RegeneRx Biopharmaceuticals, Inc.
2008 ANNUAL REPORT

REGENERX

REGENERX

3 Bethesda Metro Center
Suite 630
Bethesda, MD 20814

June 2009

Dear Fellow Stockholders,

As you are likely aware, 2008 and the first half of 2009 have been among the most turbulent economic periods in our industry's history. Although we, like our industry peers, have faced a number of challenges, we believe that during this time RegeneRx has achieved a number of important financial and scientific milestones that have further defined the potential benefits of our product candidates. For example, during this period we have raised a total of $8.6 million in equity financing from affiliates of our partner and largest stockholder, Sigma-Tau Group, in order to continue our clinical and research programs. We also received several important patents and filed applications for others in our ongoing efforts to protect our technology to the maximum extent possible, given our limited resources. In the first quarter of 2009, we initiated efforts to further preserve our cash resources by asking most of our employees and all of our board of directors to reduce their salaries and director fees by 35% in exchange for stock options. This not only helped our cash flow but we believe also indicates confidence in our mission and the potential of our product candidates.

During this period, RegeneRx executives gave presentations at several industry meetings to increase awareness of our company and our product candidates among investors. We also attended several networking events at which our efforts were specifically focused on developing prospective strategic partnerships. In May 2009, we attended the BIO International Convention in Atlanta and met with representatives of companies ranging from large multi-national pharmaceutical companies to mid-size biotechnology companies. We have been and remain in discussions with many of these companies regarding potential strategic activities.

During 2008 and early 2009, we completed two Phase II dermal wound healing trials with RGN-137 in patients with chronic pressure ulcers and venous stasis ulcers, both of which met the primary objective of safety. In terms of the secondary efficacy objectives, we did see some interesting initial acceleration of wound healing in certain patient groups, but the data from the trials did not show statistically significant differences between the placebo and active groups. We are currently evaluating, in collaboration with Sigma-Tau, our plans to pursue further trials of RGN-137 for these two dermal indications. Our decisions relating to future clinical development of RGN-137 may also take into account the results of our ongoing Phase II trial of RGN-137 for epidermolysis bullosa once they are available.

During 2009 we completed a Phase I parenteral (injectable) trial with RGN-352 that we believe will support a future Phase II cardiovascular clinical trial. As for our ophthalmic product candidate, RGN-259, we terminated our Phase II diabetic vitrectomy trial in January 2009 in order to focus our research on what we believe to be a larger commercial opportunity. In 2008, and most recently at the 2009 Advances in Research and Vision in Ophthalmology (ARVO) meeting, Drs. Steven Dunn, a corneal specialist in Detroit, and Gabriel Sosne, a member of our Scientific Advisory Board and an ophthalmologist at Wayne State University and the Kresge Eye Institute in Detroit, reported data from the treatment of the first four neurotrophic keratitis patients with RGN-259 under a "compassionate use" IND, all of whom had eye ulcers that either completely healed or demonstrated significant improvement by the end of the treatment period with no drug-related adverse events. The doctors received permission to treat an additional six patients with other corneal healing problems for an extended period, if necessary.

We have also accelerated development of potential peptides (small proteins) for the cosmeceutical market. Cosmeceuticals are typically defined as products more active than cosmetics but without the claims of pharmaceuticals and, typically, having a shorter regulatory pathway to commercialization. This

is a fast-growing market that has captured the attention of cosmetics companies throughout the world. As a result of research we have sponsored over the past eighteen months, we believe some of our novel peptides may be useful for this market. We have identified the structure and activity of many such peptides, as well as filed patent applications to protect our intellectual property (I.P.). As with our pharmaceutical product candidates, we are engaged in active discussions with several major companies with a goal of commercialization for various cosmeceutical applications.

We have attempted to be resourceful in collaborating with research institutions around the world to explore, define, and confirm the effects of our product candidates. We currently have over twenty R&D collaborations underway with leading American and European research institutions under which we provide expertise and our compounds in return for rights to any novel intellectual property that may be forthcoming. In some cases such research may confirm and/or extend previous discoveries. The research is comprehensive and time-consuming and we are pleased with our ability to effectively leverage our limited resources.

Over the last 18 months we have also benefited from numerous scientific publications and presentations that support our clinical efforts, in particular in the fields of ophthalmology and cardiology. Many of these projects were unrelated to our R&D collaborations and we believe indicate a significant and growing interest in (Thymosin beta 4) Tβ4 by researchers throughout the world:

- April 2009: Researchers from the University of Texas Southwestern Medical Center in Dallas, Texas and several other institutions published a new paper in the Journal of Molecular and Cellular Cardiology on the regenerative effects of Tβ4 on heart cells and blood vessel growth after a heart attack in a rodent model.

- April 2009: Ophthalmology Times published an article on RGN-259 and corneal wound healing entitled "Experimental drug promotes healing in patients with non-healing corneal ulcers," which described data generated by Dr. Steven Dunn on the treatment of corneal ulcers that had not previously healed for at least six weeks and in some cases several months, despite all standard treatments. The results showed that the use of RGN-259 was well-tolerated and either completely healed or significantly reduced the size of the ulcers.

- March 2009: RegeneRx announced that it completed enrollment and dosing of 40 healthy volunteers for its Phase IB double-blind and placebo-controlled clinical trial testing RGN-352, an injectable formulation of Tβ4 for potential use in treating acute myocardial infarction (heart attack) patients and, to date, RGN-352 appears safe and well-tolerated. RegeneRx previously announced completion of a Phase IA trial with 40 additional volunteers.

- December 2008: RegeneRx announced that a team of independent European scientists reported that in a group of 171 previously-treated patients with multiple myeloma (cancer of the bone marrow), the patient group whose cancer cells had the highest levels of Tβ4 had a greater chance of not having recurrences of the disease and longer overall survival than a group of patients in the study with the lowest levels of Tβ4. In addition, the researchers found higher levels of Tβ4 in control (non-myeloma) cells than in the patients' myeloma cells. The study was presented at the American Society of Hematology annual meeting in December 2008.

- September 2008: RegeneRx announced that researchers from Kresge Eye Institute, Wayne State University and Detroit Mercy School of Dentistry were presenting new data on Tβ4's ability to down-regulate inflammation in the eye at the Third Biennial Military Vision Research Symposium: Traumatic Eye and Brain Injury at the Schepens Eye Research Institute, an affiliate of Harvard University, Boston, MA. The data further elaborate Tβ4's ability to suppress inflammation stimulated and mediated by specific inflammatory molecules and pathways.

- September 2008: RegeneRx announced that researchers have shown that Tβ4 provides multi-functional protection to human gingival (gum) cells similar to its previously published activities in the eye and heart and may have significant potential for use as an oral healthcare aid due to its combined anti-microbial, anti-inflammatory, anti-apoptotic, and cytoprotective properties.

- July 2008: RegeneRx announced that it had been awarded an additional $136,000 from the FDA's Office of Orphan Products Development for continued development of RGN-137 for treatment of patients with epidermolysis bullosa, a rare and debilitating skin blistering disorder.

- July 2008: RegeneRx announced that it received a second $100,000 award from the State of Maryland to develop a novel pharmaceutical product specifically aimed at preventing reperfusion injury associated with cardiac ischemia (heart attack).

- July 2008: RegeneRx announced that it completed enrollment and dosing of 40 healthy volunteers for a Phase IA double-blind and placebo-controlled clinical trial testing RGN-352, an injectable formulation of Tβ4 for potential use in treating acute myocardial infarction (heart attack) patients. It was deemed safe and well-tolerated and the company initiated Phase IB.

- May 2008: RegeneRx announced that independent researchers at the Institute of Biopharmaceutical Science, National Yang-Ming University, Taipei, Taiwan, published a paper entitled, "Thymosin beta-4 up-regulates anti-oxidative enzymes and protects human corneal epithelial cells against oxidative damage," in the British Journal of Ophthalmology.

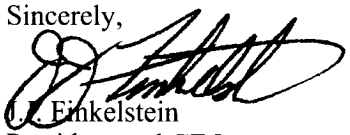
- May 2008: RegeneRx announced that independent researchers at The Institute of Neuroscience, The Fourth Military Medical University in Xi'an, Shaanxi, Peoples Republic of China found that Tβ4 significantly enhanced survival of neurons (nerve cells that send electrical signals throughout the body and control muscle movement) and promoted the process of growing neurites, which are tree-like outgrowths of nerve cells that transmit electrical signals.

- April 2008: An independent team of medical researchers from Germany and the U.S. published data showing that administration of Tβ4 significantly decreased heart damage after cardiac ischemia and reperfusion in pigs compared to placebo. The study was published in Circulation, the journal of the American Heart Association. We believe this study is notable for several important reasons: (1) this is the first time the cardioprotective effects of Tβ4 have been shown in a porcine (pig) model, the closest model to human cardiovascular structure; (2) this is the first study to show Tβ4's cardio-protective effects in an ischemia-reperfusion model; and (3) this study shows that Tβ4 is a key protein secreted from circulating stem cells and promotes cardioprotection.

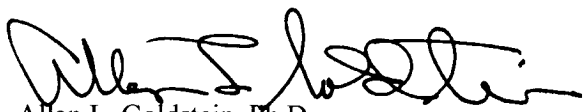
During the remainder of 2009 we plan to continue to build upon our growing body of scientific and clinical data. Options include continuing to develop one or more of our product candidates internally, if we can obtain suitable financing, or externally, if we can enter a strategic partnership that is beneficial to stockholders. We may also be able to work with our partner and largest stockholder, Sigma-Tau, to conduct such development in the U.S. or abroad. Finally, we expect a number of scientific publications and presentations to occur over the next twelve months that will continue to support our clinical efforts and, perhaps, identify other medical areas of interest.

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, 2008

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.)
3 Bethesda Metro Center, Suite 630, Bethesda, MD (Address of principal executive offices)	20814 (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

Note — Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

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 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, 2008, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $31.4 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, 2008.

The number of shares outstanding of the registrant's common stock, as of March 31, 2009, was 53,622,491.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission are incorporated by reference into Part III of this report.

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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, 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 to promote tissue and organ repair. Currently, we have formulated three product candidates based on Thymosin beta 4 ("Tβ4"), a 43-amino acid peptide, that are in clinical development:

- RGN-137, a topically applied gel for hard-to-heal chronic dermal wounds;
- RGN-259, a sterile, preservative-free topical eye drop for ophthalmic wounds; and
- RGN-352, a parenteral, or injectable, formulation for systemic delivery of Tβ4 to treat cardiovascular disease. We are initially targeting our parenteral formulation for the treatment of patients with an acute myocardial infarction, or heart attack.

We have a fourth product candidate, RGN-457, in pre-clinical development. RGN-457 is an inhaled formulation of Tβ4 targeting cystic fibrosis and other pulmonary diseases.

During 2008, we sponsored five clinical trials under Investigational New Drug applications, or INDs, that had been cleared by the U.S. Food and Drug Administration, or FDA. These five trials included three Phase II dermal wound healing trials for RGN-137, a Phase II ophthalmic wound healing trial for RGN-259, and a Phase I clinical trial for RGN-352 in support of our cardiovascular clinical program. Sigma-Tau Pharmaceuticals, 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 our Phase II clinical trial in Italy and Poland evaluating RGN-137 in the treatment of venous stasis ulcers.

In addition to the four pharmaceutical product candidates described above, we are pursuing the commercial development of active domains, or fragments, of Tβ4 for potential cosmeceutical use. These

fragments are amino acid sequences within the Tβ4 molecule that have been shown to be biologically active separate and apart from Tβ4 in *in vitro* research sponsored by RegeneRx. We believe their activity may be useful in developing active ingredients for novel cosmeceutical products for the anti-aging market. To date, *in vitro* research has suggested that these fragments can suppress inflammation, accelerate the deposition of certain types of collagen, promote the production of elastin, and inhibit apoptosis, or programmed cell death, among other activities. We are currently working with a collaborator to develop cosmeceutical formulations and test the clinical activity of certain of these fragments. We have also applied for worldwide patents based on this research.

Mechanism of Action, Research Studies and Potential Commercial Applications

Originally isolated from the thymus gland, Tβ4 is a chemically synthesized copy of a naturally-occurring 43-amino acid peptide that is found in a majority of tissue types with the highest concentrations in blood platelets and white blood cells. Tβ4 is also found extracellularly in blood plasma, 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 adding different growth factors to stimulate healing and have, to date, failed to demonstrate dramatic improvements in the healing process. Unlike those 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 agent.

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") indicated that Tβ4 stimulates the migration of human keratinocytes, or skin cells, and the migration of human endothelial cells. Endothelial cells are the major cell types responsible for the formation of blood vessels, a process known as angiogenesis, and other tissues. These 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, a license discussed in more detail under "Proprietary Rights" below, and to launch a clinical development program that targeted promising indications, all of which were related to chronic dermal wounds.

Tβ4 also reduces inflammation and stimulates the formation of collagen and up-regulates the expression of a subepithelial membrane protein, laminin-5. Both substances are central to healthy tissues and prevention of disease. In combination, these various mechanisms of action work together to play a vital role in the healing of injured or damaged tissues.

In pre-clinical research studies, Tβ4 has also been shown to prevent apoptosis in both the cornea of the eye and the myocardium, or heart muscle. Further, *in vivo* preclinical studies have shown Tβ4 to be active both topically and systemically to accelerate wound healing in the skin and corneal epithelium, and to protect the heart after an event resulting in its loss of blood supply. In combination, these various mechanisms of action work together to play a vital role in the healing of injured or damaged tissues.

Based on these biological activities, we believe Tβ4 to be an essential compound in the wound healing process that may have many potential medical applications. Tβ4 is, therefore, the basis of our clinical programs from which we intend to develop unique medical products and investigate its broad clinical potential.

We continually monitor scientific research relating to Tβ4 in order to confirm our clinical strategy and to evaluate additional indications we might target at a future date. For instance, a study published in the journal *Nature* in November 2006 identified Tβ4 as the triggering factor to stimulate

adult epicardial progenitor or stem cells to mature into blood vessels and responsible for normal fetal heart development and maintenance of a healthy adult heart. Additional research published in the journal *Circulation* in April 2008 indicated Tβ4's cardioprotective effects in a pig ischemic-reperfusion model, more closely replicating human biology and the current standard-of-care for unblocking arteries. We believe that these studies, as well as others, provide significant evidence to suggest that Tβ4's collective mechanisms of action and its anti-apoptotic properties in particular, could provide therapeutic relief in other ischemic conditions.

Clinical Development

The independent research efforts described above have guided our current clinical development program for chronic dermal wounds, ophthalmic injuries and cardiovascular damage. In 2002, following the submission of our first IND, the FDA cleared us to begin a Phase I human dermal clinical trial with RGN-137, which was successfully completed in 2003.

RGN-137 Clinical Trials

Pressure ulcers. In 2004 we commenced a Phase II trial designed to assess the safety and effectiveness of RGN-137 in the treatment of patients with chronic pressure ulcers, commonly referred to as bed sores. In this randomized, double-blind 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, 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 safe and well-tolerated at all three dose levels, with no drug-related serious adverse events, which was the primary objective of the study. Regarding the secondary objective of the study, there were no statistically significant differences observed for complete wound healing or the rate of wound healing between the placebo group and any of the three RGN-137 dose levels. The mid-dose level of RGN-137 was observed to offer more rapid initiation of wound healing when compared to placebo, although this improvement was not statistically significant.

Venous stasis ulcers. In 2005 we commenced a Phase II trial designed to assess the safety and effectiveness of RGN-137 in the treatment of venous stasis ulcers. In this randomized, double-blind dose-response trial, four 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, 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 co-managed by us and Sigma-Tau and was fully funded by Sigma-Tau.

In March 2009 we reported final data from this trial. RGN-137 was safe and well-tolerated at all three dose levels, with no drug-related adverse events, which was the primary objective of the study. In terms of efficacy, secondary endpoints included percent of patients with complete wound healing, as well as time to complete healing. One-third 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 40% compared to placebo. The difference between the active and placebo groups was not statistically significant.

Epidermolysis bullosa ("EB"). In 2005 we commenced a Phase II trial designed to assess the safety and effectiveness of RGN-137 in the treatment of EB, a genetic defect manifested by the presence of fragile skin and other tissues that can blister at the slightest trauma or friction. In this randomized, double-blind dose-response trial, nine clinical sites in the United States are enrolling a total of up to 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. Additionally, 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. Due to the small patient population, we expect to complete enrollment no earlier than in 2010.

Future Plans. Based on the reported data from both the pressure ulcer and venous ulcer trials described above, we and Sigma-Tau are currently evaluating our plans to pursue further trials of RGN-137 for these two dermal indications. Our decisions relating to future clinical development of RGN-137 may also take into account the results of our Phase II trial for EB once they are available.

RGN-259 Clinical Trials

In 2005, based on the reported results of pre-clinical animal studies indicating Tβ4's ability to accelerate corneal wound healing in the eye, we expanded our development program to include indications related to corneal injuries and opened a Phase II clinical trial targeting diabetic patients undergoing corneal epithelial debridement, or removal of the outer layer of the eye, during vitrectomy surgery. In this randomized, double-blind dose-response trial, clinical sites in the United States were enrolling a total of up to 36 patients to evaluate the safety, tolerability, and healing efficacy of three different Tβ4 concentrations compared to placebo, applied as eye drops, once daily for up to 14 consecutive days. We did not view this model as a significant commercial opportunity, but we believed that it did represent an ideal "proof-of-concept" clinical model to evaluate the safety and efficacy of RGN-259 for corneal wounds. 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 slower than anticipated due to newer surgical procedures that eliminated the need for debridement procedures to be performed, as had previously been necessary.

While this RGN-259 clinical trial was being enrolled, Dr. Steven Dunn, an ophthalmologist and corneal specialist, applied for and received a "Compassionate Use" IND from the FDA to treat six patients with neurotrophic keratitis, which are non-healing eye ulcers caused primarily by the herpes zoster virus, using RGN-259. Dr. Dunn began treating four patients with single lesions, all of whom had not healed for at least six weeks and in some cases several months, despite all standard treatments. In November 2008, we reported that, in all four patients, the eye ulcers either completely healed or demonstrated significant improvement by treatment day 28, the maximum treatment period allowed under the clinical protocol. The patients were followed for an additional 30 days post-treatment. The results indicated that completely healed ulcers remained healed and those that had demonstrated significant improvement continued to improve after treatment with RGN-259 was stopped. RGN-259 was well-tolerated and there were no drug-related adverse events.

Following these encouraging compassionate use results and slow enrollment in our Phase II diabetic vitrectomy trial, we terminated the trial in January 2009 in order to potentially focus our research on a larger commercial opportunity. At the time of our announcement, there had been no reported drug-related adverse events and the Phase II trial had completed patient treatment with the lowest dose of

RGN-259. These patients will be evaluated as part of the trial closure, and we expect to report data in the second quarter of 2009.

Dr. Dunn has expanded enrollment in the compassionate use study to up to ten patients, will allow a longer treatment period if necessary, and will include patients with other types of non-healing corneal defects. The patients will be evaluated for both corneal healing and improved visual acuity. We expect to report additional results from this compassionate use study later in 2009.

Depending on the partial results of the terminated Phase II trial and Dr. Dunn's expanded study, we may be able to accelerate the clinical development of RGN-259 in certain orphan ophthalmic indications. Subject to our ability to obtain additional financing or a strategic partner, we intend to commence a new Phase II/III ophthalmic trial using RGN-259 in a different ophthalmic indication by early 2010.

RGN-352 Clinical Trials

In 2005, based on the reported results of mouse-model pre-clinical studies indicating Tβ4's ability to accelerate healing and its apparent protective properties in the heart, we expanded our development program to include RGN-352. In 2007, the FDA cleared us to initiate a Phase I clinical trial, beginning with Phase IA. In this randomized, double-blind dose-response trial, 40 healthy subjects were enrolled in order to evaluate safety and pharmacokinetic parameters of four increasing Tβ4 doses administered intravenously, compared to placebo. In September 2008, we reported the results of the Phase IA clinical trial. A single intravenous injection of RGN-352 was determined to be safe and well-tolerated at all four dose levels.

In March 2009, we reported the preliminary results of a Phase IB clinical trial. A daily intravenous injection of RGN-352 for 14 consecutive days in 40 healthy subjects was also safe and well-tolerated. To date, there have been no reported drug-related adverse events in either part of the Phase I trial. The Phase IB trial will conclude with patient follow-up in the third quarter of 2009, and we will report those results when obtained. We are currently evaluating the design of a Phase II trial cardiac trial and believe that the best utilization of our resources for development of RGN-352 may be to enter a strategic partnership with a biotechnology or pharmaceutical company.

Other Product Development Efforts

All of our efforts to develop our current and any future product candidates will require substantial additional capital to undertake or complete. In most cases, we will seek to enter strategic partnerships to achieve these development goals, some of which are described below. There can be no assurance that we will be able to obtain capital in sufficient amounts, on acceptable terms, or at all, or that we will be able to find suitable strategic partners. 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. 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 possibly of surrendering our rights to some technologies or product opportunities, delaying our clinical trials, or ceasing operations. For additional information regarding our financial resources, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this report.

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 to be ultimately formulated as an inhaled therapeutic agent. We have completed a substantial amount of preclinical work necessary for an IND application, in addition to existing toxicology and pharmacokinetic data from our current clinical programs. 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. In 2006, the predicted median age of survival for patients with cystic fibrosis was 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.

Clinical Development Strategy. We intend to engage in strategic partnerships with companies with clinical development and commercialization strengths in desired pharmaceutical therapeutic fields. We are actively seeking partnerships with suitable infrastructure, expertise and a long-term initiative in our focus disease areas.

In 2004, RegeneRx entered into a strategic partnership with Sigma-Tau Group's wholly-owned subsidiary, Defiante Farmaceutica L.d.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 II trial of RGN-137 in Europe for the treatment of venous stasis ulcers discussed above.

Cosmeceutical Strategy. Another partnership initiative involves our peptide fragments that may be useful as active ingredients in cosmetic or cosmeceutical consumer products. Our goal is to out-license these fragments for various cosmeceutical applications to companies that specialize in formulation, manufacturing, development and commercialization in this growing market segment.

Manufacturing

We use an outside contract manufacturer to produce bulk Tβ4 by an established and proven manufacturing process known as solid-phase peptide synthesis. We are in the process of qualifying other manufacturers. Currently, we do not have any long-term supply agreements in place. We intend to establish a long-term supply arrangement with at least one of these manufacturers 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 outside contract manufacturers to formulate bulk Tβ4 into our product candidates. All of these formulations may require additional studies and undergo various modifications as we move through our clinical development programs.

Competition

We are engaged in a business that is highly competitive, and our target indications are ones with significant unmet medical needs. The cosmetic and cosmeceutical industries are significantly increasing their interest in clinically-based cosmeceutical-type products and are expanding their efforts to develop new products. 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, and 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. A brief description of some of these competitive efforts follow:

RGN-137 (topical gel) — Johnson & Johnson has marketed Regranex™ for patients with diabetic foot ulcers. Other 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 pharmaceutical products for wound healing. Moreover, dermal wound healing is a large and highly fragmented marketplace that includes therapeutic products and medical devices for treating acute and chronic dermal wounds, such as honey-based ointments and low frequency cavitational ultrasound.

RGN-259 (sterile eye drops) — Most specialty ophthalmic companies have various products on the market that could compete with RGN-259 or be modified to compete with our product candidates. Companies may also market antibiotics and steroids to treat certain conditions within our area of focus.

RGN-352 (injectable) — Currently, there are no approved pharmaceutical products for preventing or repairing cardiac damage resulting from a heart attack. However, the market for a product of this type is significant, and many pharmaceutical companies and research organizations are exploring products and technologies that may prevent such damage or improve cardiac function after a heart attack. Furthermore, if we were to successfully develop RGN-352 for other cardiovascular indications, such as acute or chronic congestive heart failure, such a product would have to compete with other drugs currently marketed by large pharmaceutical companies for such indications.

RGN-457 (inhaled) — Cystic fibrosis is a genetic defect for which there is no cure. However, there are mucolytic agents and antibiotic drugs on the market to relieve the symptoms posed by this disease that could compete with the potential therapeutic effects of RGN-457, such as Genentech's Pulmozyme.

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 and 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 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 I clinical trials are typically 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 affect on the patient. Phase II, or therapeutic exploratory, trials are conducted with somewhat larger groups of patients, who are selected by a 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 II trials should allow for the determination of the dose to be used in Phase III clinical trials. Phase III, 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 III clinical trials is to show that the drug confers therapeutic benefit that outweighs any safety risks. Clinical trials must be registered with a central public database, such as clinicaltrials.gov.

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 grant marketing approval, request additional information or deny the application if the FDA determines that the application does not satisfy its regulatory approval criteria. Therefore, even if we complete Phase III 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 IV trials, which are efficacy studies in the patient population after marketing, and surveillance to monitor the safety and effectiveness 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, Good Manufacturing Practices, and computer information system validation standards. Before approval of an NDA, the FDA will perform a prelicensing 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 victims 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. 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 growth and repair factor. During 2007, a patent 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. The issued European Patent is being opposed by a third party at the European Patent Office. In exchange for the exclusive license, we must make certain minimum royalty and milestone payments to the NIH. Through December 31, 2008 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

Licensing Agreements. As noted in "Proprietary Rights" above, we are obligated to pay royalties to the NIH and GWU. While the NIH agreement calls for a minimum annual royalty of $25,000, other royalty obligations to NIH, and all royalty obligations to GWU, are triggered only upon the sale or license of our technology to a third-party, which has not occurred to date.

Defiante Farmaceutica, LDA. We have exclusively licensed certain internal and external wound healing European rights to Tβ4 to Defiante Farmaceutica, LDA, or Defiante, a Portuguese company that is a wholly owned subsidiary of Sigma-Tau, a pharmaceutical company headquartered in Rome, Italy and who, together with its affiliates, are our largest stockholder 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, Defiante 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, Defiante is obligation 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 II clinical trial for the covered indications that yields positive results in terms of efficacy and safety, Defiante must either pay us a $5 million milestone payment or initiate and fund a pivotal Phase III clinical trial of the applicable product candidate in order to maintain the license. As described elsewhere in this report, we have recently completed two Phase II 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 cannot assure you that the reported 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 III clinical trial of RGN-137 under this provision.

The license agreement with Defiante also contains future clinical and regulatory milestones in the licensed territory. As 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.

Clinical 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 pre-clinical 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 two part-time employees, 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 3 Bethesda Metro Center, Suite 630, Bethesda, Maryland 20814.

Available Information

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

We estimate that our current liquidity and capital resources are sufficient to fund our operations into early 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: the results of a Phase II clinical trial evaluating our topical gel product candidate RGN-137 in patients with pressure ulcers; the results of a Phase II clinical trial evaluating our topical gel product candidate RGN-137 in patients with venous stasis ulcers; the results of a Phase I clinical trial evaluating our injectable product candidate RGN-352 in healthy volunteers; and the early termination of a Phase I clinical trial evaluating our ophthalmic product candidate RGN-259 due to data obtained under a compassionate IND indicating RGN-259's positive effects on corneal wound healing. As of the date of this report, we are continuing to enroll patients in our Phase II clinical trial evaluating our topical gel product candidate RGN-137 in patients with EB, furthering our research with our peptide fragments targeting the cosmeceutical market and actively pursuing potential licensing partnerships for our other product candidates. As of the date of this report, we believe we have sufficient liquidity and capital resources to fund our operations into early 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 early 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 certain of our intellectual property rights.

A significant portion of our operating expenses are variable, as opposed to fixed costs. Accordingly, we believe that we have the ability to reduce costs to offset the results of a prolonged or severe economic downturn. Management has been closely monitoring expenditures and intends to restrict such expenditures to those expenses that are necessary to complete activities related to existing clinical trials, identifying additional sources of working capital and general administrative costs in support of these activities. We continue to actively seek new sources of working capital.

We have recently implemented a number of efforts to preserve our cash, including salary reductions for certain of our employees and reductions in non-employee director fees, and we recently entered into an agreement with affiliates of Sigma-Tau Group, our largest stockholder group, to obtain an additional $600,000 in equity financing. With our expected reduced monthly cash outflows and the additional funds raised from this financing that we expect to receive later in April 2009, we believe that our cash and cash equivalents, which were approximately $5.7 million at December 31, 2008, will fund our operations into the first quarter of 2010. 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 and to address our liabilities and raise additional capital for our existing business. We are attempting to pursue asset out-licenses, asset sales, mergers or 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 early 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, 2008, our accumulated deficit totaled $78.0 million and our cash and cash equivalents totaled $5.7 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 of 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 end of 2009 or early 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.

If we are unable to successfully implement our cash preservation efforts, our business could be materially adversely affected.

We incurred a net loss of approximately $10.6 million for 2008. In light of our current cash position, we have taken, and we plan to undertake, a number of actions intended to preserve our cash balances in 2009. In April 2009, we initiated activities to reduce monthly cash outflows, including salary reductions for certain of our employees, reductions in general and administrative expenses and reductions in non-employee director fees. If these reductions are not effectively managed, or if our management and key employees do not continue with us, we may experience unanticipated effects from these reductions causing harm to our business and our relationships with third parties.

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 would likely make capital raising efforts more difficult.

Because of our historical losses from operations, NYSE Amex rules require that we maintain a minimum shareholders' equity of $6 million, unless our market capitalization exceeds $50 million. As of December 31, 2008, our total stockholders' equity was $4.6 million, and subsequently, our market capitalization has fallen below $50 million. While we have not received a formal deficiency letter from NYSE Amex, we may be deemed to be out of compliance with NYSE Amex listing rules. In the event that we were to receive a formal deficiency notice, we would be required to issue a press release and to file the appropriate report with the SEC. We would then expect to have an opportunity to regain compliance within a specified period of time or to provide the exchange with a plan to regain compliance with the appropriate listing standard or, if the exchange does not accept such a plan, appeal any decision by the exchange to delist our shares. There can be no assurance that the exchange would accept such a plan, that such a plan would be successful, or that any appeals by us to the exchange would be successful.

If at the conclusion of compliance periods described above, 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. Many OTC Bulletin Board and pink sheets stocks trade less frequently and in smaller volumes than securities traded on the NYSE Amex, which could have a material adverse effect on the liquidity of our common stock. 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. 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 beyond a commitment from affiliates of Sigma-Tau Group to purchase $600,000 in shares of our common stock and warrants to purchase common stock in the near term. Even with this additional $600,000 in funding, 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.

In addition, 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 Finanziaria S.p.A, which together with its affiliates comprise our largest stockholder 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 Finanziaria S.p.A, who with its affiliated entities are collectively our largest stockholder group. Sigma-Tau Pharmaceuticals 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 affiliates of Sigma-Tau in two private placement financing transactions, but we retained the right to repurchase some of these shares under certain circumstances. In April 2009, we signed a securities purchase agreement with affiliates of Sigma-Tau under which these investors have agreed to purchase $600,000 of our common stock and warrants.

We have licensed certain rights to our product candidates generally for the treatment of dermal and internal wounds, to Defiante Farmaceutica S.p.A., a wholly-owned subsidiary of Sigma-Tau, in Europe. Under the license agreement, upon the completion of a

Phase II clinical trial of either of these product candidates that yields positive results in terms of clinical efficacy and safety, Defiante is obligated to either make a $5 million milestone payment to us or to initiate and fund a pivotal Phase III clinical trial of the product candidate. As described elsewhere in this report, we have recently completed two Phase II 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 cannot assure you 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 III clinical trial of RGN-137 under this provision. As a result of Mr. Bove's relationship with Sigma-Tau, there could be a conflict of interest between Mr. Bove and our stockholders other than Sigma-Tau with respect to these and other agreements and circumstances that may require the exercise of the Board's discretion with respect to Sigma-Tau. Any decision in the best interests of Sigma-Tau may not be in the best interest of our other stockholders.

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 Tβ4-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. As described elsewhere in this report, we have recently initiated salary reductions for our employees, including Dr. Goldstein and Mr. Finkelstein. However, we cannot assure you that such agreements would prevent them 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 recent 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 is marketing 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 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.

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, that any reimbursement granted will be maintained, or that limits on reimbursement available from third-party payers 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, 2008 through March 31, 2009, our closing stock price has ranged from $0.42 to $1.92 with an average daily trading volume of approximately 29,000 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 31, 2009, our officers, directors and principal stockholders together control approximately 55% of our outstanding common stock. Included in this group is Sigma-Tau and its

affiliates, which together hold outstanding shares representing approximately 44% of our outstanding common stock. As described elsewhere in this report, in April 2009 we entered into an agreement to issue an additional 1,052,631 shares of common stock to affiliates of Sigma-Tau Group at $0.57 per share, and warrants to purchase an additional 263,158 shares of common stock, for total proceeds of approximately $600,000. We expect that this transaction will, if it closes, increase the ownership of Sigma-Tau to approximately 45% of our outstanding common stock and approximately 48% of our common stock assuming the exercise of their warrants. A portion of the shares of common stock currently held by Sigma-Tau and its affiliates, representing 16% of our outstanding common stock, are subject to voting agreements under which our Board controls the voting power of such stock. We cannot assure you that such voting agreements would prevent Sigma-Tau and its affiliates from taking actions not in your best interests and effectively exercising control over us. These voting agreements expire between June 2010 and December 2011. After such time, we will have no control over the voting of these shares controlled by Sigma-Tau, including with respect to the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock, and therefore may not be in the best interest of our other stockholders.

Our rights to repurchase certain shares of stock held by Sigma-Tau 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 equal to the lesser of the shares sold to Sigma-Tau in connection with our private placement of securities in June 2005, or the number of shares necessary to reduce Sigma-Tau'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, 2009, for $2.00 per share or, at any time between January 1, 2010 and December 31, 2010, for $2.50 per share, up to 5,000,000 shares of common stock issued to Sigma-Tau 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 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 31, 2009, there were issued and outstanding 53,622,491 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 31, 2009, there were outstanding options to purchase an aggregate of 4,117,500 shares of our common stock at exercise prices ranging from $0.28 per share to $3.82 per share, of which options to purchase 2,644,833 shares were exercisable as of such date. As of March 31, 2009, there were exercisable warrants to purchase 4,915,758 shares of our common stock, at a weighted average exercise

price of $2.80. 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 Bethesda, Maryland where we lease office space with a term through December 31, 2009. 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. Submission of Matters to a Vote of Security Holders.

None.

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.

	2008		2007	
	High	Low	High	Low
First Quarter	1.10	0.80	2.41	2.06
Second Quarter	1.92	0.83	2.75	2.00
Third Quarter	1.43	1.02	2.18	1.57
Fourth Quarter	1.66	0.85	1.75	1.00

As of March 31, 2009, there were approximately 886 holders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Corporation (or "DTC"). All of the shares of Common Stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one stockholder.

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 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; RGN-259, a sterile eye drop for ophthalmic injuries; and RGN-352, a parenteral (injectable) formulation for systemic delivery anticipated to be used in a Phase II acute myocardial infarction ("AMI"), or heart attack trial. We are also seeking a partner for development of an inhaled formulation of Tβ4 known as RGN-457 that is in preclinical development targeting cystic fibrosis.

In the first quarter of 2009, we completed and reported results from two Phase II dermal wound healing clinical trials using RGN-137 and terminated a proof-of-concept Phase II ophthalmic wound healing trial using RGN-259, due to slow enrollment of patients in the trial and the receipt of encouraging

data following treatment of four patients with RGN-259 under a separate compassionate use Investigational New Drug Application ("IND") that indicated potential healing effects in patients with non-healing corneal ulcers. Subject to our ability to obtain additional financing, we intend to initiate in late 2009 or early 2010 a new Phase II/III trial to evaluate RGN-259 in a different ophthalmic indication. We have also finished treating 80 healthy subjects, consisting of 40 subjects in each of two phases, in a Phase I clinical trial utilizing RGN-352 to support our cardiovascular clinical program, and to date there have been no reported drug-related adverse events. These healthy subjects will be followed for six months after treatment, at which time we will report final results from this trial.

We are currently enrolling patients in one ongoing Phase II dermal wound healing clinical trial evaluating RGN-137 in the treatment of Epidermolysis Bullosa, or EB, which we expect to complete no earlier than in 2010.

An affiliate of Sigma-Tau Group, who together with its affiliates is our largest stockholder group, funded all costs associated with one of the Phase II dermal wound healing clinical trials for RGN-137 in the European Union. We have been primarily responsible for the costs associated with the other completed trials as well as the ongoing Phase II trial for EB.

We have incurred net losses of $10.6 million and $11.2 million for the years ended December 31, 2008 and 2007, respectively. Since inception, and through December 31, 2008, we have an accumulated deficit of $78.0 million and we had cash and cash equivalents of $5.7 million as of December 31, 2008. A significant portion of our operating expenses are variable, as opposed to fixed costs. Accordingly, we believe that we have the ability to reduce costs to offset the results of a prolonged or severe economic downturn. Management has been closely monitoring expenditures and intends to restrict such expenditures to those expenses that are necessary to complete activities related to existing clinical trials, identifying additional sources of working capital and general administrative costs in support of these activities. We have recently begun a number of efforts to reduce our monthly cash outflows, including salary reductions and reductions in non-employee director fees in exchange for stock options to our non-employee directors and certain of our employees, and we recently entered into an agreement with affiliates of Sigma-Tau Group, our largest stockholder group, to obtain an additional $600,000 in equity financing. Based on our operating plan, with our reduced monthly cash outflows and additional funds to be raised from this financing, we believe that our cash and cash equivalents will fund our operations into the first quarter of 2010.

We will need substantial additional funds in order to initiate any further preclinical studies or clinical trials, and to fund our operations beyond early 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, corporate collaborations, licensing arrangements or the sale of our company or 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.

Historically, we received only immaterial amounts of revenue from non-refundable government grants and do not anticipate future grant revenue. 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 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. Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards ("SFAS") No. 123R ("FAS 123R"), using the modified-prospective transition method, and therefore have not restated results for prior periods. Under this method we recognize compensation expense for all share-based payments granted to employees after January 1, 2006 and prior to but not yet vested as of January 1, 2006, in accordance with FAS 123R. Under the fair value recognition provisions of FAS 123R, we recognize stock-based compensation net of an estimated forfeiture rate and only recognize compensation cost for those shares expected to vest on a straight-line basis over the requisite service period of the award. Prior to adopting FAS 123R, we accounted for share-based payments to employees under Accounting

Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB 25") and accordingly, we generally recognized compensation expense only when we granted options with a discounted exercise price.

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 September 2006 and February 2007, the FASB issued SFAS No. 157, "Fair Value Measurements" ("FAS 157"), and SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("FAS 159"), respectively. Both standards prescribe changes to fair value measurements of certain assets and liabilities and became effective for fiscal years beginning after November 15, 2007. The adoption of these standards did not have a material impact on our financial statements.

In September 2007, the Emerging Issues Task Force ("EITF") reached a consensus on EITF Issue No. 07-03, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities." EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If and when an entity no longer expects to receive the goods or services contracted, any remaining capitalized, nonrefundable, advance payments should then be charged to expense. This consensus was effective for fiscal years beginning after December 15, 2007. Historically we expensed nonrefundable advance payments when paid. We determined that approximately $35,000 in qualifying transactions required capitalization in accordance with EITF 07-03 as of January 1, 2008, and we accordingly recognized a cumulative-effect adjustment to retained earnings as of that date.

Results of Operations

Comparison of years ended December 31, 2008 and 2007

Revenues. For the year ended December 31, 2008, our revenue decreased by approximately $72,000, or 30%, to approximately $168,000, from approximately $240,000 in 2007. Our revenue in these years consisted entirely of costs recoverable as revenue through our grant from the NIH for trials of RGN-137 to treat the orphan indication EB. The reduced level of revenue was directly related to the fact that there were less amounts of funding available under this grant during 2008.

Expenses — Research and development. For the year ended December 31, 2008, our R&D expenditures decreased by approximately $1.8 million, or 20%, to approximately $7.1 million, from approximately $8.9 million in 2007. This net decrease is explained by four factors. First, we incurred approximately $2.3 million to manufacture Tβ4 and dermal clinical drug product in 2007 that did not need to be repeated in 2008. Also in 2007, we initiated our Phase II ophthalmic trial of RGN-259 which required one-time, start-up costs of approximately $0.6 million. These decreases were offset by approximately $0.9 million in one-time costs to initiate our Phase IA and Phase IB clinical trials evaluating RGN-352 in 2008 and approximately $0.2 million in fees for consultants needed to complete and evaluate our Phase II pressure ulcer trial for RGN-137, the data from which was reported in early January 2009.

As described above, we concluded or terminated three Phase II clinical trials during the first quarter of 2009, and we have also incurred the majority of costs to be incurred under Phase I trial evaluating RGN-352. Our clinical program is actively enrolling patients in only one trial, the Phase II EB trial. Consequently, we expect that our research and development expenditures will decrease for the remainder of 2009 and will remain at lower levels unless and until we initiate follow-on trials.

Expenses — General and administrative. For the year ended December 31, 2008, our G&A expenses increased by approximately $0.6 million, or 20%, to approximately $3.8 million, from approximately $3.2 million in 2007. The majority of this increase was attributable to increased outside professional fees associated with various business development matters.

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. We had cash, cash equivalents and short-term investments totaling $5.7 million and $8.3 million for the years ending December 31, 2008 and 2007, respectively. The $2.6 million decrease during 2008 results from the use of $10.6 million in cash for operating activities, offset by $8.0 million in cash raised through the private placement of common stock and warrants as more fully described in Note 7 to our financial statements.

Cash Flows

Net Cash Used in Operating Activities. Net cash used in operating activities was approximately $10.6 million and $8.8 million for the years ended December 31, 2008 and 2007, respectively. While our reported net loss for the year ended December 31, 2008 was also approximately $10.6 million, it included approximately $1.1 million in non-cash expenses, primarily non-cash share-based compensation, which was offset by a similar amount of cash used to retire current liabilities as compared to the liabilities reported as of December 31, 2007. Our net loss in 2007 was approximately $2.4 million higher than our net cash used in operating activities in the same period also due in part to non-cash share based compensation expenses that were slightly more than $1.0 million and an increase in current liabilities over

those reported as of December 31, 2006 of approximately $1.2 million. The remaining $0.2 million difference between the net loss and the cash used in operating activities for the year ended December 31, 2007 was due to the collection of accounts receivable recorded in 2006.

Net Cash Provided by (Used in) Investing Activities. Net cash provided by (used in) investing activities was approximately $4.6 million and ($0.6) million for the years ended December 31, 2008 and 2007, respectively. In both years these amounts relate to the net (investments in) or sales of short-term, highly-liquid, investment-grade financial instruments. Depending on whether these financial instruments have a maturity date, at time of purchase, of more than 90 days from the date of purchase, the financial instrument is either classified as a short-term investment on our balance sheet (which is reflected in investing activities), or it is classified as a cash equivalent (which is not so reflected). We had more net qualifying short-term investments in 2007 than in 2008 as a result of our cash management activity.

Net Cash Provided by Financing Activities. Net cash provided by financing activities totaled approximately $7.9 million and $46,000 for the years ended December 31, 2008 and 2007, respectively. In 2008, we completed two issuances of common stock that netted approximately $7.9 million in proceeds after deducting the costs of the transactions. The amounts provided in 2007 relate solely to the exercise of warrants.

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 of December 31, 2008, we had three product candidates in clinical trials, the development of each of which is primarily accomplished through cancellable third-party contracts.

However, as described elsewhere in this report, during 2009 we completed two Phase II clinical trials, closed one additional Phase II clinical trial and completed the treatment phase of another Phase I clinical trial. As a result, we are actively enrolling patients in only one trial as of the date of this report. In order to continue the development of our product candidates, we intend to conduct additional clinical trials, the timing of which is uncertain.

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 December 31, 2009 that requires monthly rental payments of approximately $7,300.

In the first quarter of 2009, we also began a number of cash preservation initiatives, including salary reductions and reductions in director fees in exchange for stock options to our non-employee directors and certain of our executives and other key employees. We expect these efforts to preserve approximately $400,000 through the end of 2009.

As described elsewhere in this report, we recently entered into an agreement with affiliates of Sigma-Tau Group, our largest stockholder group, to obtain an additional $600,000 in equity financing. Based on this financing, our current cash position and our current operating plan, we believe that we will have adequate resources to fund our operations into early 2010, without considering the benefits of any potential future milestone payments that we may receive under our license agreement described below.

Sources of Liquidity

During 2007 and 2008, we were dependent on our largest stockholder group, Sigma-Tau Group and its affiliates, to provide the necessary funding in order to continue our operations. In 2008, we raised

approximately $8.0 million from Sigma-Tau and its affiliates through the sale of common stock and warrants.

As described in Item 1 of this report under "Material Agreements," we are party to a license agreement with an affiliate of Sigma-Tau Pharmaceuticals 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 private placement of common stock and warrants to purchase common stock involving Sigma-Tau and its affiliates in the fourth quarter of 2008, and these investors have committed to purchase an additional $600,000 in common stock and warrants in another private placement, 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 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, 2008, these cash equivalents and short-term investments were $5.7 million. Due to the short-term nature of these investments, if market interest rates were to increase immediately and uniformly by 10% from levels as of December 31, 2008, the decline in fair value would not be 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, 2008, 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, 2008 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, 2008 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, 2008, 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.

The information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of our Stockholders (the "Proxy Statement"), under the headings "Election of Directors," "Information Regarding the Board of Directors and Corporate Governance," "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance" and is incorporated in this report by reference.

Item 11. Executive Compensation.

The information required by this item will be set forth in the Proxy Statement under the heading "Executive Compensation" and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement under the headings "Certain Relationships and Related Transactions" and "Information Regarding the Board of Directors and Corporate Governance — Independence of the Board of Directors" and is incorporated in this report by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in the Proxy Statement under the heading "Ratification of Selection of Independent Auditors" and is incorporated in this report by reference.

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,
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	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)

Exhibit No.	Description of Exhibit	Reference*
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 LDA	Exhibit 10.10 to the Company's Registration Statement on Form SB-2 (File No. 333-113417) (filed March 9, 2004)**
10.4^	Second Amended and Restated Employment Agreement, dated March 11, 2009, between the Company and Allan L. Goldstein, as amended	Filed herewith
10.5^	Second Amended and Restated Employment Agreement, dated March 12, 2009, between the Company and J.J. Finkelstein, as amended	Filed herewith
10.6^	Second Amended and Restated Employment Agreement, dated March 31, 2009, between the Company and C. Neil Lyons, as amended	Filed herewith
10.7^	Second Amended and Restated Employment Agreement, dated March 31, 2009, between the Company and David	Filed herewith
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)

Exhibit No.	Description of Exhibit	Reference*
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*
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	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: April 15, 2009

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

/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	April 15, 2009
/s/ J.J. Finkelstein J.J. Finkelstein	President, Chief Executive Officer, and Director (Principal Executive Officer)	April 15, 2009
/s/ C. Neil Lyons C. Neil Lyons	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	April 15, 2009
/s/ Richard J. Hindin Richard J. Hindin	Director	April 15, 2009
/s/ Joseph C. McNay Joseph C. McNay	Director	April 15, 2009
Mauro Bove	Director	
/s/ L. Thompson Bowles L. Thompson Bowles	Director	April 15, 2009

RegeneRx Biopharmaceuticals, Inc.
Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of RegeneRx Biopharmaceuticals, Inc. (the "Company") as of December 31, 2008 and 2007, 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, 2008. 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, 2008 and 2007, and the results of its operations, and its cash flows for each of the years in the two-year period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America.

/s/ REZNICK GROUP, P.C.

Vienna, Virginia
April 15, 2009

RegeneRx Biopharmaceuticals, Inc.
Balance Sheets

	December 31, 2008	December 31, 2007
ASSETS		
Current assets		
Cash and cash equivalents	$ 5,655,367	$ 3,696,878
Short-term investments	—	4,579,592
Accounts receivable	—	26,951
Prepaid expenses and other current assets	236,477	268,244
Total current assets	5,891,844	8,571,665
Property and equipment, net of accumulated depreciation of $81,623 and $62,227	25,039	44,435
Other assets	5,693	5,693
Total assets	$ 5,922,576	$ 8,621,793
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 70,554	$ 273,561
Accrued expenses	1,255,358	2,195,508
Total current liabilities	1,325,912	2,469,069
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; 53,622,491 and 46,553,527 issued and outstanding	53,623	46,554
Additional paid-in capital	82,550,585	73,513,292
Accumulated other comprehensive loss	—	(1,543)
Accumulated deficit	(78,007,544)	(67,405,579)
Total stockholders' equity	4,596,664	6,152,724
Total liabilities and stockholders' equity	$ 5,922,576	$ 8,621,793

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Operations

	Years ended December 31,	
	2008	2007
Sponsored research revenue	$ 168,412	$ 240,324
Operating expenses		
Research and development	7,109,808	8,887,255
General and administrative	3,845,346	3,197,685
Total operating expenses	10,955,154	12,084,940
Loss from operations	(10,786,742)	(11,844,616)
Interest income	149,777	666,458
Net loss	$ (10,636,965)	$ (11,178,158)
Basic and diluted net loss per common share	$ (0.21)	$ (0.24)
Weighted average number of common shares outstanding	50,967,617	46,465,982

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Changes in Stockholders' Equity
Years ended December 31, 2008 and 2007

	Common stock		Additional	Accumulated	Accumulated other Comprehensive	Total stockholders'
	Shares	Amount	Paid-in capital	Deficit	Income/(loss)	equity
Balance, December 31, 2006	**46,096,477**	**$ 46,096**	**$ 72,433,660**	**$ (56,227,421)**	**$ —**	**$ 16,252,335**
Issuance of common stock upon exercise of warrants	457,050	458	45,248			45,706
Share-based compensation expense	—	—	**1,034,384**	—	—	**1,034,384**
Net loss	—	—	—	(11,178,158)	—	(11,178,158)
Unrealized loss on available for sale securities	—	—	—	—	**(1,543)**	**(1,543)**
Total comprehensive loss						(11,179,701)
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 — EITF 07-03	—	—	—	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

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Cash Flows

	For the Year ended December 31, 2008	2007
Operating activities:		
Net loss	$ (10,636,965)	$ (11,178,158)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	19,396	21,197
Non-cash share-based compensation	1,096,602	1,034,384
Changes in operating assets and liabilities:		
Accounts receivable	26,951	245,540
Prepaid expenses and other current assets	66,767	(156,565)
Other assets	—	6,056
Accounts payable	(203,007)	(88,841)
Accrued expenses	(940,150)	1,308,620
Net cash used in operating activities	(10,570,406)	(8,807,767)
Investing activities:		
Purchase of short-term investments	—	(20,681,135)
Sales/maturities of short-term investments	4,581,135	20,100,000
Purchase of property and equipment	—	(12,234)
Net cash provided by (used in) investing activities	4,581,135	(593,369)
Financing activities:		
Net proceeds from issuance of common stock	7,947,760	—
Proceeds from exercise of warrants	—	45,706
Net cash provided by financing activities	7,947,760	45,706
Net increase (decrease) in cash and cash equivalents	1,958,489	(9,355,430)
Cash and cash equivalents at beginning of year	3,696,878	13,052,308
Cash and cash equivalents at end of year	$ 5,655,367	$ 3,696,878

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. Statement of Financial Accounting Standards ("SFAS") No. 131, "Disclosures about Segments of an Enterprise and Related Information," requires an enterprise to report segment information based on how management internally evaluates the operating performance of its business units ("segments"). 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 $10.6 million and $11.2 million for the years ended December 31, 2008 and 2007, respectively. Since inception, and through December 31, 2008, we have an accumulated deficit of $78.0 million and we had cash and cash equivalents of $5.7 million as of December 31, 2008. We have recently entered into an agreement with affiliates of Sigma-Tau Group, our largest stockholder group, to sell and issue additional shares of our common stock and warrants for gross proceeds of $600,000. We have 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. We expect the aggregate cash savings from these salary and fee reductions to be approximately $400,000 through December 31, 2009. Based on our operating plan, with our expected reduced monthly cash outflows and additional funds raised from this financing, we believe that our cash and cash equivalents will fund our operations into the first 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 early 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.

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.

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 U.S. generally accepted accounting principles requires management to make certain estimates and assumptions that affect the reported earnings, financial position and various disclosures. Actual results could differ from those 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.

Short-term Investments. Short-term investments consist of investments with remaining maturities of greater than three months but less than twelve months at the time of purchase, and are generally comprised of investment grade commercial paper issued by major corporations and financial institutions, and short-term securities issued by the U.S. Government. All of these investments were classified as available-for-sale securities and stated at fair value. For all short-term investments, at each reset period, the Company accounts for the transaction as "Sales/maturities of short-term investments" for the security relinquished, and a "Purchase of short-investments" for the security purchased, in the accompanying statement of cash flows. Unrealized gains and losses were recognized in "Accumulated other comprehensive income (loss)" in the accompanying balance sheets.

Concentration of Credit Risk. Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash, cash equivalents and short-term investments. We limit our exposure to credit loss by placing our cash and investments 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 $19,396 and $21,197 for the years ended December 31, 2008 and 2007, 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, 2008 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.

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. The Company uses the liability method of accounting for income taxes. Deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax bases of assets and liabilities given the provisions of the enacted tax laws. Management records valuation allowances against net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and when temporary differences become deductible. The Company considers, among other available information, uncertainties surrounding the recoverability of deferred tax assets, scheduled reversals of deferred tax liabilities, projected future taxable income and other matters in making this assessment.

The Company adopted Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109" ("FIN 48"), effective January 1, 2008. FIN 48 clarifies the accounting and disclosure for uncertainty in tax positions, as defined. The Company has analyzed filing positions in all of the federal and state jurisdictions where it is required to file income tax returns, as well as all open tax years in these jurisdictions. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to FIN 48. In addition, the Company did not record a cumulative effect adjustment related to the adoption of FIN 48.

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.

Net Loss Per Common Share. Net loss per common share for the years ended December 31, 2008 and 2007, 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 9,366,590 shares and 7,067,544 shares in 2008 and 2007, respectively, reserved for the exercise of outstanding options and warrants.

Share-Based Compensation. SFAS No. 123 (revised 2004), "Share-Based Payment," ("FAS 123R") requires companies to recognize expense in the income statement for the fair value of all share-based payments to employees and directors, including grants of employee stock options and other share-based awards. We adopted FAS 123R on January 1, 2006 using the modified-prospective transition method. We record compensation expense for all awards granted after the date of adoption and for the unvested portion of previously granted awards that were outstanding at the date of adoption. We use the Black-Scholes option valuation model ("Black-Scholes") and use the single-option award approach and straight-line attribution method for stock options granted since January 1, 2006. Using this approach, the compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally four years.

We estimate forfeitures when recognizing expense under FAS 123R and adjust this estimate 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.

Pronouncements Implemented. In September 2007, the Emerging Issues Task Force ("EITF") reached a consensus on EITF Issue No. 07-03, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities." EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If and when an entity no longer expects to receive the goods or services contracted, any remaining capitalized, nonrefundable, advance payments should then be charged to expense. This consensus was effective for fiscal years beginning after December 15, 2007. Historically we expensed nonrefundable advance payments when paid. We have determined that approximately $35,000 in qualifying transactions required capitalization in accordance with EITF 07-03 as of January 1, 2008, and accordingly recognized a cumulative-effect adjustment to our accumulated deficit as of that date.

Pronouncements Not Yet Implemented. In February 2008, the FASB issued Statement of Financial Position ("FSP") No. 157-2, which delays the effective date of SFAS No. 157 "Fair Value Measurements" ("FAS 157") for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value on a recurring basis (items that are remeasured at least annually). The FSP deferred the effective date of FAS 157 for non-financial assets and non-financial liabilities until our fiscal year beginning on January 1, 2009. We do not expect the adoption of FAS 157 for non-financial assets and non-financial liabilities to have a material effect on our financial statements.

3. FAIR VALUE MEASUREMENTS

We adopted FAS 157 on January 1, 2008 for our financial assets and liabilities which did not have an impact on our results of operations, financial position or cash flows. FAS 157 establishes a framework regarding the methods used for measuring fair value and expands disclosure about such fair value measurements. FAS 157 does not require assets and liabilities that were previously recorded at cost to be recorded at fair value. For assets and liabilities that are already required to be disclosed at fair value, FAS 157 introduced, or reiterated, a number of key concepts which form the foundation of the fair value measurement approach to be used for financial reporting purposes. Namely, fair values should reflect the amounts that we estimate to receive in connection with the sale of an asset or paid in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (the "exit price"). To facilitate the determination of these estimates, FAS 157 established a hierarchy that prioritizes the use of inputs used in valuation techniques into the following three levels:

- 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, 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 $5.7 million using Level 1 inputs.

We adopted SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities-including an amendment of FASB Statement No. 115" ("FAS 159") on January 1, 2008. Under this statement, an entity may elect to use fair value to measure eligible items. We currently do not have any instruments eligible for election of the fair value option. Therefore, the adoption of FAS 159 in the first quarter of fiscal 2008 did not impact our financial position, results of operations or cash flows.

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, 2008 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.

We have entered into a License and Supply Agreement (the "Agreement") with Defiante Farmaceutica, LDA ("Defiante") a Portuguese company that is a wholly owned subsidiary of Sigma-Tau, S.p.A. ("Sigma-Tau") a pharmaceutical company headquartered in Rome, Italy. 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 T β 4-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. Sigma-Tau and its affiliates are collectively our largest stockholder.

In furtherance of Defiante's licensed rights under the Agreement, Sigma-Tau volunteered to fund and manage 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,	
	2008	2007
Accrued clinical research	$ 944,283	$ 1,915,132
Accrued professional fees	155,000	148,962
Accrued compensation	84,361	83,002
Accrued vacation	61,714	43,745
Other	10,000	4,667
	$ 1,255,358	$ 2,195,508

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 $51,494 and $47,873 for the years ended December 31, 2008 and 2007, respectively.

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 require 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 two affiliates of the Company's largest shareholder, Sigma Tau. 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.

Under the terms of the February 2008 Private Placement, the Company may, in its sole discretion, repurchase the shares at any time until December 31, 2009, for $2.00 per share or, 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. The warrants have a term of three years. One-third of the warrants vested upon the closing of the February 2008 Private Placement, one-third vested on December 31, 2008, and one-third is scheduled to vest on December 31, 2009. However, should the Company repurchase all of the shares prior to December 31, 2009, any unvested warrants would terminate as of the date of repurchase.

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 two affiliates of the Company's largest shareholder, Sigma Tau. 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.

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. The warrants have a term of three years and were fully exercisable upon issuance.

During March 2007, we issued 457,050 shares of our common stock pursuant to the exercise of warrants for an average price of $0.10 per share, raising gross proceeds of $45,706.

Share-Based Compensation. We recognized $1,096,602 and $1,034,384 in stock-based compensation expense for the years ended December 31, 2008 and 2007, respectively. Given our current estimates of future forfeitures, we expect to recognize the compensation cost related to non-vested options as of December 31, 2008 of $1,354,000 over the weighted average remaining recognition period of 1.2 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, 2008, there were 6,500,000 shares reserved for issuance under the plan, of which 4,117,500 were outstanding and 2,347,500 were available for issuance.

The following summarizes stock option activity for the years ended December 31, 2008 and 2007:

		Options outstanding		
	Shares available for grant	**Number of shares**	**Exercise price range**	**Weighted average exercise price**
December 31, 2006	1,480,000	2,685,000	$ 0.28 – $3.82	$ 1.66
Grants	(860,000)	860,000	1.93 – 2.34	2.24
Exercises	—	—	—	—
Cancellations	—	—	—	—
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

The following summarizes information about stock options outstanding at December 31, 2008:

	Outstanding options			Exercisable options		
Range of exercise	Number of shares outstanding	Weighted-average remaining contractual life (in years)	Weighted-average exercise price	Number of shares outstanding	Weighted-average remaining contractual life (in years)	Weighted-average exercise price
$0.28 – $0.86	1,290,000	3.2	$ 0.38	1,252,500	3.1	$ 0.37
$1.07 – $1.93	852,500	6.3	$ 1.32	282,084	5.2	$ 1.50
$2.02 – $2.68	900,000	5.4	$ 2.27	174,000	5.6	$ 2.33
$3.00 – $3.82	1,075,000	6.4	$ 3.19	692,915	6.4	$ 3.19
	4,117,500			2,401,499		
Intrinsic value of in-the-money options, using the December 31, 2008 closing price of $1.18	$ 1,083,300			$ 1,018,050		

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, 2008 and 2007:

	2008	2007
Dividend yield	0.0%	0.0%
Risk free rate of return	0.8 – 3.7%	3.9 – 5.1%
Expected life in years	1.00 – 4.75	3.0 – 5.0
Volatility	68-82%	68-75%

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. Using Black-Scholes and these factors, the weighted average fair value of stock options granted to employees and directors was $0.73 for the year ended December 31, 2008 and $1.37 for the year ended December 31, 2007.

Warrants to Purchase Common Stock.

The following table summarizes our warrant activity for 2007 and 2008:

	Warrants outstanding		
	Number of shares	**Exercise price range**	**Weighted average exercise price**
December 31, 2006	3,979,594	$ 0.10 – $4.06	$ 2.90
Grants	—	—	—
Exercises	(457,050)	0.10	0.10
Cancellations	—	—	—
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

8. INCOME TAXES

Significant components of the Company's deferred tax assets at December 31, 2008 and 2007 and related valuation reserves are presented below:

	December 31,	
	2008	**2007**
Deferred tax assets:		
Net operating loss carryforwards	$ 18,370,000	$ 20,491,000
Research and development tax credit carryforward	1,628,000	1,649,000
Charitable contribution carryforward	39,000	42,000
Accrued vacation	12,000	8,000
Accrued expenses	150,000	93,000
Amortization	6,000	6,000
Other	919,000	677,000
	21,124,000	22,966,000
Less — valuation allowance	(21,123,00)	(22,963,00)
Net deferred tax asset	1,000	3,000
Deferred tax liabilities:		
Depreciation	(1,000)	(3,000)
Net deferred tax amounts	$ —	$ —

A full valuation allowance has been provided at December 31, 2008 and 2007 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, 2008, we had net operating loss carryforwards for income tax purposes of approximately $46.6 million, which are available to offset future federal and state taxable income, if any, and, research and development tax credit carryforwards of approximately $1.6 million. The carryforwards, if not utilized, will expire in increments through 2028.

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, 2008.

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2008 and 2007, due to the following:

	December 31,	
	2008	**2007**
Tax benefit at statutory rate	$ (3,617,000)	$ (3,800,000)
State taxes	(579,000)	(516,000)
Permanent M-1s	563,000	673,000
Limited/expired net operating loss carryforwards	6,150,000	1,378,000
Limited/expired research and development tax credit	284,000	80,000
Research and development tax credit carryforward	(504,000)	(695,000)
Change in effective tax rate	(455,000)	—
Change in valuation allowance	(1,842,000)	2,880,000
	$ —	$ —

During the twelve month period ended December 31, 2008, the Company recorded no liability or benefit with regard to FIN 48.

9. COMMITMENTS

Lease. Our rent expense, related solely to office space, for 2008 and 2007 was $100,196 and $83,361, respectively. We are committed under an office space lease that expires on December 31, 2009 that requires monthly rental payments of approximately $7,300.

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, 2008 these obligations, if triggered, could amount to a maximum of $755,000 in the aggregate.

10. SUBSEQUENT EVENT

On April 13, 2009 we entered into an agreement with affiliates of Sigma-Tau to sell 1,052,631 shares of common stock at a price per share of $0.57, for gross proceeds of $600,000 (the "Private Placement"). In connection with the Private Placement, we have also agreed to issue warrants to purchase an additional 263,158 shares of common stock with an exercise price of $0.91 per share. Subject to stock exchange listing approval, we expect the Private Placement to close in April 2009. There are no discounts or brokerage fees associated with the Private Placement.