collaborating, through a Material Transfer Agreement, with the U.S. military in evaluating RGN-259 for the prevention or reduction of eye damage caused by chemical warfare agents. In each case we will report data as it comes available. These data will help us determine the role of RGN-259 for corneal indications and allow us to evaluate future clinical development plans. Moreover, we continue to engage in discussions with potential partners regarding the clinical development of this product candidate.

RGN-352 Clinical Trials

In 2005, based on published pre-clinical studies indicating Tβ4's ability to reduce myocardial damage and promote tissue regeneration, we expanded our clinical development program to include RGN-352. In 2007, the FDA cleared us to initiate a Phase 1 clinical trial evaluating the safety, tolerability and the pharmacokinetics of the intravenous administration of RGN-352. We designed this Phase 1 trial in two consecutive parts (Phase 1A and Phase 1B), both of which were double-blind, placebo-controlled, and dose-escalating over four doses, and enrolled a total of 60 healthy subjects (40 in each phase, 20 of who participated in both phases). Phase 1A evaluated a single administration of RGN-352 and Phase 1B evaluated once daily administration for 14 consecutive days. In September 2008, we reported the results of the Phase 1A clinical trial demonstrating that a single intravenous injection of RGN-352 was safe and well-tolerated at all four dose levels.

In December 2009, we reported the results of Phase 1B demonstrating that a daily intravenous injection of RGN-352 for 14 consecutive days was also safe and well-tolerated at all four dose levels. There were no reported dose-limiting adverse events in either segment of the Phase 1 trial.

Future Plans with RGN-352. We are currently designing a Phase 2 trial to evaluate RGN-352's cardioprotective effects and its ability to limit damage to cardiac tissue and improve cardiac function after a heart attack, which we expect to initiate in 2010, subject to available funding. Depending on capital resources, we may sponsor the trial while we continue strategic partnership discussions with biotechnology and pharmaceutical companies.

Additionally, and based on published preclinical data demonstrating that Tβ4 can induce the remyelination of nerve cells in the brain of EAE mice by stimulating oligodendrogenesis, reduce inflammation and thus improve neurologic functional recovery, we intend to support a proposed Phase 1 or 1/2 clinical trial to be conducted under a physician-sponsored IND at a major U.S. medical center using RGN-352 to treat patients with multiple sclerosis. We currently plan on supplying study drug and may provide other assistance, depending on available financial resources.

RGN-457 (inhaled formulation of Tβ4)

In October 2008, we announced that we were seeking a strategic partner to assist in the development of RGN-457 for the treatment of cystic fibrosis (CF). RGN-457 is based on Tβ4 formulated as an inhaled therapeutic agent. We have completed a substantial amount of preclinical work necessary for an IND application. 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 30,000 CF patients in the U.S. and 40,000 CF patients in Europe. It is, therefore, considered to be an "orphan" disease in both territories. While we believe the prospects for RGN-457 are compelling, we remain focused primarily on development of our other products candidates while we continue strategic partnership discussions.

Product Development

Pharmaceutical Strategy. Our strategy is to maximize the value of our product candidates by advancing their clinical development as far as possible, then identifying suitable partners for additional development, regulatory approval, and marketing. We intend to continue holding partnering discussions and ultimately 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.

In 2004, RegeneRx entered into a strategic partnership with Sigma-Tau Group's wholly-owned subsidiary, Defiante Farmaceutica S.A., for development and marketing of RGN-137, and certain indications relating to RGN-352, in Europe and certain contiguous countries. See "Material Agreements" below. Sigma-Tau fully funded and co-managed the Phase 2 trial of RGN-137 in Europe for the treatment of venous stasis ulcers discussed above.

Cosmeceutical Strategy. Another commercial initiative involves identifying and testing Tβ4 peptide fragments that may be useful as novel components in cosmeceutical and consumer products. We have identified several such peptides, tested them in various *in vitro* systems, and filed patents worldwide. Our goal is to identify suitable commercial partners to license these novel fragments for various cosmeceutical applications. We are currently holding discussions with several multinational cosmetics and consumer products companies.

Manufacturing

We use a contract manufacturer to produce bulk Tβ4 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 Tβ4 into our product candidates. All of these formulations may require modifications along with additional studies as we move through our clinical development programs.

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/cosmeceutical industry is 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-137 (topical gel) — Johnson & Johnson has marketed Regranex™ for patients with diabetic foot ulcers. Companies, such as Novartis, are developing and marketing artificial skins, which could 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 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-259 (sterile eye drops) — Most specialty ophthalmic companies have various 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. Restasis™ is a relatively new approved eye drop to treat dry eye, a condition related to a number of diseases and one that we believe could benefit from the use of RGN-259.

RGN-352 (injectable) — 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 MS patients. However, the markets for products of this type are significant and many pharmaceutical companies and research organizations are developing products and technologies that 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 MS 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-457 (inhaled) — Cystic fibrosis is a genetic defect for which there is no cure. There are mucolytic agents and antibiotic drugs on the market that relieve the symptoms posed by this disease and could compete with the potential therapeutic effects of RGN-457. One such product is Genentech's pulmozyme. Another is Novartis' product, TOBI®, an inhaled version of tobramycin.

Cosmeceutical Products — 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 pre-clinical 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.

Pre-clinical studies must ordinarily be conducted to evaluate an investigational new drug's potential safety by toxicology studies and potential efficacy by pharmacology studies and potential safety by toxicology 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 and approved 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 pre-clinical 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 restrictions on the use of the drug 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.

In June 2004, we received orphan drug designation from the FDA for Tβ4 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 is entitled to receive certain 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. In 2006, we received a two-year grant for $545,000 from the FDA's Office of Orphan Product Developments. In 2008, we received additional government funding of $136,000. 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.

Proprietary Rights

We have applied for or hold over 60 worldwide patents on 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 covering the use of Tβ4 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 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. In exchange for the exclusive license, we agreed to make certain minimum royalty and milestone payments to the NIH. Through December 31, 2009 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 Tβ4 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 February 2006, we were issued a patent in China for the use of Tβ4 to treat EB, which expires in 2022.

Under a research agreement with The George Washington University ("GWU"), we funded Tβ4 research at GWU and received a sole and exclusive worldwide license to any resulting patents. While we no longer fund 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 Tβ4 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 Tβ4, as well as for novel peptides resulting from our research efforts. 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. As noted in "Proprietary Rights" above, we have a license 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.

Defiante Farmaceutica, S.A. We have exclusively licensed certain internal and external wound healing European rights to Tβ4 to Defiante Farmaceutica, S.A., or Defiante, a Portuguese company that is a wholly owned subsidiary of Sigma-Tau Group. These licensed rights to Tβ4 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 Tβ4 in ophthalmic indications and other indications that are disease-based and not the result of a wound. Under the agreement, Sigma-Tau Group will develop Tβ4 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 Group is obligated to pay us a royalty on commercial sales, if any, and we will supply all required Tβ4 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 Group 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 Tβ4, the formulation of Tβ4 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 up front 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 "Item 7. 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. Our principal executive offices are located at 15245 Shady Grove Road, Suite 470, Rockville, Maryland 20850.

Available Information

Our corporate website is www.regenerx.com. Our electronic filings with the U.S. Securities and Exchange Commission (the "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

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 independent auditor's report on our financial statements contains explanatory language that substantial doubt exists about our ability to continue as a going concern, without raising additional capital. 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. The report of our independent registered public accounting firm regarding our financial statements for the year ended December 31, 2009 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. 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.

We estimate that our current liquidity and capital resources are sufficient to fund our operations into the third quarter of 2010. However, we will need substantial additional funds to expand operations, which we may not be able to raise on favorable terms, or at all.

In the first quarter of 2009, we reported on several trials in our clinical program. As of the date of this report, we are continuing to enroll patients in our Phase 2 clinical trial evaluating our topical gel product candidate, RGN-137, in patients with EB. We continue to collaborate on the compassionate use of RGN-259 by investigators treating patients unresponsive to current standards of care by providing RGN-259 and regulatory and clinical guidance. We are planning to similarly collaborate on a clinical trial under a physician-sponsored IND in 2010 in patients with dry eye secondary to GvHD. We are currently designing a Phase 2 trial to evaluate RGN-352's cardioprotective effects in 2010. Additionally, we intend to supply study drug and may provide other assistance, depending on available financial resources, in support of a proposed Phase 1/2 clinical trial under a physician-sponsored IND at a major U.S. medical center to use RGN-352 in MS patients.

As of the date of this report, we believe we have sufficient liquidity and capital resources to fund our operations, including these clinical trials and other research initiatives, into the third quarter of 2010. However, we will need substantial additional funds in order to initiate any further preclinical studies or clinical trials, and to fund our operations beyond that time. Therefore, we will not be able to continue or complete any of the trials we intend to initiate in 2010 or beyond 2010 without additional funding. Accordingly, we 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, corporate collaboration and licensing arrangements, and the sale of certain of our intellectual property rights.

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 take actions that may result in stockholders having little or no continuing interest in our assets, such as ceasing operations, seeking protection under the provisions of the U.S. Bankruptcy Code or liquidating and dissolving our company.

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 these risk factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

We are seeking to maximize the value of our assets, address our liabilities, and raise additional capital for our existing business. We are pursuing asset out-licenses, asset sales, mergers and similar strategic transactions. There can be no assurance that we will be successful in executing a strategic transaction.

We are actively considering strategic alternatives with the goal of maximizing the value of our assets. In addition, we are considering restructuring alternatives, including business arrangements such as the out-licensing or sale of product candidates or our company as a whole. There are substantial challenges and risks which will make it difficult to successfully implement any of these opportunities before the third quarter of 2010, after which we may not be able to fund our current operations without additional financing. Even if we determine to pursue one or more of these alternatives, we may be unable to do so on acceptable terms, if at all.

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

We have 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 Tβ4. As of December 31, 2009, our accumulated deficit totaled $84.5 million.

We anticipate substantial and increasing operating losses over the next several years as we continue our research and development efforts and seek to obtain regulatory approval of our product candidates to make them commercially viable. 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.

The recent downturn in the U.S. economy and the recent pressure on capital markets increase the possibility, and may exacerbate the impact, of any adverse effects on our financial position and business prospects. Continued economic adversity may lead to or accelerate a decrease in the trading price of our common stock and make it more difficult for us to raise capital, enter into collaborations or maintain our compliance with the minimum listing standards of the NYSE Amex stock exchange.

The recent downturn in the U.S. economy and the extraordinary pressure being placed on both debt and equity markets have led to significant retraction in U.S. businesses, sudden and severe decreases in the prices of U.S. equities generally and a severe shortage in available credit. These factors have made it more difficult, in general, for companies to expand or maintain their current operations and have increased the likelihood that certain companies will fail. Although we cannot say with certainty the impact the current economic crises has had on us to date or may have on us in the future, continued pressure on the U.S. economy and its capital markets may make it more difficult for us to raise capital or enter into collaborations or licensing relationships for purposes of developing our technology and/or increasing our liquidity. Any inability for us to raise capital or enter into strategic relationships, as a result of the economic downturn or otherwise, would make it more difficult or impossible for us to continue operations after the third quarter of 2010. The economic downturn may also lead to or accelerate a decrease in the trading price of our common stock, which could make it more difficult for us to maintain compliance with certain continued listing requirements of the NYSE Amex exchange, including a market capitalization of at least $50 million, as described below.

We are currently not in compliance with NYSE Amex rules regarding the minimum shareholders' equity requirement and are at risk of being delisted from the NYSE Amex stock exchange, which may subject us to the SEC's penny stock rules and decrease the liquidity of our common stock. If our common stock is delisted, this may make capital raising efforts more difficult.

Because of our historical losses from operations, NYSE Amex rules require that we maintain a minimum stockholders' equity of $6 million, unless our market capitalization exceeds $50 million. As of December 31, 2009, our total stockholders' equity was $3.7 million, and our market capitalization was below $50 million. In April 2009, we received a notice from NYSE Amex indicating that we were below certain of the exchange's continued listing standards.

In the second quarter of 2009, we submitted a plan of compliance to NYSE Amex that forecasted our ability to regain compliance with the listing standards by October 2010. NYSE Amex has accepted our compliance plan, which is subject to periodic review by NYSE Amex to determine whether we are making progress consistent with the plan. Our compliance plan contemplated the raise of additional equity capital, which we achieved in October 2009 through the issuance of common stock and warrants for aggregate gross proceeds of approximately $4.7 million. Following these transactions our stockholders' equity remains below $6 million. Consequently we will need to raise additional funds to regain compliance with that requirement, and the NYSE Amex may determine at any time before October 2010 that we are not making sufficient progress on our plan. There can be no assurance that our compliance plan will ultimately be successful.

If during the remediation period we fail to make substantial progress towards compliance, or at the conclusion of the remediation period we have not achieved compliance, we expect that our common stock would be delisted from the NYSE Amex exchange. Following any such delisting, our common stock may be traded over-the-counter on the OTC Bulletin Board or in the "pink sheets." These alternative markets, however, are generally considered to be less efficient than, and not as broad as, the NYSE Amex exchange. If our common stock is delisted from NYSE Amex, there may be a limited market for our stock, trading in our stock may become more difficult and our share price could decrease even further. 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, if our common stock is delisted, our ability to raise additional capital may be impaired because of the less liquid nature of the OTC Bulletin Board and the pink sheets. 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 the OTC Bulletin Board or the pink sheets would likely be substantially greater than if we were to complete the financing while our common stock is traded on the NYSE Amex exchange.

In the event our common stock is delisted, it may also become subject to penny stock rules. 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. We are not currently subject to the penny stock rules because our common stock qualifies for an exception to the SEC's penny stock rules for companies that have an equity security that is quoted on an exchange. However, if we were delisted, our common stock would become subject to the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell our common stock. If our common stock were considered penny stock, the ability of broker-dealers to sell our common stock and the ability of our stockholders to sell their shares in the secondary market would be limited and, as a result, the market liquidity for our common stock may be adversely affected. We cannot assure you that trading in our securities will not be subject to these or other regulations in the future.

In addition to our current operational requirements, we will need substantial additional capital to develop our product candidates and for our future operations. If we are unable to obtain such funds when needed, we may have to delay, scale back or terminate our product development efforts or our business.

Beyond our current liquidity needs, we anticipate that substantial new capital resources will be required to continue our independent product development efforts, including any and all follow-on trials that will result from our current clinical programs, and to scale up manufacturing processes for our product candidates. While we currently intend to initiate a Phase 2 trial to treat patients after acute myocardial infarction in 2010 we will not be able to conduct this trial without additional funding. 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.

Potential sources of outside capital include entering into strategic business relationships, public or private sales of shares of our capital stock, or the issuance of debt, or other similar financial instruments. We do not have any committed sources of outside capital at this time, and there can be no assurance that we will be able to obtain further capital in sufficient amounts, or on acceptable terms, or in the timeframe needed to ensure the uninterrupted execution of our business strategy.

Emerging biotechnology companies like us may raise capital 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. If we are successful in raising additional capital through such a license, we may have to give up valuable short- and/or long-term rights to our intellectual property. In addition, the business priorities of the strategic partner may change over time, which creates the possibility that the interests of the strategic partner in developing our technology may diminish, which could have a potentially material negative impact on the value of our interest in the licensed intellectual property or product candidates.

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

Our failure to successfully address ongoing 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.

Risks Related to Our Business and Operations

Our business prospects are difficult to evaluate because we are developing complex and novel medical product candidates.

Since our product candidates rely on complex technologies, it may be difficult for you to assess our growth, licensing and earnings potential. It is likely we will face many of the difficulties that companies developing new biological or pharmaceutical technologies often face. These include, among others:

- limited financial resources;
- developing novel, commercial-grade drug substances;

- testing and evaluating a new chemical entity and its effects in highly-complex biological systems;
- marketing new products for which a market is not yet established and may never become established;
- challenges related to the approval and acceptance of drug candidates by United States federal and international regulatory authorities;
- delays inherent in the execution of clinical trials;
- high product development costs that result from all of these factors;
- competition from other therapies and drug candidates promoted by entities with significantly more capital resources and marketing expertise than us; and
- difficulty recruiting qualified employees for management and other positions.

We will likely face these and other difficulties in the future, some of which may be beyond our control. If we are unable to successfully address these difficulties as they arise, our future results of operations and business prospects will be negatively affected. We cannot be certain that our product candidates will prove safe and efficacious, that our business strategies will be successful or that we will successfully address any and all problems that may arise.

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 Tβ4 into the product candidates used in our clinical trials, develop assays to assess Tβ4'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 pre-clinical 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 pre-clinical 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 government regulation and we may not receive regulatory approvals for our new 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. In addition, the timing of clinical trials necessary for FDA approval is dependent on, among other things, FDA and investigational review board, or IRB reviews, clinical site approvals, successful manufacturing of clinical materials, sufficient funding, eligible patient enrollment and other factors outside of our control. 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.

As a consequence, we may need to perform more or larger clinical trials than planned, for reasons such as:

- the FDA or other health regulatory authorities, 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, or data is adversely affected by trial conduct or patient drop out;
- 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;
- 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;
- 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.

Any failure to obtain or any delay in obtaining regulatory approvals would have a material adverse impact on our ability to develop and commercialize our product candidates.

Mauro Bove, a member of our Board, is also a director and officer of Sigma-Tau Group, 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 Sigma-Tau Group. Sigma-Tau Group is also our strategic partner in Europe with respect to the development of certain of our drug candidates. During 2008, we issued shares of common stock and common stock warrants to Sigma-Tau Group in two private placement financing transactions, but we retained the right to repurchase some of these shares under certain circumstances. In 2009, we sold additional common stock and warrants to Sigma-Tau Group in two private placements for aggregate gross proceeds of $1.6 million.

We have licensed certain rights to our product candidates generally for the treatment of dermal and internal wounds, to Sigma-Tau Group. 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 Group 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, we do not believe that the results of these trials will be sufficient to trigger the milestone obligation described above, and 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 under this provision. As a result of Mr. Bove's relationship with Sigma-Tau Group, there could be a conflict of interest between Mr. Bove and our stockholders other than Sigma-Tau Group with respect to these and other agreements and circumstances that may require the exercise of the Board's discretion with respect to Sigma-Tau Group. Any decision in the best interests of Sigma-Tau Group may not be in the best interest of our other stockholders.

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 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. We rely on this license for a significant portion of our business. This license may be terminated for a number of reasons, including 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.

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 Tβ4, and its analogues, derivatives and fragments, for the treatment of non-healing wounds and other conditions. While we have in the past explored and may in the future explore the use of other compounds for the treatment of other medical conditions, we presently have no immediate plans to develop products for such purposes. Unlike many pharmaceutical companies that have a number of unique chemical entities in development, we are dependent on a single molecule, formulated for different administrations, for our potential commercial success. As a result, any common safety or efficacy concerns for T β4-based products that cross formulations would have a much greater impact on our business prospects than if our product pipeline were more diversified.

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 pre-clinical 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 Tβ4-based products.

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 one of the leading peptide manufacturers to supply us with Tβ4 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 each for RGN-137, RGN-259 and RGN-352. We currently do not have an alternative source of supply for either Tβ4 or the individual drug candidates. If these suppliers, together or individually, are not able to supply us with either Tβ4 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 our product candidates include:

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

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. For part of 2009, we effected salary reductions for certain of our employees, including Dr. Goldstein and Mr. Finkelstein. Although their salaries were restored effective as of October 1, 2009, we cannot assure you that their employment agreements would prevent Dr. Goldstein or Mr. Finkelstein from terminating their employment with or without good reason, and they, or other key employees, may elect to terminate their employment as a result of the salary reductions or for other reasons. 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.

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

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

With respect to 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 could compete with our product candidates in certain wound healing areas. 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. Additionally, most large pharmaceutical companies and many smaller biomedical companies are vigorously pursuing therapeutics to treat patients after heart attacks and other cardiovascular indications.

There are also numerous ophthalmic companies developing drugs for corneal wound healing and other outside-of-the-eye diseases and injuries. Amniotic membranes have been successfully used to treat corneal wounds in certain cases, as have topical steroids and antibacterial agents.

We 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 from large multinational companies to very small specialty companies. New cosmeceutical products often have a short shelf 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.

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 Tβ4 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, 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.

Governmental and third-party payers 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 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 legislative proposals to reform healthcare and 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.

Clinical trials could be delayed or fail to show efficacy, resulting in additional cost or failure to commercialize our technology platform.

All of our drug candidates are currently in the clinical stage and we cannot be certain that a collaborator or we will successfully complete the clinical trials necessary to receive regulatory product approvals. This process is lengthy, unpredictable and expensive. To obtain regulatory approvals, a collaborator or we must ultimately demonstrate to the satisfaction of the FDA and others that our product candidates are sufficiently safe and effective for their proposed use. Many factors, known and unknown, can adversely impact clinical trials and the ability to evaluate a product candidate's safety and efficacy, including unexpected delays in the initiation of clinical sites, slower than projected enrollment, competition with ongoing clinical trials and scheduling conflicts with participating clinicians, regulatory requirements, limits on manufacturing capacity and failure of a product candidate to meet required standards for administration to humans. Such factors 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. 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.

Clinical trials for product candidates such as ours are often conducted with patients who have more advanced forms of a particular condition and/or other unrelated conditions. For example, in clinical trials for our lead product candidate RGN-137, we have studied patients who are not only suffering from chronic epidermal wounds but 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. Furthermore, and as a consequence of all of our drug candidates being based on Tβ4, cross-over 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.

Our ability to complete clinical trials depends on many factors, including obtaining adequate clinical supplies and having a sufficient rate of patient recruitment. For example, patient recruitment is a function of many factors, including 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. Even if patients are successfully recruited, we cannot be sure they will complete the treatment process. Delays in patient enrollment or treatment in clinical trials may result in increased costs, program delays, or failure, any of which can substantially affect our business or perceived value.

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. Development costs will increase if we experience any future delays in our clinical trials or if we need to perform more or larger clinical trials than we currently plan. If the delays or costs are significant, our financial results and our ability to commercialize our product candidates will be adversely affected.

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.

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

Our drug candidates, which are all based on the molecule Tβ4, are new and rapidly evolving and have not been shown to be effective on a widespread basis. Our product candidates, and the technology underlying them, 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. Our success will depend in part on our ability to demonstrate sufficient clinical benefits, reliability, safety, and cost effectiveness of our product candidates and technology 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 and technologies are continually evolving. There can be no assurance that our technologies and product candidates will prove superior to technologies and products that may currently be available or may become available in the future or that our technologies or research and development activities will result in any commercially profitable products.

Our technologies and product candidates may have unacceptable side effects that could delay or prevent product approval.

Possible side effects of therapeutic technologies may be serious and life threatening. The occurrence of any unacceptable side effects with our product candidates, during or after pre-clinical studies and clinical trials, or the perception or possibility that our product candidates cause or could cause such side effects, could delay or prevent approval of our product candidates and negatively impact our business.

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.

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.

Risks Related To Our Intellectual Property

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 under a patent application filed by the NIH for the use of Tβ4 in the treatment of non-healing wounds. While this patent has issued in certain countries, we cannot guarantee whether or when the patent will be issued or the scope of the patent 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 technologies 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 (i) any patents will be issued from any pending or future patent applications of ours or our collaborators; (ii) the scope of any patent protection will be sufficient to provide us with competitive advantages; (iii) any patents obtained by us or our collaborators will be held valid if subsequently challenged; or (iv) 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 operations. 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 United States 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 Common Stock

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

For the period from January 1, 2009 through the date of this report, our closing stock price has fluctuated between prices of $0.42 to $1.75 per share, with an average daily trading volume of approximately 73,000 shares. In light of our small size and limited resources, as well as the uncertainties and risks that can affect our business and industry, our stock price is expected to continue to be highly volatile and can be subject to substantial drops, with or even in the absence of news affecting our business. The following factors, in addition to the other risk factors described in this report, and the potentially low volume of trades in our common stock, may have a significant impact on the market price of our common stock, some of which are beyond our control:

- results of pre-clinical studies and clinical trials;
- commercial success of approved products;
- corporate partnerships;
- technological innovations by us or competitors;
- changes in laws and government regulations both in the U.S. and overseas;
- changes in key personnel at our company;
- developments concerning proprietary rights, including patents and litigation matters;
- public perception relating to the commercial value or safety of any of our product candidates;
- future sales of our common stock;
- future issuance 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.

We have never paid dividends on our common stock.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt or credit facility may preclude or limit our ability to pay any dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

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

As of March 15, 2010, our officers, directors and principal stockholders together control approximately 52% of our outstanding common stock. Included in this group is Sigma-Tau Group which holds approximately 43% of our outstanding common stock. A portion of the shares of common stock currently held by Sigma-Tau Group, representing 18% of our outstanding common stock, is 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 Group from taking actions not in your best interests and effectively exercising control over us. These voting agreements expire between June 2010 and September 2012. After such time, we will have no control over the voting of these shares controlled by Sigma-Tau Group, 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.

Our rights to repurchase certain shares of stock held by Sigma-Tau Group expire over time, and we may never be able or elect to exercise these rights.

Until June 2010, we have the right to repurchase at a price of $5.00 per share a number of shares of common stock issued to Sigma-Tau Group equal to the lesser of the shares sold to Sigma-Tau Group in connection with our private placement of securities in June 2005, or the number of shares necessary to reduce Sigma-Tau Group's ownership of our outstanding capital stock to an aggregate of approximately 30% at the time of such repurchase. In addition, we have the right to repurchase at any time until December 31, 2010, for $2.50 per share, up to 5,000,000 shares of common stock issued to Sigma-Tau Group in connection with a private placement of securities in February 2008. After December 31, 2010, our rights to repurchase common stock held by Sigma-Tau Group will expire. These provisions could, under certain circumstances, allow us to reduce dilution by repurchasing these shares at prices lower than the then-prevailing market price of our common stock. However, we cannot assure you that our share price will increase sufficiently to make such repurchases economically feasible or that we would avail ourselves of the opportunity to make such repurchases even if our share price had risen to such a level.

A sale of a substantial number of shares of our common stock, or the perception that such sales will occur, may cause the price of our common stock to decline.

Currently, we are authorized to issue up to 100,000,000 shares of our common stock, and as of March 15, 2010, there were issued and outstanding 60,406,828 shares of our common stock. The authorized but unissued shares may be issued by us in such transactions and at such times as our Board considers appropriate, whether in public or private offerings, as stock splits or dividends or in connection with mergers and acquisitions or otherwise. Sales of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to decline.

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

As of March 15, 2010, there were outstanding options to purchase an aggregate of 4,914,112 shares of our common stock at exercise prices ranging from $0.28 per share to $3.82 per share, of which options to purchase 3,613,069 shares were exercisable as of such date. As of March 15, 2010, there were warrants outstanding to purchase 7,933,851 shares of our common stock, at a weighted average exercise price of $1.03 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.

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, certain warrants to purchase shares of our common stock currently contain an exercise price above the current market price for the common stock, or above-market warrants. As a result, these warrants may not be exercised prior to their expiration and we may not realize any proceeds from their exercise.

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. These provisions 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 trades on the NYSE Amex stock exchange under the symbol RGN.

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

	2009		2008	
	High	Low	High	Low
First Quarter	$ 1.75	$ 0.42	$ 1.10	$ 0.80
Second Quarter	$ 0.85	$ 0.45	$ 1.92	$ 0.83
Third Quarter	$ 1.12	$ 0.52	$ 1.43	$ 1.02
Fourth Quarter	$ 0.83	$ 0.55	$ 1.66	$ 0.85

As of March 15, 2010, there were approximately 4400 holders of record 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

Our operations consist primarily of pre-clinical studies and clinical trials related to the development of product candidates based on Thymosin beta 4 ("Tβ4"), a naturally-occurring 43 amino acid peptide. Currently, we have three Tβ4-based drug formulations in clinical development: RGN-137, a topically applied gel product candidate for chronic dermal wounds and reduction of scar tissue; RGN-259, a sterile, preservative-free, topical eye drop for ophthalmic indications; and RGN-352, a parenteral (injectable) formulation for systemic delivery to treat cardiovascular diseases, central nervous system diseases and other medical indications that require administration by injection. We are initially targeting RGN-352 for the treatment of patients who have suffered an acute myocardial infarction ("AMI"), or heart attack. Recent animal research suggests that this formulation may also prove efficacious for patients with multiple sclerosis ("MS") and acute stroke. We are also seeking a partner for development of an inhaled formulation of Tβ4 targeting cystic fibrosis known as RGN-457 that is in preclinical development.

In the first quarter of 2009, we completed and reported results from two Phase 2 dermal wound healing trials of RGN-137 and closed a proof-of-concept Phase 2 ophthalmic wound healing trial with RGN-259. During the remainder of 2009 and into 2010, we have continued to enroll patients in a Phase 2 clinical trial evaluating RGN-137 for the treatment of patients with epidermolysis bullosa ("EB"), which we expect to complete later in 2010. We are also supporting clinical development of RGN-259 in two ophthalmic indications under a compassionate use IND. We intend to support clinical development of RGN-259 by providing the drug candidate, and regulatory and clinical guidance, to a principal investigator under a physician-sponsored clinical trial in patients with dry eye secondary to GvHD in order to gain further insight into RGN-259's ability to repair and regenerate ophthalmic tissues. We are also collaborating with the U.S. military under a Material Transfer Agreement in evaluating RGN-259 for the prevention or reduction of eye damage caused by chemical warfare agents. In addition, we evaluated RGN-352 in a Phase 1 clinical trial in 60 healthy subjects (40 in each phase, 20 of whom participated in both phases) that was completed in 2009. The trial consisted of two phases and was designed to support our cardiovascular clinical program, as well as other indications in which acute administration of RGN-352 may be warranted. RGN-352 appeared to be safe and well-tolerated, and there were no reported drug-related adverse events. Based on the results of this Phase 1 trial, subject to available funding, we intend to initiate a Phase 2 clinical trial in 2010 to evaluate RGN-352 in patients who have suffered an AMI. We also intend to supply study drug and may provide other assistance, depending on available financial resources, in support of a proposed Phase 1 or 1/2 clinical trial under a physician-sponsored IND at a major U.S. medical center to use RGN-352 in MS patients.

In addition to the four pharmaceutical product candidates described above, we are pursuing the commercial development of peptide fragments of Tβ4 for potential cosmeceutical use. These fragments are amino acid sequences, and variations thereof, within the Tβ4 molecule that exhibited activity in various *in vitro* research studies sponsored by RegeneRx. We believe their biological activities may be useful in developing novel cosmeceutical products for the anti-aging market. To date, *in vitro* research has suggested that these fragments suppress inflammation, accelerate the deposition of certain types of collagen, promote the production of elastin, and inhibit apoptosis (programmed cell death) among other activities. We are currently holding discussions with several companies regarding the development of cosmeceutical formulations based on these peptides. Several worldwide patents, based on this research, are pending.

As of the date of this report, we believe we have sufficient liquidity and capital resources to fund our operations, including our ongoing clinical trials and other research initiatives, into the third quarter of 2010. However, we will need substantial additional funds in order to initiate any further preclinical studies or clinical trials, and to fund our operations beyond that time. Accordingly, we 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, corporate collaboration and licensing arrangements, and the sale of certain of our intellectual property rights.

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.

We have incurred net losses of $6.5 million and $10.6 million for the years ended December 31, 2009 and 2008, respectively. Since inception, and through December 31, 2009, we have an accumulated deficit of $84.5 million. On April 30, 2009, we issued 1,052,631 shares of common stock and warrants to purchase 263,158 shares of our common stock to Sigma-Tau Group for gross proceeds of $600,000. 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 gross proceeds of approximately $3.7 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. Between April 1, 2009 and September 30, 2009 we also reduced our ongoing monthly cash outflows through salary reductions and reductions in director fees in exchange for the issuance of stock options to our non-employee directors and certain of our executives and employees. Those actions reduced our cash expenses by approximately $0.3 million through September 30, 2009. We restored salaries and directors fees to their prior levels effective as of October 1, 2009 and have continued our research efforts. At December 31, 2009, we had cash and cash equivalents of $4.4 million, and we intend to maintain tight cost controls and continue to operate under a closely monitored budget approved by the Board of Directors until sufficient funding is obtained to enable expanded research activities.

Historically, we received only immaterial amounts of revenue from non-refundable government grants and may never receive future grants. 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 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 pre-clinical studies and new clinical trials as we explore the potential of our current product candidates in other indications and/or explore new formulations of Tβ4-based product candidates. Consequently, we expect to incur substantial and increasing losses for at least the next several years. Accordingly, we will need to generate significant product revenues to achieve and then maintain profitability. Also, we expect that we will need to raise substantial additional outside 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 activities ("R&D") and General and Administrative ("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 Tβ4 and peptide fragments; formulation of Tβ4 into our various product candidates; stability studies 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, 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.

G&A costs include outside professional fees for legal, audit and accounting services, including the costs to maintain our intellectual property portfolio. 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.

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 Note 2 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 February 2010, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (ASU 2010 — 09) to address potential practice issues associated with FASB ASC 855 (formerly SFAS 165), "Subsequent Events." The ASU was effective upon issuance and eliminated the requirement for entities that file or furnish financial statements with the SEC to disclose the date through which subsequent events have been evaluated in originally issued and reissued financial statements. Other entities would continue to be required to disclose the date through which subsequent events have been evaluated; however, disclosures about the date would be required only in financial statements revised because of an error correction or retrospective application of U.S. GAAP. Our adoption of this standard changed our presentation of subsequent events when preparing our financial statements.

In September 2009, the FASB ratified ASU 2009-13 (formerly EITF 08-1), "Revenue Recognition" (ASC 605): Multiple-Deliverable Revenue Arrangements, the final consensus reached by the Emerging Issues Task Force that revised the authoritative guidance for revenue arrangements with multiple deliverables. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The guidance will be effective for our fiscal year beginning January 1, 2011 with early adoption permitted. The guidance may be applied retrospectively or prospectively for new or materially modified arrangements. We currently do not have any multiple-deliverable revenue arrangements, accordingly, the adoption of the guidance will not have an impact on our financial statements.

In August 2009, the FASB issued ASU No. 2009-05, "Fair Value Measurements and Disclosures (ASC 820) — Measuring Liabilities at Fair Value" (ASU 2009-05). ASU 2009-05 provides clarification that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using a valuation technique that uses the quoted price of the identical liability when traded as an asset or the quoted prices for similar liabilities or similar liabilities when traded as assets. The guidance provided is effective for the first reporting period (including interim periods) beginning after issuance. Our adoption of ASU 2009-05 did not impact our financial position or results of operations.

In June 2009, the FASB issued ASC 105 (formerly SFAS 168), "The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles" (ASC 105). ASC 105 is now the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernment entities. It also modifies the GAAP hierarchy to include only two levels of GAAP: authoritative and non-authoritative. ASC 105 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of this standard in 2009 changed how we reference various elements of U.S. GAAP when preparing our financial statement disclosures, but did not have an impact on our financial position or results of operations.

Other new pronouncements issued but not effective until after December 31, 2009 are not expected to have a significant effect on our financial position or results of operations.

Results of Operations

Comparison of years ended December 31, 2009 and 2008

Revenues. For the year ended December 31, 2009, grant revenue was $0 compared to approximately $168,000 for the year ended December 31, 2008 as our grant from the NIH for the trial of RGN-137 to treat the orphan indication EB was exhausted. We do not expect to receive additional funding for this trial.

Expenses — Research and development. For the year ended December 31, 2009, our R&D expenditures decreased by approximately $3.4 million, or 48%, to approximately $3.7 million, from approximately $7.1 million in 2008.

Our outsourced R&D costs, which are costs paid directly to contract research organizations and outside consultants, decreased by approximately $2.9 million, or 58%, to approximately $2.1 million, from approximately $5.0 million. This net decrease is directly related to the conclusion of several clinical trials in late 2008 and early 2009.

Throughout 2008 we were actively enrolling our Phase 2 trials of RGN-137 to treat patients with pressure ulcers as well as EB. Having completed enrollment of our Phase 2 pressure ulcer trial at the end of 2008, we incurred relatively less cost in early 2009 to evaluate the trial's data and report the information, while our Phase 2 EB trial continued enrollment throughout both periods. Consequently, our R&D expenditures for RGN-137 decreased by approximately $1.3 million, or 89%, to approximately $0.2 million, from approximately $1.5 million in 2008.

Regarding RGN-352, we completed the majority of work associated with a Phase 1 safety trial in 2008 including the initiation and completion of a Phase 1A portion with 40 healthy volunteers followed by the initiation and treatment of approximately 30 healthy volunteers in Phase 1B. During 2009, only a relatively minor portion of clinical activity on Phase 1B occurred for the remaining 10 healthy volunteers, along with that phase's data evaluation and wrap up. Consequently, our R&D expenditures for RGN-352 decreased by approximately $1.2 million, or 65%, to approximately $0.6 million, from approximately $1.8 million in 2008.

Regarding RGN-259, during 2008 we were actively enrolling our Phase 2 trial to treat diabetic patients whose corneal epithelium was scraped during vitrectomy surgery. In January 2009 we completed enrollment of the first cohort of our Phase 2 diabetic vitrectomy study and terminated the trial for reasons described in Item 1 of this report under "Clinical Development." Consequently, our R&D expenditures for RGN-259 decreased by approximately $0.1 million, or 15%, to approximately $0.8 million, from approximately $0.9 million in 2008.

Some of our outsourced R&D costs are for various miscellaneous development efforts or are for certain services that span several formulations or trials. These include certain stability, pharmacokinetic, and medical monitoring services. Given the overall decrease in clinical activity between years, these costs decreased by approximately $0.3 million, or 35%, to approximately $0.5 million, from approximately $0.8 million in 2008.

Our internal R&D costs decreased by approximately $0.5 million, or 25%, to approximately $1.6 million, from approximately $2.1 million. As described elsewhere in this report, we implemented a salary reduction program for six months of 2009. Additionally, we reduced our R&D headcount by one person during the year and some of our R&D personnel only worked part time during a portion of 2009. Finally, as described in Note 7 to the Financial Statements, we increased our forfeiture assumption for stock options, which reduced the employee-related non-cash stock-based compensation expense associated with the grant of stock options. In combination, these variances yielded a decrease in our cost of employment for our R&D personnel of approximately $0.4 million, or 23%, to approximately $1.4 million, from approximately $1.8 million in 2008. Our other cost cutting measures as well as a reduction in travel associated with less clinical activity yielded a decrease in our other internal R&D costs of approximately $0.1 million, or 35%, to approximately $0.2 million, from approximately $0.3 million in 2008.

Expenses — General and administrative. For the year ended December 31, 2009, our G&A expenses decreased by approximately $1.0 million, or 27%, to approximately $2.8 million, from approximately $3.8 million in 2008. The combination of our 2009 salary reduction program and reductions in stock-based compensation expense resulting from changes in forfeiture assumptions yielded a decrease in our G&A personnel expenses of approximately $0.5 million, or 32%, to approximately $0.9 million, from approximately $1.4 million in 2008. We also reduced our outside accounting, legal and business development personnel costs by $0.5 million, or 28%, to approximately $1.5 million, from approximately $2.0 million in 2008. Our other G&A costs for facilities, investor relations, insurance, and travel remained consistent between years at approximately $0.4 million.

Interest Income. For the year ended December 31, 2009, our interest income decreased by $137,000, or 92%, to approximately $12,000, from approximately $150,000 in 2008. The decrease was due to lower average interest-bearing cash balances during 2009.

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. The report of our independent registered public accounting firm regarding our financial statements for the year ended December 31, 2009 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. 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. 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.

We had cash, cash equivalents and short-term investments totaling $4.4 million and $5.7 million at December 31, 2009 and 2008, respectively. The $1.3 million decrease during 2009 results from the use of $6.2 million in cash for operating activities, offset by $4.9 million in cash raised through the private placement of common stock and warrants as more fully described in Note 7 to the Financial Statements in this report.

As of February 28, 2010, we had approximately $3.6 million of cash, cash equivalents and short-term investments. Based on our current operations, we believe our cash resources will be adequate to fund our operations into the third quarter of 2010.

Cash Flows

Net Cash Used in Operating Activities. Net cash used in operating activities was approximately $6.2 million and $10.6 million for the years ended December 31, 2009 and 2008, respectively. While our reported net loss for the year ended December 31, 2009 was approximately $6.5 million, it included approximately $0.8 million in non-cash expenses, primarily non-cash share-based compensation, which was offset by approximately $0.5 million of cash used to retire current liabilities as compared to the liabilities reported as of December 31, 2008. Our net loss in 2008 of $10.6 million approximated the net cash used in operating activities in the same period as the non-cash share based compensation expenses of approximately $1.1 million were fully offset by a similar reduction in liabilities as compared to those reported as of December 31, 2007.

Net Cash Provided by Investing Activities. Net cash provided by investing activities was approximately $0 and approximately $4.6 million for the years ended December 31, 2009 and 2008, respectively. In early 2008 we sold all of our short-term, highly-liquid, investment-grade financial instruments that had more than a 90 day maturity from the date of purchase and invested the proceeds in cash-equivalents.

Net Cash Provided by Financing Activities. Net cash provided by financing activities totaled approximately $4.9 million and $7.9 million for the years ended December 31, 2009 and 2008, 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 the Financial Statements 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. As described elsewhere in this report, 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 one Phase 2 trial, for RGN-137 in EB patients, although we intend to commence a Phase 2 clinical trial of RGN-352 for AMI patients and support a Phase 1 clinical trial of RGN-352 for MS patients, as well as a small compassionate use IND for RGN-259. Although we expect to initiate these trials later in 2010, their ultimate timing is uncertain. We currently do not have sufficient capital resources to continue clinical development beyond the third quarter of 2010.

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

- the progress of our clinical trials,
- the progress of our research activities,
- the number and scope of our research programs,
- the progress of our pre-clinical 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 pre-clinical, 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.

Also, 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 that expires on January 31, 2013 that requires average monthly rental payments of approximately $7,300 during the 36-month period.

Sources of Liquidity

Sigma-Tau Group has historically provided significant equity capital to us. In 2009, Sigma-Tau Group provided approximately $1.6 million in gross proceeds out of the approximately $5.3 million in total gross proceeds raised during the year. New investors provided the remaining $3.7 million. Sigma-Tau Group provided all of the $8.0 million in gross proceeds raised during 2008.

As described in Item 1 of this report under "Material Agreements," we are party to a license agreement with Sigma-Tau Group that provides the opportunity for us to receive milestone payments upon specified events and royalty payments upon commercial sales of Tβ4 in Europe. However, there can be no assurance that we will be able to attain such milestones and generate any such payments under the agreement.

Potential sources of outside capital include entering into strategic business relationships, public or private sales of shares of our capital stock, or debt, or other similar financial instruments. While we closed a sale of common stock and warrants to purchase common stock involving the Sigma-Tau Group and new investors in the fourth quarter of 2009, we do not have any other committed sources of outside capital at this time. Consequently, there can be no assurance that we will be able to obtain additional capital in sufficient amounts, on acceptable terms, or at all.

If we raise additional capital through such a strategic business relationship, we may have to give up valuable short- and/or long-term rights to 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.

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, 2009, these cash equivalents and short-term investments were $4.4 million. Due to the short-term nature of these investments, if market interest rates differed by 10% from their levels as of December 31, 2009, the change in fair value of our financial instruments would not have been material.

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A(T). 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, 2009, 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, 2009 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, 2009 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.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management's report in this Annual Report on Form 10-K.

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, 2009, 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, 2010 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	58	President, Chief Executive Officer and Director
Mr. C. Neil Lyons	53	Chief Financial Officer
Mr. David R. Crockford	64	Vice President, Clinical and Regulatory Affairs
Directors:		
Dr. Allan L. Goldstein	72	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. Richard J. Hindin	67	Entrepreneur
Mr. Joseph C. McNay	76	Chairman, Chief Investment Officer and Managing Principal, Essex Investment Management Company
Mr. Mauro Bove	55	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.	78	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 28 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 β4 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. Hindin has served as a member of our Board of Directors since 2002. Mr. Hindin has been an entrepreneur during his more than 40 year career and is currently the principal stockholder of Chicken Out Rotisserie, Inc., which operates 15 restaurants in three states and the District of Columbia. Mr. Hindin has served since 1987 as a member and since 1989 as the chairman of the board of directors of The Institute for Advanced Studies in Aging & Geriatric Medicine, or IASIA, a non-profit corporation that disseminates medical information to the public as well as providing the pharmaceutical industry with an independent source for testing vaccines and drugs for the elderly. Mr. Hindin's entrepreneurial background includes several companies and commenced with Britches of Georgetown, Inc., a clothing retailer specializing in the sale of upscale men's and women's apparel and accessories which he co-founded. Mr. Hindin has also served as Chairman of the Board of Hinsilblon Laboratories Ltd., a company based in Fort Myers, Florida which sells odor neutralization products and delivery systems, since 1990. Finally, Mr. Hindin has served as President of Adworks Inc, a Washington D.C.-based advertising and marketing consulting agency, since 1987. During 2009, Mr. Hindin filed for personal bankruptcy under the U.S. Bankruptcy Code and is currently involved in proceedings related to the matter. The Board believes that Mr. Hindin's extensive experience as an entrepreneur will be increasingly valuable to the Board as we seek to expand and finance our operations.

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, 2009, 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. Hindin, McNay and Bowles. Mr. Hindin 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.

Our board of directors has also determined that each of Mr. Hindin and Mr. McNay 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, 2009 and 2008, compensation awarded to or paid to, or earned by, our chief executive officer and our two other most highly compensated executive officers during 2009 who were serving as executive officers at December 31, 2009. For purposes of this Annual 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, 2008 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 currently 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, 2009" section below.

Name and Principal Position	Year	Salary[1] ($)	Bonus[2] ($)	Option Awards[3] ($)	Non-Equity Incentive Plan Compensation[4] ($)	All Other Compensation[5] ($)	Total ($)
Mr. J.J. Finkelstein, President and Chief Executive Officer	2009	244,608	18,720	116,198	—	13,005	392,531
	2008	299,520	22,464	86,137	14,976	17,690	440,787
Mr. C. Neil Lyons, Chief Financial Officer	2009	167,093	11,140	74,395	—	4,999	257,627
	2008	200,817	12,152	68,848	10,127	8,508	300,452
Mr. David R. Crockford, Vice President, Clinical and Regulatory Affairs	2009	210,223	5,781	—	—	6,818	222,822
	2008	209,203	12,613	51,682	10,511	11,681	295,690

(1) Reflects base salary before pretax contributions and therefore includes compensation deferred under our 401(k) plan.

(2) Reflects the discretionary portion of our bonus plan.

(3) These amounts reflect the aggregate full grant date fair values (computed in accordance with FASB ASC Topic 718) of options granted to executives during the respective fiscal years.

(4) Reflects amounts earned under our bonus plan subject to the achievement of corporate performance goals.

(5) 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 Amended and Restated 2000 Stock Option and Incentive Plan (the "2000 Plan"). 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 2000 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, 2009, 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 $8,772.

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 2000 Plan or in Mr. Finkelstein's employment agreement, then the unvested portion of Mr. Finkelstein's options outstanding as of December 31, 2009 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 the 2000 Plan. 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 2000 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, 2009, 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 $17,208.

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 2000 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, 2009 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 the 2000 Plan. 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 2000 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, 2009, 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 $14,664. 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, 2009

The following table shows certain information regarding outstanding equity awards at December 31, 2009 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	
	62,500	62,500	2.34	3/15/2014	(1)
	31,250	93,750	1.15	4/15/2015	(1)
	114,748	—	0.57	4/10/2019	
	—	125,000	0.76	10/11/2016	(1)
Mr. Lyons	133,332	66,668	3.10	4/7/2015	(2)
	37,500	37,500	2.34	3/15/2014	(1)
	18,750	56,250	1.50	6/15/2015	(1)
	77,728	—	0.57	4/10/2019	
	—	75,000	0.76	10/11/2016	(1)
Mr. Crockford	15,000	—	1.07	7/1/2013	
	125,000	—	0.86	1/1/2014	
	70,000	30,000	3.21	4/1/2015	(3)
	17,500	7,500	3.82	5/25/2015	(3)
	25,000	25,000	2.15	1/16/2014	(1)
	37,500	37,500	2.34	3/15/2014	(1)
	18,750	56,250	1.15	4/15/2015	(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.

(3) This option vests on the first five anniversaries of the grant date in the following installments: 10%, 15%, 20%, 25%, 30%. In each case these options were granted ten years prior to the listed expiration dates.

Post-Employment Compensation

We do not maintain any plans providing for payment or other benefits at, following, or in connection with retirement other than a 401(k) plan made available to all employees. In addition, we do not maintain any non-qualified deferred compensation plans.

Director Compensation

The following table set forth certain information for the fiscal year ended December 31, 2009 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. Hindin currently serves as the chairman of each of these committees.

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 the 2000 Plan to purchase 15,000 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 under the 2000 Plan to purchase 35,000 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.

Of note, our annual rates of director compensation in effect at December 31, 2008 and 2009 remain the same. However, given our limited cash resources during most of 2009, the Board elected to reduce the cash fees payable to the Board for their services by 35% for the period from April 1 to September 30, 2009. Consequently, the following charts of actual compensation may differ from the disclosed annual rates of compensation currently in effect.

In return for the 35% director fee reduction, each director received options to purchase shares of our common stock at an exercise price of $0.57 per share. Effective October 1, 2009, their fees 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 to the extent vested as of September 30, 2009 in accordance with the terms of our stock option plan. The number of shares vested and outstanding from these option grants are included within the amounts set forth in Footnote 1 to the table below.

Director Compensation for Fiscal 2009

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Dr. Goldstein	—	71,348	162,466[2]	233,814
Mr. Hindin	37,877	16,039	—	53,916
Dr. Bowles	21,105	11,875	—	32,980
Mr. McNay	18,028	10,917	—	28,945
Mr. Bove	16,292	10,459	—	26,751

(1) These amounts reflect the aggregate full grant date fair values (computed in accordance with FASB ASC Topic 718) of options granted to directors during 2009, a portion of which vested during 2009 as described above. Options held by each Board member as of December 31, 2009, are as follows:

Dr. Goldstein	696,942
Mr. Hindin	237,749
Dr. Bowles	154,843
Mr. McNay	228,024
Mr. Bove	227,155

(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 $153,093 for 2009, and a discretionary cash bonus of $9,373. 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, 2009, 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 the 2000 Plan. 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 2000 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 2000 Plan or in any option agreement between Dr. Goldstein and us.

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

The following table sets forth certain information regarding the ownership of our common stock as of March 15, 2010 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	30,142,859[2]	46.9%
Named Executive Officers and Other Directors:		
J.J. Finkelstein	2,299,636[3]	3.8%
Allan L. Goldstein	2,152,538[4]	3.6%
Richard J. Hindin	1,175,459[5]	1.9%
Joseph C. McNay	1,537,135[6]	2.5%
Mauro Bove	197,155[7]	*
L. Thompson Bowles	124,843[8]	*
C. Neil Lyons	329,393[9]	*
David R. Crockford	388,750[8]	*
All directors and executive officers as a group (8 persons)	38,347,768[10]	63.5%

* Less than one percent.

(1) This table is based upon information supplied by officers, directors and principal stockholders. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 60,406,828 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"); 12,011,185 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, 2010; 5,052,582 shares of common stock held of record and 1,228,486 shares of common stock issuable upon exercise of warrants held by Inverlochy-Consultadoria e Servicos (S.U.) LDA ("Inverlochy"), an entity wholly owned by Claudio Cavazza, who directly and indirectly owns 57% of Sigma-Tau, that are exercisable within 60 days of March 15, 2010; and 8,175,110 shares of common stock held of record and 2,101,400 shares of common stock issuable upon exercise of warrants held by Chaumiere-Consultadoria e Servicos SDC Unipessoal LDA ("Chaumiere"), 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, 2010. 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 minor daughter over which Mr. Finkelstein shares voting and dispositive power. Also includes 870,998 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2010.

(4) Consists of 1,586,846 shares of common stock held of record by Dr. Goldstein and 565,692 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2010.

(5) Consists of 967,710 shares of common stock held of record by Mr. Hindin and 207,749 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2010.

(6) Consists of 1,339,111 shares of common stock held of record by Mr. McNay and 198,024 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2010.

(7) Consists of shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2010. 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.

(8) Consists of shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2010.

(9) Consists of 10,000 shares of common stock held of record by Mr. Lyons and 319,393 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2010.

(10) Consists of 31,555,797 shares of common stock held of record, 3,919,367 shares of common stock issuable upon exercise of warrants exercisable within 60 days of March 15, 2010 and 2,872,604 shares of common stock issuable upon exercise of options exercisable within 60 days of March 15, 2010.

Equity Compensation Plan Information

The following table provides information as of December 31, 2009 about the securities authorized for issuance to our employees, directors and other eligible participants under our equity compensation plans, consisting solely of the 2000 Plan. Under the 2000 Plan, the Board of Directors, or the compensation committee thereof, may grant options to purchase shares of our common stock. Options may only be granted to our directors, officers, employees, consultants or advisors, and no single participant can receive options for more than 450,000 shares in any one year. The exercise price and term of any grant is determined at the time of grant but may not be less than the fair market value of our common stock on the date of the grant, and the term of an option may not exceed ten years. There are currently 6,500,000 shares authorized for issuance under the 2000 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	4,914,112	$ 1.53	1,550,888
Equity compensation plans not approved by security holders	—	—	—
Total	4,914,112	$ 1.53	1,550,888

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

Related Party Transactions

Since January 1, 2008, we have entered into four financing transactions with Sigma-Tau and its affiliates as described below. As described above, Mr. Bove 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 February 29, 2008, pursuant to Securities Purchase Agreements dated as of February 27, 2008 (the "February 2008 Purchase Agreements") between us and each of Chaumiere and Inverlochy (collectively, the "Purchasers"), Chaumiere purchased 2,500,000 shares of our common stock and Inverlochy purchased 2,500,000 shares of our common stock for a purchase price of $1.00 per share in a private placement. The February 2008 Purchase Agreements provide that (i) the Purchasers may not transfer the shares through December 31, 2010 (the "Restricted Period") except for transfers to Affiliates (as defined therein), (ii) we, rather than the Purchasers, have all voting rights in respect of the shares during the Restricted Period, and (iii) we shall have the right to repurchase the shares at any time during the Restricted Period at a price of $2.00 per share, with respect to any repurchases made on or prior to December 31, 2009, and at a price of $2.50 per share with respect to any repurchases made between January 1, 2010 and December 31, 2010. In consideration for the purchase of such shares, on February 29, 2008, we issued warrants (i) to Inverlochy to purchase 500,000 shares of common stock and (ii) to Chaumiere to purchase 500,000 shares of common stock, in each case exercisable at a price of $1.60 per share. One-third of the warrants vested on February 29, 2008, one-third vested on December 31, 2008, and one-third vested on December 31, 2009.

On December 10, 2008, pursuant to Securities Purchase Agreements dated as of December 10, 2008 (the "December 2008 Purchase Agreements") between us and each of Chaumiere and Inverlochy, Chaumiere purchased 1,034,482 shares of common stock and Inverlochy purchased 1,034,482 shares of common stock for a purchase price of $1.45 per share in a private placement. The December 2008 Purchase Agreements provide that (i) the Purchasers may not transfer the shares through December 31, 2011 except for transfers to Affiliates (as defined therein) and (ii) we, rather than the Purchasers, have all voting rights in respect to the shares through December 31, 2011. In consideration for the purchase of such shares, on December 10, 2008 we issued warrants (i) to Inverlochy to purchase 372,552 shares of common stock and (ii) to Chaumiere to purchase 372,552 shares of common stock, in each case vested upon issuance and exercisable at a price of $1.74 per share, in whole or in part, at any time and from time to time until December 31, 2011.

On April 30, 2009, pursuant to a Securities Purchase Agreement (the "April 2009 Purchase Agreement") between us and Chaumiere, Chaumiere purchased 1,052,631 shares of common stock for a purchase price of $0.57 per share in a private placement. The April 2009 Purchase Agreement provides that (i) Chaumiere may not transfer the shares through April 30, 2012 except for transfers to Affiliates (as defined therein) and (ii) we, rather than Chaumiere, have all voting rights in respect to any shares issued under the April 2009 Purchase Agreement through April 30, 2012. In consideration for the purchase of such shares, on April 30, 2009, we issued a fully vested warrant to Chaumiere to purchase 263,158 shares of common stock, exercisable at a price of $0.91 per share, in whole or in part, at any time and from time to time until April 30, 2012.

On October 15, 2009, pursuant to a Securities Purchase Agreement (the "October 2009 Purchase Agreement") between us and Chaumiere, Chaumiere purchased 1,219,512 shares of common stock and warrants to purchase 609,756 shares of our common stock for a purchase price of $0.82 per share in a private placement. In consideration for the purchase of such shares, on October 15, 2009, we issued a warrant to Chaumiere to purchase 609,756 shares of common stock, exercisable at a price of $1.12 per share, in whole or in part, at any time from April 15, 2010 until September 30, 2014.

Director Independence

After review of all relevant transactions or relationships between each director, or any of his family members, and our company, its senior management and its independent auditors, our board has determined that each of our current directors other than Mr. Finkelstein and Dr. Goldstein, and each member of the audit and compensation committees of our board of directors, are independent directors within the meaning of the listing standards of the NYSE Amex stock exchange. Mr. Finkelstein and Dr. Goldstein are not independent by virtue of their employment with us.

In making its determination as to independence, our board of directors found that none of the independent directors had a material or other disqualifying relationship 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 would 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, 2009 and 2008 by Reznick Group, P.C., our independent registered public accounting firm. All such fees described below were approved by the audit committee.

	2009	2008
Audit fees	$ 76,000	$ 51,000
Tax fees [1]	25,000	11,650
Total Fees	$ 101,000	$ 62,650

[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 Amendment No. 1 to Registration Statement (File No. 33-9370) (filed November 26, 1986)
3.2	Certificate of Amendment	Exhibit 3.2 to the Company's Transitional Report on Form 10-K (File No. 1-15070) (filed March 18, 1991)
3.3	Certificate of Amendment	Exhibit 3.3 to the Company's Annual Report on Form 10-KSB (File No. 1-15070) (filed April 2, 2001)
3.4	Certificate of Designation of Series A Participating Cumulative Preferred Stock	Exhibit 2 to the Company's Current Report on Form 10-K (File No. 1-15070) (filed May 2, 1994)
3.5	Amended and Restated Bylaws of the Company	Exhibit 3.4 to the Company's Quarterly Report on Form 10-Q (filed August 14, 2006)
3.6	Amendment to Amended and Restated Bylaws of the Company	Exhibit 3.6 to the Company's Registration Statement on Form S-8 (File No. 333-152250) (filed July 10, 2008)
4.1	Form of Stock Certificate	Exhibit 4.1 to Amendment No. 1 to Registration Statement (File No. 33-9370) (filed November 26, 1986)
4.2	Form of Rights Certificate	Exhibit 3 to the Company's Current Report on Form 8-K (File No. 1-15070) (filed May 2, 1994)
4.3	Rights Agreement, dated April 29, 1994, between the Company and American Stock Transfer & Trust Company, as Rights Agent	Exhibit 1 to the Company's Current Report on Form 8-K (File No. 1-15070) (filed May 2, 1994)
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 4.3 to the Company's Annual Report on Form 10-KSB (filed March 31, 2006)
10.1^	Amended and Restated 2000 Stock Option and Incentive Plan, as amended	Annex A to the Company's Proxy Statement on Schedule 14A (filed May 9, 2008)
10.2	Patent License Agreement — Exclusive, dated January 24, 2001, between the Company and the U.S. Public Health Service	Exhibit 10.1 to the Company's Annual Report on Form 10-KSB (File No. 1-15070) (filed April 2, 2001)**
10.3	Thymosin Beta 4 License and Supply Agreement, dated January 21, 2004, between the Company and Defiante Farmaceutica S.A.	Exhibit 10.10 to the Company's Registration Statement on Form SB-2 (File No. 333-113417) (filed March 9, 2004)**

Exhibit No.	Description of Exhibit	Reference*
10.4^	Second Amended and Restated Employment Agreement, dated March 11, 2009, between the Company and Allan L. Goldstein, as amended	Exhibit 10.4 to the Company's Annual Report on Form 10-K (filed on April 15, 2009)
10.5^	Second Amended and Restated Employment Agreement, dated March 12, 2009, between the Company and J.J. Finkelstein, as amended	Exhibit 10.5 to the Company's Annual Report on Form 10-K (filed on April 15, 2009)
10.6^	Second Amended and Restated Employment Agreement, dated March 31, 2009, between the Company and C. Neil Lyons, as amended	Exhibit 10.6 to the Company's Annual Report on Form 10-K (filed on April 15, 2009)
10.7^	Second Amended and Restated Employment Agreement, dated March 31, 2009, between the Company and David Crockford	Exhibit 10.7 to the Company's Annual Report on Form 10-K (filed on April 15, 2009)
10.8	Form of Warrant to Purchase Common Stock	Exhibit 4.1 to the Company's Current Report on Form 8-K (filed on January 6, 2005)
10.9	Form of Amendment to Warrant to Purchase Common Stock	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed January 7, 2008)
10.10	Form of Second Amendment to Warrant to Purchase Common Stock	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed April 4, 2008)
10.11	Stock Purchase Agreement, dated June 23, 2005	Exhibit 99.2 to the Company's Current Report on Form 8-K (filed June 23, 2005)
10.12	Form of Warrant to Purchase Common Stock	Exhibit 4.1 to the Company's Current Report on Form 8-K (filed March 7, 2006)
10.13	Registration Rights Agreement, dated December 15, 2006	Exhibit 10.2 to the Company's Current Report on Form 8-K (filed on December 18, 2006)
10.14	Form of Warrant to Purchase Common Stock	Exhibit 4.1 to the Company's Current Report on Form 8-K (filed on December 18, 2006)
10.15	Form of Securities Purchase Agreement	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed February 27, 2008)
10.16	Form of Warrant to Purchase Common Stock	Exhibit 4.1 to the Company's Current Report on Form 8-K (filed February 27, 2008)
10.17	Form of Securities Purchase Agreement, dated December 10, 2008	Exhibit 99.1 to the Company's Current Report on Form 8-K (filed on December 12, 2008)
10.18	Form of Warrant to Purchase Common Stock	Exhibit 4.1 to the Company's Current Report on Form 8-K (filed December 12, 2008)

Exhibit No.	Description of Exhibit	Reference*
10.19	Form of Warrant	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed April 16, 2009)
10.20	Securities Purchase Agreement, dated as of April 13, 2009	Exhibit 10.2 to the Company's Current Report on Form 8-K (filed April 16, 2009)
10.21	Form of Common Stock Purchase Warrant	Exhibit 4.1 to the Company's Current Report on Form 8-K (filed September 30, 2009)
10.22	Securities Purchase Agreement, dated as of September 30, 2009, by and between the Company and each of the purchasers identified on the signature pages thereto	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed September 30, 2009)
10.23	Form of Warrant	Exhibit 4.1 to the Company's Current Report on Form 8-K (filed October 5, 2009)
10.24	Securities Purchase Agreement, dated as of September 30, 2009	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed October 5, 2009)
10.25	Lease by and between RegeneRx Biopharmaceuticals, Inc. and The Realty Associates Fund V, L.P., dated December 10, 2009	Filed herewith
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, 2010

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, 2010
/s/ J.J. Finkelstein J.J. Finkelstein	President, Chief Executive Officer, and Director (Principal Executive Officer)	March 31, 2010
/s/ C. Neil Lyons C. Neil Lyons	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2010
/s/ Richard J. Hindin Richard J. Hindin	Director	March 31, 2010
/s/ Joseph C. McNay Joseph C. McNay	Director	March 31, 2010
/s/ Mauro Bove Mauro Bove	Director	March 31, 2010
/s/ L. Thompson Bowles L. Thompson Bowles	Director	March 31, 2010

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

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

We have audited the accompanying balance sheets of RegeneRx Biopharmaceuticals, Inc. (the "Company") as of December 31, 2009 and 2008, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2009. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of RegeneRx Biopharmaceuticals, Inc. as of December 31, 2009 and 2008, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2009 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 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, 2010

RegeneRx Biopharmaceuticals, Inc.
Balance Sheets

	December 31, 2009	December 31, 2008
ASSETS		
Current assets		
Cash and cash equivalents	$ 4,355,768	$ 5,655,367
Prepaid expenses and other current assets	196,546	236,477
Total current assets	4,552,314	5,891,844
Property and equipment, net of accumulated depreciation of $98,171 and $81,623	8,492	25,039
Other assets	22,948	5,693
Total assets	$ 4,583,754	$ 5,922,576
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 140,206	$ 70,554
Accrued expenses	740,198	1,255,358
Total current liabilities	880,404	1,325,912
Commitments	—	—
Stockholders' equity		
Preferred stock, $.001 par value per share, 1,000,000 shares authorized; no shares issued	—	—
Common stock, $.001 par value per share, 100,000,000 shares authorized; 60,406,828 and 53,622,491 issued and outstanding	60,407	53,623
Additional paid-in capital	88,144,347	82,550,585
Accumulated deficit	(84,501,404)	(78,007,544)
Total stockholders' equity	3,703,350	4,596,664
Total liabilities and stockholders' equity	$ 4,583,754	$ 5,922,576

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Operations

	Years ended December 31,	
	2009	2008
Sponsored research revenue	$ —	$ 168,412
Operating expenses		
Research and development	3,724,514	7,149,808
General and administrative	2,781,790	3,805,346
Total operating expenses	6,506,304	10,955,154
Loss from operations	(6,506,304)	(10,786,742)
Interest income	12,444	149,777
Net loss	$ (6,493,860)	$ (10,636,965)
Basic and diluted net loss per common share	$ (0.12)	$ (0.21)
Weighted average number of common shares outstanding	55,680,525	50,967,617

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Changes in Stockholders' Equity
Years ended December 31, 2009 and 2008

	Common stock		Additional	Accumulated	Accumulated other comprehensive	Total stockholders'
	Shares	Amount	paid-in capital	deficit	income/(loss)	equity
Balance, December 31, 2007	46,553,527	$ 46,554	$ 73,513,292	$(67,405,579)	$ (1,543)	$ 6,152,724
Cumulative effect of a change in accounting principle — ASC Topic 730	—	—	—	35,000	—	35,000
Issuance of common stock, net of offering costs of $52,240	7,068,964	7,069	7,940,691	—	—	7,947,760
Share-based compensation expense	—	—	1,096,602	—	—	1,096,602
Net loss	—	—	—	(10,636,965)	—	(10,636,965)
Unrealized gain on available for sale securities	—	—	—	—	1,543	1,543
Total comprehensive loss						(10,635,422)
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

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Cash Flows

	Years ended December 31,	
	2009	2008
Operating activities:		
Net loss	$ (6,493,860)	$ (10,636,965)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	16,547	19,396
Non-cash share-based compensation	748,480	1,096,602
Gain on settlement of accrued expenses	(100,000)	—
Changes in operating assets and liabilities:		
Accounts receivable	—	26,951
Prepaid expenses and other current assets	39,931	66,767
Other assets	(17,255)	—
Accounts payable	69,652	(203,007)
Accrued expenses	(415,160)	(940,150)
Net cash used in operating activities	(6,151,665)	(10,570,406)
Investing activities:		
Sales/maturities of short-term investments	—	4,581,135
Net cash provided by investing activities	—	4,581,135
Financing activities:		
Net proceeds from issuance of common stock	4,852,066	7,947,760
Net cash provided by financing activities	4,852,066	7,947,760
Net (decrease) increase in cash and cash equivalents	(1,299,599)	1,958,489
Cash and cash equivalents at beginning of year	5,655,367	3,696,878
Cash and cash equivalents at end of year	$ 4,355,768	$ 5,655,367

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

1. ORGANIZATION AND BUSINESS

Organization and Nature of Operations. RegeneRx Biopharmaceuticals, Inc. (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 $6.5 million and $10.6 million for the years ended December 31, 2009 and 2008, respectively. Since inception, and through December 31, 2009, we have an accumulated deficit of $84.5 million and we had cash and cash equivalents of $4.4 million as of December 31, 2009. Based on our operating plan, we believe that our cash and cash equivalents will fund our operations into the third quarter of 2010.

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 third quarter of 2010. 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 Tβ4. 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 $16,547 and $19,396 for the years ended December 31, 2009 and 2008, 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, 2009 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. Revenues are recognized when the associated research has been performed and the related underlying costs are incurred.

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, seven 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.

On January 1, 2008, pursuant to Accounting Standards Codification ("ASC") 730-20 (formerly EITF Issue No. 07-3, "Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities"), "Research and Development Costs," we changed our accounting for non-refundable advance payments to acquire goods or pay for services that will be consumed or performed in a future period in conducting research and development activities on behalf of the entity. Advance payments are recorded as an asset when the advance payments are made. Capitalized amounts are recognized as expense when the research and development activities are performed; that is, when the goods without alternative future use are acquired or the service is rendered. We determined that approximately $35,000 in qualifying transactions required capitalization as of January 1, 2008, and accordingly recognized a cumulative-effect adjustment to our accumulated deficit as of that date.

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, 2009 and 2008. 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, 2009 and 2008, 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 12,847,963 shares and 9,366,590 shares in 2009 and 2008, 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 $748,480 and $1,096,602 in share-based compensation expense for the years ended December 31, 2009 and 2008, 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 February 2010, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (ASU 2010 — 09) to address potential practice issues associated with FASB ASC 855 (formerly SFAS 165), "Subsequent Events." The ASU was effective upon issuance and eliminated the requirement for entities that file or furnish financial statements with the SEC to disclose the date through which subsequent events have been evaluated in originally issued and reissued financial statements. Other entities would continue to be required to disclose the date through which subsequent events have been evaluated; however, disclosures about the date would be required only in financial statements revised because of an error correction or retrospective application of U.S. GAAP. Our adoption of this standard changed our presentation of subsequent events when preparing our financial statements.

In September 2009, the FASB ratified ASU 2009-13 (formerly EITF 08-1), "Revenue Recognition" (ASC 605): Multiple-Deliverable Revenue Arrangements, the final consensus reached by the Emerging Issues Task Force that revised the authoritative guidance for revenue arrangements with multiple deliverables. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The guidance will be effective for our fiscal year beginning January 1, 2011 with early adoption permitted. The guidance may be applied retrospectively or prospectively for new or materially modified arrangements. We currently do not have any multiple-deliverable revenue arrangements, accordingly, the adoption of the guidance will not have an impact on our financial statements.

In August 2009, the FASB issued ASU No. 2009-05, "Fair Value Measurements and Disclosures (ASC 820) — Measuring Liabilities at Fair Value" (ASU 2009-05). ASU 2009-05 provides clarification that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using a valuation technique that uses the quoted price of the identical liability when traded as an asset or the quoted prices for similar liabilities or similar liabilities when traded as assets. The guidance provided is effective for the first reporting period (including interim periods) beginning after issuance. Our adoption of ASU 2009-05 did not impact our financial position or results of operations.

In June 2009, the FASB issued ASC 105 (formerly SFAS 168), "The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles" (ASC 105). ASC 105 is now the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernment entities. It also modifies the GAAP hierarchy to include only two levels of GAAP: authoritative and non-authoritative. ASC 105 is effective for financial statements issued for interim and annual periods ended after September 15, 2009. The adoption of this standard in 2009 changed how we reference various elements of U.S. GAAP when preparing our financial statement disclosures, but did not have an impact on our financial position or results of operations.

Other new pronouncements issued but not effective until after December 31, 2009 are not expected to have a significant effect on our financial position or results of operations.

Reclassifications. Certain account balances as of and for the year ended December 31, 2008 were reclassified to conform to current year presentation.

3. FAIR VALUE MEASUREMENTS

We adopted a new accounting standard that defines fair value and establishes a framework for fair value measurements effective January 1, 2008 for financial assets and liabilities and effective January 1, 2009 for non-financial assets and liabilities. This standard establishes a three-level hierarchy for fair value measurements. The hierarchy is based upon the transparency of inputs and the valuation of an asset or a liability as of the measurement date. The three levels of inputs are as follows:

- 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, 2009 and 2008, 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 $4.4 million and $5.7 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, 2009 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, 2009 and 2008 were $25,000.

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

Accrued expenses are comprised of the following:

	December 31,	
	2009	2008
Accrued clinical research	$ 496,997	$ 944,283
Accrued professional fees	122,590	155,000
Accrued vacation	35,300	61,714
Accrued license fees	30,000	—
Accrued compensation	28,995	84,361
Other	26,316	10,000
	$ 740,198	$ 1,255,358

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 $18,269 and $51,494 for the years ended December 31, 2009 and 2008, 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. In February 2008, the Company sold 5,000,000 shares of its common stock at a price of $1.00 per share, raising net proceeds of $4,947,760 (the "February 2008 Private Placement") from Sigma Tau Group. In connection with the February 2008 Private Placement, the Company also issued warrants to the investors. The warrants are exercisable for an aggregate of 1,000,000 shares of common stock at an exercise price of $1.60 per share. The warrants, which have a term of three years and an exercise price of $1.60 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 $0.3 million.

Under the terms of the February 2008 Private Placement, the Company may, in its sole discretion, repurchase the shares at any time between January 1, 2010 and December 31, 2010, for $2.50 per share. The Company's repurchase right terminates after December 31, 2010. In addition, the investors have agreed to vote the shares, and any additional shares issued pursuant to the exercise of the warrants, as recommended by the Company's Board of Directors until December 31, 2010.

In December 2008, the Company sold 2,068,964 shares of its common stock at a price of $1.45 per share, raising net proceeds of $3,000,000 (the "December 2008 Private Placement") from Sigma Tau Group. In connection with the December 2008 Private Placement, the Company also issued warrants to the investors. The warrants are exercisable for an aggregate of 745,104 shares of common stock at an exercise price of $1.74 per share. The warrants, which have a term of three years and an exercise price of $1.74 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 $0.4 million.

Under the terms of the December 2008 Private Placement, the investors have agreed to vote the shares, and any additional shares issued pursuant to the exercise of the warrants, as recommended by the Company's Board of Directors until December 31, 2011.

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.

Share-Based Compensation. We recognized $748,480 and $1,096,602 in stock-based compensation expense for the years ended December 31, 2009 and 2008, respectively. Given our current estimates of future forfeitures, we expect to recognize the compensation cost related to non-vested options as of December 31, 2009 of $723,000 over the weighted average remaining recognition period of 1.1 years.

2000 Stock Option and Incentive Plan, as amended. Our Board of Directors (the "Board") and stockholders have approved the 2000 Stock Option and Incentive Plan under which the Board may grant options to purchase shares of our common stock. Options may only be granted to our directors, officers, employees, consultants or advisors, and no single participant can receive more than 450,000 shares in any one year. The exercise price and term of any grant are determined by the Board at the time of grant but the exercise price may not be less than the fair market value of our common stock on the date of the grant, and the term of the option shall not exceed ten years. As of December 31, 2009, there were 6,500,000 shares reserved for issuance under the plan, of which 4,914,112 were outstanding and 1,550,888 were available for issuance.

The following summarizes share-based compensation expense for the years ended December 31, 2009 and 2008, which was allocated as follows:

	December 31, 2009	December 31, 2008
Research and development	$ 369,814	$ 440,850
General and administrative	378,666	655,752
	$ 748,480	$ 1,096,602

The following summarizes stock option activity for the years ended December 31, 2009 and 2008:

	Shares available for grant	Options outstanding: Number of shares	Options outstanding: Exercise price range	Options outstanding: Weighted average exercise price
December 31, 2007	620,000	3,545,000	$ 0.28 – $3.82	$ 1.80
Grants	(572,500)	572,500	1.14 – 1.50	1.23
Exercises	—	—	—	—
Cancellations	—	—	—	—
Newly authorized	2,300,000	—	—	—
December 31, 2008	2,347,500	4,117,500	0.28 – 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

The following summarizes information about stock options outstanding at December 31, 2009:

	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
$0.28 – $0.86	2,151,612	4.5	$ 0.50	1,724,112	4.0	$ 0.43
$1.07 – $1.93	827,500	5.0	$ 1.31	435,625	4.6	$ 1.40
$2.02 – $2.68	860,000	4.3	$ 2.26	323,750	4.4	$ 2.31
$3.00 – $3.82	1,075,000	5.4	$ 3.19	950,832	5.4	$ 3.19
	4,914,112			3,434,319		
Intrinsic value of in-the-money options, using the December 31, 2009 closing price of $0.55	$ 254,450			$ 254,450		

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, 2009 and 2008:

	2009	2008
Dividend yield	0.0%	0.0%
Risk free rate of return	1.9 – 2.3%	0.8 – 3.7%
Expected life in years	4.75 – 5.38	1.00 – 4.75
Volatility	71 – 72%	68 – 82%
Forfeitures	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 $0.39 for the year ended December 31, 2009 and $0.73 for the year ended December 31, 2008.

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 2009 and 2008:

	Warrants outstanding		
	Number of shares	**Exercise price range**	**Weighted average exercise price**
December 31, 2007	3,522,544	$ 2.75 – $4.06	$ 3.26
Grants	1,745,104	1.60 – 1.74	1.66
Exercises	—	—	—
Cancellations	(18,558)	4.05 – 4.06	4.05
December 31, 2008	5,249,090	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	7,933,851	$ 0.91 – $4.06	$ 2.01

8. INCOME TAXES

Significant components of the Company's deferred tax assets at December 31, 2009 and 2008 and related valuation reserves are presented below:

	December 31, 2009	December 31, 2008
Deferred tax assets:		
Net operating loss carryforwards	$ 16,988,000	$ 18,370,000
Research and development tax credit carryforward	1,710,000	1,628,000
Charitable contribution carryforward	37,000	39,000
Accrued vacation	8,000	12,000
Accrued expenses	163,000	150,000
Amortization	5,000	6,000
Depreciation	1,000	—
Stock option expense	975,000	919,000
	19,887,000	21,124,000
Less — valuation allowance	(19,887,000)	(21,123,000)
Net deferred tax asset	—	1,000
Deferred tax liabilities:		
Depreciation	—	(1,000)
Net deferred tax amounts	$ —	$ —

A full valuation allowance has been provided at December 31, 2009 and 2008 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, 2009, we had net operating loss carryforwards for income tax purposes of approximately $43.1 million, which are available to offset future federal and state taxable income, if any, and, research and development tax credit carryforwards of approximately $1.7 million. The carryforwards, if not utilized, will expire in increments through 2029.

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, 2009 and 2008.

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2009 and 2008, due to the following:

	December 31, 2009	December 31, 2008
Tax benefit at statutory rate	$ (2,213,000)	$ (3,617,000)
State taxes	(354,000)	(579,000)
Permanent M-1s	339,000	563,000
Limited/expired net operating loss carryforwards	3,546,000	6,150,000
Limited/expired research and development tax credit carryforward	120,000	284,000
Research and development tax credit carryforward	(202,000)	(504,000)
Change in effective tax rate	—	(455,000)
Change in valuation allowance	(1,236,000)	(1,842,000
	$ —	$ —

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, 2009, and December 31, 2008 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, 2009 and 2008.

9. COMMITMENTS

Lease. Our rent expense, related solely to office space, for 2009 and 2008 was $91,183 and $100,196, respectively. We are committed under an office space lease that expires on January 31, 2013 that requires the following approximate annual lease payments: $63,000, $94,000, $98,000 and $8,000 for the years ending December 31, 2010, 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, 2009 these obligations, if triggered, could amount to a maximum of approximately $900,000 in the aggregate.

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