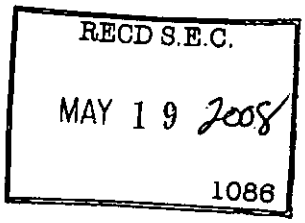


RegeneRx Biopharmaceuticals, Inc.

2007 ANNUAL REPORT

REGENERX

REGENERX

3 Bethesda Metro Center
Suite 630
Bethesda, MD 20814

May 2008

Dear Fellow Stockholders,

The past year was a year of important scientific as well as clinical progress. During the year RegeneRx received two INDs to begin a Phase II ophthalmic wound healing clinical trial and a Phase IA parenteral (injectable) clinical trial that we hope will support a future Phase II cardiovascular clinical trial. Both trials were initiated and are currently enrolling patients. We also made substantial progress on our Phase II dermal clinical trials in the U.S. and Europe and expect to finish enrolling patients in two of those trials, our pressure ulcer and venous stasis trials, by the end of the second quarter 2008 and expect to obtain data from both trials and our Phase IA trial in the third quarter.

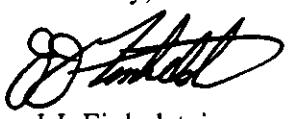
There were numerous papers and presentations reinforcing the therapeutic potential of Tβ4, most notable of which was the cardiovascular research presented by an international research team at an American Heart Association meeting in November highlighting Tβ4's cardio-protective capabilities in an *in vivo* ischemia-reperfusion model. This was followed more recently by a publication in the scientific journal, Circulation. Other scientific papers covering the various potential applications of Tβ4 were published in Nature, Experimental Eye Research, Journal of Cellular Physiology, Protein Expression and Purification, and Annals of the New York Academy of Sciences. During 2007 research presentations on Tβ4 were made at National Heart, Lung, and Blood Institute's "Symposium on Cardiovascular Regenerative Medicine," the "20th Annual Symposium on Advanced Wound Care," the "Association for Research in Vision and Ophthalmology," and "Thymosins in Health and Disease." RegeneRx executives also gave corporate presentations and interviews at numerous industry and investment banking venues in 2007.

We also began implementing numeric naming for our current drug products to differentiate between formulations and create a unique identity for each product. RegeneRx's topical gel is now known as RGN-137, our ophthalmic eye drop is RGN-259, and our parenteral (injectable) formulation is RGN-352. The active pharmaceutical ingredient in each of these formulations will be referred to as Tβ4 peptide. We believe uniquely naming each of our drug products will facilitate discussions with prospective partners and investors, and differentiate RegeneRx drug products in scientific publications. This should also help to more clearly define our product pipeline and highlight new products as they enter development.

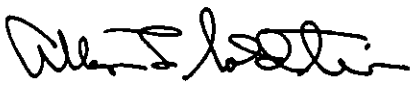
We believe that our outsourcing business model continued to be the most cost-effective way in which to advance our research and clinical development programs, without substantial investment in infrastructure and overhead. We remained at ten full time employees and a handful of consultants during 2007, and have been able to sponsor five clinical trials – a ratio of only two employees per trial. We are also engaged in approximately fifteen research and development collaborations, many of which will support our ongoing clinical efforts while others may provide additional information for new uses of our product candidates. To support this effort we conducted a private placement of common stock for $5 million to two affiliates, which stock we have the right to repurchase through December 31, 2010.

On behalf of the RegeneRx Board of Directors and staff, thank you for your continued support and we look forward to a very exciting year!

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, 2007**

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	**20814**
(Address of principal executive offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock $0.001 par value	American Stock Exchange

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 ☐	Smaller reporting company ☒
(Do not check if a smaller reporting company)	

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

As of June 30, 2007, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $49.8 million. Such aggregate market value was computed by reference to the closing price of the Common Stock as reported on the American Stock Exchange on June 30, 2007.

The number of shares outstanding of the registrant's common stock, as of March 17, 2008 was 51,553,527.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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, the anticipated approval of shares under our additional listing application with Amex, 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 drug products based on Thymosin beta 4 ("Tβ4"), a 43 amino acid peptide. Current research suggests that these drug products may prove efficacious for multiple medical indications when administered either topically or systemically. Therefore, we are developing several Tβ4-based therapeutic drug candidates: RGN-137, a topically applied gel product for hard-to-heal chronic dermal wounds; RGN-259, a sterile, preservative-free topical eye drop for ophthalmic wounds; and RGN-352, a parenteral (injectable) formulation for systemic delivery for treatment of patients with an acute myocardial infarction ("AMI"), or heart attack.. We hold more than 60 world-wide patents and patent applications related to dermal, ophthalmic, and other organ and tissue repair. Under three Investigational New Drug Applications ("INDs"), cleared by the U.S. Food and Drug Administration ("FDA"), we are sponsoring, in parallel, three Phase II dermal wound healing clinical trials for RGN-137, a Phase II ophthalmic wound healing trial for RGN-259 and a Phase I clinical trial utilizing RGN-352 in support of our cardiovascular clinical program. Under one of our INDs and with European regulatory approval, an affiliate of Sigma-Tau Finanziaria S.p.A., or Sigma-Tau, our largest stockholder and a leading international pharmaceutical company, is conducting one of the Phase II dermal wound healing clinical trials in venous stasis ulcers in Italy and Poland. Sigma-Tau has assumed all associated costs.

We utilize an outsourcing business strategy, as we believe this helps us to control costs while focusing on the clinical development of Tβ4-based product candidates. We use this model for certain research and development programs, nonclinical pharmacology and toxicology studies, clinical trials, and manufacturing operations, as well as other administrative functions such as legal and accounting services. In tandem with an experienced management staff, we believe this approach enhances our ability to allocate resources rapidly to different projects while reducing the need for expensive infrastructure. The strategy utilizes vendors and contract manufacturers to supply clinical grade material and to formulate and manufacture each drug candidate. It also includes utilizing third-party contract research organizations to perform pre-clinical studies and/or clinical trials in accordance with our designed protocols.

Primary Commercial Development Focus — Thymosin Beta 4

General. 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 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 (formation of the cytoskeleton) and in the movement of cells throughout the body. Research studies from the National Institutes of Health ("NIH") established that Tβ4 stimulates the migration of human keratinocytes (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.

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.

Tβ4 has also been shown to prevent apoptosis (programmed cell death) in both the cornea (eye) and myocardium (heart). Further, *in vivo* preclinical studies have shown Tβ4 to be active both topically and systemically to accelerate wound healing in the skin to be cardioprotective in the ischemic heart failure. In combination, these various mechanisms of action work together to play a vital role in the healing of injured or damaged tissues.

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

Product Development. With time, we have learned more about Tβ4's therapeutic potential and its underlying mechanisms of action, and have expanded our clinical development program beyond the chronic dermal wound indications initially targeted. Tβ4's role in healing dermal wounds in pre-clinical *in vivo* models was initially established by the National Institutes of Health ("NIH"). These data led management to license 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. Researchers at Wayne State University and the Kresge Eye Institute subsequently published pre-clinical *in-vivo* data that suggested Tβ4 may have significant healing potential in the cornea. These findings were followed by results published in Nature, November 25, 2004, based on research conducted by the University of Texas — Southwestern Medical Center, that suggested Tβ4 may prevent damage of myocardium (heart tissue) immediately after an acute myocardial infarction ("AMI") in pre-clinical *in vivo* models.

These independent foundational research efforts have guided our current clinical development program for chronic dermal wounds, ophthalmic injuries and AMIs. Management and our Board of Directors, or our Board, are focused on proving human efficacy of Tβ4 in these areas. And, while we are not currently initiating additional clinical programs, we continually monitor all of the scientific research surrounding Tβ4 to confirm our clinical strategy and to evaluate additional indications we might target at a future date. For instance, a study published in *Nature*, November 15, 2006 by the collective efforts of scientists from University College — London, Massachusetts General Hospital, and Baylor University identified Tβ4 as the triggering factor to stimulate adult epicardial progenitor or stem cells to mature into blood vessels and being responsible for normal fetal heart development and maintenance of a healthy adult heart. Further, on November 5, 2007, at an American Heart Association meeting in Orlando, Florida, researchers from the University of Munich, Vanderbilt University, and the University of Texas - Southwestern Medical Center reported Tβ4's cardio- protective effects in an ischemic-reperfusion model, thus, closely replicating the human procedure for unblocking arteries and then utilizing Tβ4 to protect the heart. These results, 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 elsewhere in the body.

Clinical Development. In December of 2002, following the submission of our first IND, the FDA allowed us to begin Phase I human dermal clinical trials with RGN-137. The Phase I trial was successfully completed in September of 2003. In November 2004, January 2005 and February 2005, we were cleared to initiate our first of three dermal Phase II wound healing clinical trials using our dermal product, RGN-137. The first Phase II trial assesses the safety and effectiveness of RGN-137 in the treatment of patients with chronic pressure ulcers, more commonly referred to as bed sores. Based on the latest enrollment information, we believe full patient enrollment should be completed in the second quarter of 2008 and we expect to report data in the third quarter of 2008. The second trial is designed to assess safety and effectiveness of RGN-137 in the treatment of patients with venous stasis ulcers that result from poor blood circulation (venous insufficiency). The venous stasis trial is being co-managed by RegeneRx and Sigma-Tau, is paid for in its entirety by Sigma-Tau, and is being conducted pursuant to our U.S. IND. We also believe this trial should complete enrollment in the second quarter of 2008. The third Phase II trial targets the treatment of patients with epidermolysis bullosa ("EB"), a genetic defect manifested by the presence of fragile skin and other tissues that can blister at the slightest trauma or friction. Of our three current Phase II trials, EB has been designated as an "orphan" indication due to a prevalence in the U.S. of less than 200,000 patients. Additionally, RegeneRx was awarded a $545,000 grant from the Office of Orphan Drug Products at the FDA to support the EB clinical trial. We expect patient accrual to be completed later in the fourth quarter of 2008 or the first quarter of 2009, with the reporting of data as soon as practicable thereafter. For additional information regarding the regulatory approval process for our product candidates, see "Government Regulation" below.

In 2005, based on the reported results of pre-clinical studies indicating Tβ4's ability to accelerate corneal wound healing in the eye and its healing and protective properties in the heart, we decided to expand our development program to include the following additional clinical indications. We are currently enrolling diabetic patients who undergo corneal epithelial debridement (removing the outer layer of the eye) during vitrectomy surgery and, due to their diabetes, often heal slowly or incompletely. The design of the study allows us to assess the safety and effectiveness of RGN-259 in this patient population in a highly controlled manner. Therefore, we believe this to be an excellent model with which to measure the efficacy and safety of our ophthalmic product candidate, RGN-259. However, we do not view this model as a significant commercial indication, but rather a proof-of-concept trial, after which we will target other ophthalmic indications with larger market potential. We expect to complete enrollment in the fourth quarter of 2008 or the first quarter of 2009, with the reporting of data as soon as practicable thereafter. It is possible, however, that due to the declining number of debridement procedures in general with this type of surgery, patient accrual could be slower than we have targeted.

We have also conducted a series of pre-clinical studies and are sponsoring a Phase I clinical trials in healthy volunteers for parenteral administration of RGN-352 to support future use in Phase II clinical trials in patients with AMIs. In 2006 we held a pre-IND meeting with the FDA and subsequently filed an IND for this indication at the end of the first quarter of 2007. The FDA cleared us to initiate a Phase I clinical trial, beginning with Phase IA followed by Phase IB. This clinical trial is currently being initiated. We expect the Phase IA to complete enrollment in the second quarter of calendar year 2008 and report data in the later part of the third quarter of 2008.

All of our efforts to develop these applications will likely require substantial additional capital to undertake or complete. There can be no assurance that we will be able to obtain capital in sufficient amounts, or on acceptable terms, or at all. 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 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 "Liquidity and Capital Resources under Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" below. For additional information regarding our efforts to commercialize Tβ4, see "Proprietary Rights" below.

Licensing Efforts. We also are continuing to focus on finding one or more third-party pharmaceutical companies to license our technology and to help us continue the development of our product candidates. We believe that having such partners would enable us to both defray the costs associated with the development of our product candidates and accelerate the speed with which we may be able to complete development of and obtain regulatory approval for our product candidates and commercialize such products. However, we can offer no assurance that we will be able to enter into license and development agreements with third-party pharmaceutical companies or that any such relationships would in fact decrease our costs or accelerate our product development efforts.

Manufacturing

We use an outside contract manufacturer to produce bulk Tβ4, i.e., the active pharmaceutical ingredient ("API") via 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. Therefore, we intend to establish a long-term supply arrangement with at least one of these manufacturers in the near future, followed by a second manufacturer at the earliest practicable time. 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 ("GMP") requirements of the FDA, and ability to meet our established specifications.

We also use outside contract manufacturers to formulate bulk Tβ4 into a final drug product. We have finished the formulation and development work for RGN-137 used in our three Phase II chronic dermal wound trials currently underway. We have completed formulation of a sterile eye drop, RGN-259, that we are using in our ophthalmic ("DV") trial. And, we have completed the formulation development of RGN-352, a sterile, parenteral (injectable) solution we will use in our Phase I and AMI trials. 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. Research and development activities for the development of new drugs to treat patients with our targeted indications are being sponsored or conducted by private and public institutions and by major pharmaceutical companies located in the United States and a number of foreign countries. 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.

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

There are numerous companies and institutions engaged in research, development and marketing of products for ophthalmic wound healing and treatment of ophthalmic disorders where Tβ4 may be useful. Most specialty ophthalmic companies have various products on the market that could compete with Tβ4 or be modified to compete with our product candidates. Other companies market antibiotics and steroids to treat certain conditions within our area of focus.

Currently, there are no approved pharmaceutical products for preventing or repairing cardiac damage resulting from an AMI. 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 an AMI. 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.

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, approving, advertising, and promoting 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 require the expenditure of substantial resources.

Pre-clinical studies must ordinarily be conducted to evaluate the potential efficacy by pharmacology studies and the safety of an investigational new drug 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 allowed to go into effect by the agency before clinical trials can begin. Typically, clinical evaluation involves a three-stage process. In Phase I clinical trials are typically conducted with a small number of healthy volunteers to determine the safety profile, the pattern of drug distribution, metabolism and excretion, and to assess the drugs affect on the subject. In Phase II (therapeutic exploratory), trials are conducted with somewhat larger groups of patients, who are selected by a relatively narrow criteria yielding a relatively homogenous population that are afflicted with the target disease, in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. Phase II studies should allow for the determination of the dose to be used in Phase III. In Phase III (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 and safety 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.

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. 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 certain of our product candidates, and submit an NDA to the FDA, there can be no assurance that the FDA will grant marketing approvals, or if granted, that they 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 studies (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 an NDA approval, is the requirement that the applicable manufacturing, clinical, pharmacovigilance, quality control and manufacturing procedures conform on an ongoing basis with current Good Clinical Practices, Good Laboratory Practices, current Good Manufacturing Practices, and computer information system validation standards. Before approval of an NDA, the FDA will perform a prelicensing inspection of clinical sites, manufacturing facilities and the related quality control records to determine its 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 the applicant is licensed for the manufacture 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 recent years, an increasing number of legislative proposals have been introduced or proposed in Congress related to the regulation of drug products, and we cannot predict the outcome or effect of such legislation on our business.

In June 2004, we received Orphan Drug designation from the FDA for Tβ4 for the treatment of Epidermolysis Bullosa, a rare genetic disease characterized by the presence of extremely fragile skin and other tissues, resulting in recurrent blisters from minor mechanical friction or trauma. Under the Act, the FDA may designate a product or products as having Orphan Drug status to treat "a rare disease or condition" which is a disease or condition that affects populations of less than 200,000 individuals in the United States, or, if victims of a disease number more than 200,000, the sponsor establishes 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 Products. Another such incentive, once approved, is marketing exclusivity for a period of seven years. There may be multiple designations of Orphan Drug status for a given drug and for different indications. The sponsor of the first approved NDA for a given drug for its use in treating a rare disease may receive marketing exclusivity for that specific use. 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 it 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 entered into a Material Transfer — Cooperative Research and Development Agreement with the NIH during the second quarter of 1997. Under this agreement, we received an option to elect an exclusive or non-exclusive commercialization license from the NIH for any patent rights that might result from the NIH research study that relate to the use of Tβ4 as a tissue growth and repair factor. A provisional patent application was filed by NIH in July 1998, with a Patent Cooperation Treaty application filed in July 1999, pertaining to the work performed on Tβ4. On February 6, 2001, we executed an agreement with the NIH giving us an exclusive worldwide license from the NIH for all claims to Tβ4 within the patent application. In exchange for the exclusive license, we must make certain royalty and milestone payments to the NIH. Through December 31, 2007 we have complied with these requirements.

No assurance can be given as to whether or when certain patents will be issued, or as to any claims that may be included or excluded within the patent, or subsequent to its issuance 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. During 2007, we were issued a patent in Europe and the U.S. related to the original NIH patent that expires twenty years from the filing date July 29, 1999. 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 addition, we hold a U.S. patent relating to the treatment of an autoimmune skin disease that results in hair loss, Alopecia. The patent, No. 6,030,948, entitled "Hair Regeneration Compositions for Treatment of Alopecia and Method of Application Related Thereto," issued February 29, 2000 and expires in December of 2017, with corresponding patents granted in Europe and Singapore which expire December 18, 2018. In February 2006, we were issued a patent in China entitled "Treating Epidermolysis Bullosa with Thymosin β4," which expires May 16, 2022. 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.

Under a research agreement with The George Washington University ("GWU"), we funded Tβ4 research at GWU and were granted a sole and exclusive world-wide license to any patents that resulted from such research. 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 have been issued. The first patent, No. 5,578,570, entitled "Method of Treating Septic Shock Using Tβ4," issued on November 26, 1996 and expires in November 2013 and the second patent, No. 5,593,964, entitled "Method of Treating Septic Shock By Preventing Actin Polymerization," issued on January 14, 1997 and expires in October 2014. No sales have occurred and as a result, no royalty payments have yet been incurred or paid to GWU pursuant to the research agreement. We have also filed other patent applications related to Tβ4 and related compounds and indications for their use in countries throughout the world.

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 obligations will be triggered only upon the sale or license of our technology to a third-party.

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 our largest stockholder. These rights include indications relative to all of our current dermal clinical trials and AMIs, but exclude ophthalmic indications and other indications that are disease-based and not the result of a wound. Defiante will develop Tβ4 for internal and external wounds in Europe and certain other contiguous and geographically relevant countries. The 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 twelve years from the effective date of the agreement (which was in January 2004).

Under the Agreement, Defiante will pay us a royalty on commercial sales and we will supply all required Tβ4. When at least one positive Phase II clinical trial is completed, Defiante must either pay us $5 million or initiate a Pivotal Phase III clinical trial to maintain the license. Defiante also will be obligated to attain 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 required 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 entered into various agreements with a variety of outside service providers for the manufacture and development of Tβ4, formulation of product candidates, the conduct of pre-clinical safety, toxicology and efficacy studies in animal models, and management/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 the costs incurred for our clinical development over the past two years, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

Employees

To balance costs and optimize control, we utilize an outsourcing business strategy, whereby our internal, experienced management experts, tightly control outsourced activities for many of our research and development and administrative functions. Recognizing the periodic spikes in costs associated with a focused clinical development effort, complicated further by the constant variation in skills needed at any one time, ranging from chemical drug formulation to pre-clinical studies to clinical trial management, we believe that the use of outside contractors as and when needed is more cost-effective than directly employing and maintaining facilities to support these varied efforts. We currently have ten full-time employees.

Corporation Information

We were organized as a Delaware corporation in 1982. Our principal executive offices are located at 3 Bethesda Metro Center, Suite 630, Bethesda, Maryland 20814.

Available Information

For more information about us, visit our web site at www.regenerx.com. Our electronic filings with the U.S. Securities and Exchange Commission (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) are available free of charge through our web site as soon as reasonably practicable after we have electronically filed such information with, or furnished such information to, the Securities and Exchange Commission (the "SEC"). In addition, the public may read and copy any materials we filed with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC, 20549, on official business days during the hours of 10:00 a.m. to 3:00 p.m. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding our electronic filings with the SEC.

Item 1A. Risk Factors,

Risks Related to Our Business

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

We have sustained operating losses since our inception in 1982. We believe these losses will continue for the foreseeable future as we pursue our product development efforts related to Tβ4. As of December 31, 2007, our accumulated deficit totaled $67.4 million and our cash and cash equivalents totaled $8.3 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 potential to become profitable will depend largely on our ability, alone or through the efforts of third-party licensees, 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 these objectives will occur 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.

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.

We anticipate that substantial new capital resources will be required to continue our independent development efforts, including any and all follow-on trials that will result from our current clinical programs, and increasingly scaled-up manufacturing processes for RGN-137, RGN-259 and RGN-352. 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 complete and the requirements established by regulatory authorities,
- the speed with which we complete our clinical trials complete, which depends on the speed with which we can 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 patent legal regimes and claims/infringement assertions that may arise between us and third-parties,
- the ability to manufacture at scales sufficient to supply commercial quantities, which may require levels of effort not currently anticipated and
- the successful commercialization of our drug 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 debt, or other similar financial instruments. While we recently closed a private placement of $5 million in common stock and warrants to purchase common stock involving certain of our existing investors, 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 capital in sufficient amounts, or on acceptable terms, or at times critical to the uninterrupted execution of our business strategy.

One potential source of capital often capitalized on by emerging biotechnology companies similar to RegeneRx is through licensing certain intellectual property rights to other biotechnology or pharmaceutical enterprises, i.e. a "strategic partner." 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. In addition and as the business priorities of the strategic partner change over time, the possibility exists that the interests of the strategic partner may shift causing a material negative impact on the value of our interest in the licensed products. 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 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.

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, partnering and earnings potential. It is likely we will face many of the difficulties that new technology companies 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 Federal and International regulatory authorities,
- delays inherent in and increasingly more common 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 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 growth and earnings 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 parties, 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 ("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 Tβ4; formulate RGN-137, RGN-259 and RGN-352 into the drug candidates RGN-137, RGN-259 and RGN-352; develop requisite assays to assess Tβ4's affect in complex biological systems, recruit 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 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 discovery and 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, 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 is dependent on, among other things, FDA and investigational review board ("IRB") reviews, clinical site approvals, successful manufacturing of clinical materials, sufficient funding 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 following:

- the FDA or other health regulatory authorities, or institutional review boards, 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;
- patients die during a clinical trial for a variety of reasons that may or may not be related to our product candidates, including the advanced stage of their disease and 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.

We may not be able to enter into strategic relationships with third parties related to the development and commercialization of our product candidates

One of our strategic focuses is to enter into relationships with one or more third-party pharmaceutical companies to license our technology and to help us continue the development of our product candidates. We believe that having such partners would enable us to both defray the costs associated with the development of our product candidates and accelerate the speed with which we may be able to complete development of and obtain regulatory approval for our product candidates and commercialize such products. However, we can offer no assurance that we will be able to enter into license and development agreements with third-party pharmaceutical companies or that any such relationships would in fact decrease our costs or accelerate our product development efforts. If we are unable to enter into such relationships, our product development efforts may be slowed or related costs may increase. In addition, any such relationships would require us to give up significant rights in our product candidates, which rights may, over time, have been worth more to us if we had been able to commercialize such product candidates without entering into third-party agreements.

Mauro Bove, a member of our Board, is also a director and officer of Sigma-Tau, our largest stockholder, which could give rise to a conflict of interest involving Mr. Bove.

Mauro Bove, a member of our Board, is also a director and officer of Sigma-Tau, our largest stockholder and our partner in Europe with respect to the development of certain of our drug candidates. We recently issued shares of common stock and common stock warrants to certain affiliates of Sigma-Tau in a private placement that gave us the right to repurchase the shares under certain circumstances. Also, in 2004, we licensed Tβ4 to Defiante Farmaceutica S.p.A., a wholly-owned subsidiary of Sigma-Tau, for internal and external wound healing for the European Union. Upon the successful completion of a Phase II trial Defiante is obligated to either make a $5 million milestone payment or initiate and pay for a Pivotal Phase III trial. 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.

We are heavily reliant on our license from the National Institutes of Health and may be unable to maintain our license.

We have received an exclusive world-wide license to intellectual property discovered at the National Institutes of Health, or NIH, pertaining to wound healing and tissue repair. 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. 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 product candidates.

All of our drug candidates are based on a single compound that has yet to be proven effective.

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 the success of our company. 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 we were more diversified.

Our new 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 reasons 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 and if we are unable to identify suitable replacement suppliers, 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; and, if we are unable to identify a replacement manufacturer to perform these functions on acceptable terms, our development programs, collectively or individually, 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;
- 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 executives 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 and the loss of our chairman, Allan Goldstein, or 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. However, we cannot assure you that such agreements would prevent them from terminating their employment with or without good reason. 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 will 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.

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 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 that have extensive experience in conducting research and development activities and clinical trials and in obtaining the regulatory approvals necessary to market pharmaceutical products. 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, 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 communicated. We will 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 the 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 of Tβ4 is dependent in part on our ability to obtain sufficient product liability insurance or to collaborate with corporate partners that have adequate insurance. Although we intend to obtain 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 organizations such as HMOs, 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 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 payors will not reduce the demand for, or the price of, our product candidates. The lack or inadequacy of third-party reimbursements for certain of 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 collaborative partner 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 expect to study 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, these 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 that all of our drug candidates are based on Tβ4 cross-over risk exists, that is a patient in one trial may be adversely impacted by one drug candidate and that adverse event may have implications to our other trials and other drug candidates. However, even if unrelated to our product candidates, such events can nevertheless adversely impact our clinical trials. As a result, our business and ability to ultimately develop and market the product candidates and obtain revenues 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.

A number of factors, 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 may cause significant delays in the completion of our clinical trials. In addition, it may take longer than we expect to achieve study endpoints and complete data analysis for a trial. We may not complete our clinical trials when or as projected or commence or complete clinical trials involving any of our other product candidates as projected or may not conduct them successfully.

If we fail to complete or if we experience material delays in completing the Phase II 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 relatively novel and 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 or product candidates, when and if we are able to commercialize them, then we may never become profitable. Factors that could delay or inhibit 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
- effective 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 market and technology 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 use hazardous and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly, 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.

To the extent 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 in markets outside the United States that we must overcome to the extent we enter or attempt to enter markets in countries other than the United States. We currently intend to market any approved products in the United States, Europe, Japan, India and territories surrounding the Pacific Rim. We will 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 to the extent we enter markets outside the United States.

We may not be able to obtain orphan drug exclusivity for our product candidates. If our competitors are able to obtain orphan drug exclusivity for a product that is competitive with one or more of our product candidates and we cannot show that our product candidate is clinically superior, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including Europe and the United States, may designate drugs that target relatively small patient populations as orphan drugs. In June 2004, we received Orphan Drug designation from the FDA for Tβ4 for the treatment of Epidermolysis Bullosa, or EB, a rare genetic disease characterized by the presence of extremely fragile skin and other tissues, resulting in recurrent blisters from minor mechanical friction or trauma, and we may pursue orphan drug designation for additional product candidates. 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 a period of marketing exclusivity. The exclusivity applies only to the indication for which the drug has been designated and approved. The applicable exclusivity period is seven years in the United States, but this period may be interrupted if a sponsor of a competitive product that is otherwise the same drug for the same use can show that its drug is clinically superior to our orphan drug candidate. The European exclusivity period is ten years, but may be reduced to six years if a drug no longer meets the criteria for orphan drug designation, including where it is shown that the drug is sufficiently profitable so that market exclusivity is no longer justified. In addition, European regulations establish that a competitor's marketing authorization for a similar product with the same indication may be granted if there is an insufficient supply of the product or if another applicant can establish that its product is safer, more effective or otherwise clinically superior. If a competitor obtains orphan drug exclusivity for a product competitive with EB before we do and if the competitor's product is the same drug with the same indication as ours, we would be excluded from the market, unless we can show that our drug is safer, more effective or otherwise clinically superior. Even if we obtain orphan drug exclusivity for EB for these indications, we may not be able to maintain it if a competitor with a product that is otherwise the same drug can establish that its product is clinically superior.

Risks Related To Our Intellectual Property

If we are not able to maintain adequate patent protection for our product candidates and product candidates, we may be unable to prevent our competitors from using our technology or technology that we license.

Our success also 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 a research agreement with The George Washington University, we have rights to two U.S. patents relating to the treatment of septic shock. We also own patents related to the use of Tβ4, among other thymic peptides, for the stimulation of hair growth. Pursuant to an exclusive world-wide 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 as to 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 lesson the value of our rights under any patents that may be obtained and may decrease revenues derived from its patents. The United States patent laws were amended in 1995 to change the term of patent protection 17 years from 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. This would shorten our period of patent exclusivity and may decrease the revenues that we might derive from the patents and the value of our patent portfolio.

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

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

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

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

Risks Related To Our Securities

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

During the year ended December 31, 2007, our closing stock price has ranged from $1.00 to $2.75 with an average daily trading volume of 23,543 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; and
- 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 the common stock, which could cause a decline in the value of the common stock. 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 17, 2008, our officers, directors and principal stockholders together control approximately 53% of our outstanding common stock. Included in this group is Sigma-Tau and its affiliates which together hold outstanding shares representing 41% of our outstanding common stock. Certain shares of common stock held by Sigma-Tau and its affiliates, representing 13% 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. In addition, these voting agreements expire with respect to securities representing 10% of our outstanding common stock on February 22, 2011 and with respect to securities representing 3% of our outstanding common stock on June 23, 2010. After such time, we will have no control over the voting and disposition of these securities, 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. This concentration of ownership may not be in the best interest of our other stockholders.

A sale of a substantial number of shares of our common stock 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 17, 2008, there were issued and outstanding 51,553,527 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 harm the market price of our common stock. As of March 17, 2008, directors, officers and ten percent (10%) stockholders hold 27,456,290 shares of our common stock and may sell such shares at their discretion subject to certain contractual and regulatory limitations.

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 17, 2008, there were outstanding options to purchase an aggregate of 3,545,000 shares of our common stock at prices ranging from $0.28 per share to $3.80 per share, of which options to purchase 2,153,416 shares were exercisable as of such date. As of March 17, 2008, there were outstanding warrants to purchase 3,855,878 shares of our common stock, at a weighted average exercise price of $3.12. 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 (as in a stock dividend or stock split) will result in dilution to each stockholder by reducing his or her percentage ownership of the total outstanding shares. Moreover, to the extent that we issue options or warrants to purchase our common stock in the future and those options or warrants are exercised or we issue restricted stock, stockholders may experience further dilution. Holders of shares of our common stock have no preemptive rights that entitle them to purchase their pro rata share of any offering of shares of any class or series.

Our certificate of incorporation, our rights agreement and Delaware law contain provisions that could discourage a takeover, even if such a transaction would be in your best interests.

Our certificate of incorporation provides our Board with the power to issue shares of preferred stock without stockholder approval. In addition, under our rights agreement, 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 during the three-year period following the time that such stockholder becomes an interested stockholder. This provision could 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.

Item IB. Unresolved Staff Comments.

We are not currently involved in, nor are there any pending, material legal proceedings.

Item 2. Properties.

Our corporate headquarters are located in Bethesda, Maryland where we lease office space. Our lease was extended in January 2008 for twenty-four (24) months through December 31, 2009. We currently are exploring other facilities for our corporate headquarters and believe that there are larger and more suitable properties available requiring financial commitments that are not materially different than our current location.

Item 3. Legal Proceedings.

We are not currently involved in, nor are there pending, any material legal proceedings.

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 American 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.

	2007		2006	
	High	Low	High	Low
First Quarter	$ 2.41	$ 2.06	$ 3.41	$ 2.85
Second Quarter	$ 2.75	$ 2.00	$ 3.05	$ 2.52
Third Quarter	$ 2.18	$ 0.93	$ 2.75	$ 1.79
Fourth Quarter	$ 1.75	$ 0.94	$ 2.96	$ 1.97

As of March 21, 2008, there were approximately 894 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 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 are developing three Tβ4-based drug formulations including: 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 our planned Phase II acute myocardial infarction ("AMI"), or heart attack trial. We are currently sponsoring, in parallel, three Phase II dermal wound healing clinical trials using RGN-137, a Phase II ophthalmic wound healing trial using RGN-259, and a Phase IA clinical trial utilizing RGN-352 to support our cardiovascular clinical program. Under our Phase II Investigational New Drug Application ("IND"), an affiliate of our largest stockholder is conducting one of the Phase II dermal wound healing clinical trials in the European Union and has assumed all associated costs. Accordingly, we are primarily responsible for the costs associated with the other four trials.

We have never generated revenues, and we do not expect to generate revenues until the FDA approves one of our product candidates, if ever, and we begin marketing it. 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 revenues to achieve and then maintain profitability. Also, we expect that we will need to raise substantial additional outside capital in order to meet these capital requirements. We cannot assure you 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; 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 also 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. 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 expect to incur in future research and development costs for our pre-clinical studies as these amounts are subject to the outcome of current pre-clinical 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; review, draft and negotiate various financing, manufacturing and other corporate documents; research and conclude on appropriate financial reporting issues, Sarbanes-Oxley compliance, and financial audits required by the Securities and Exchange Commission. 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 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 Statement of Financial Accounting Standards No. 123R ("SFAS No. 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 Statement No. 123R. Under the fair value recognition provisions of Statement No. 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 Statement No. 123R adoption, 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, 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 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, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement 109" ("FIN 48"). This statement clarifies the criteria that an individual tax position must satisfy for some or all of the benefits of that position to be recognized in a company's financial statements. FIN 48 prescribes a recognition threshold of more-likely-than-not, and a measurement attribute for all tax positions taken or expected to be taken on a tax return, in order for those tax positions to be recognized in the financial statements. Effective January 1, 2007, we adopted the provisions of FIN 48, and determined that the impact had no material effect on our financial statements.

In September 2006, and February 2007 the FASB issued FASB Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("FAS 157"), and Statement of Financial Accounting Standards 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 are effective for fiscal years beginning after November 15, 2007. We do not anticipate the adoption of these standards will 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 is effective for fiscal years beginning after December 15, 2007. Historically we expense nonrefundable advance payments when paid. We have determined that approximately $35,000 in qualifying transactions require capitalization in accordance with EITF 07-03 as of January 1, 2008. In order to adopt the provisions of this statement, we will recognize a cumulative-effect adjustment to retained earnings as of that date.

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS No. 141(R)"). SFAS 141(R) requires the acquiring entity in a business combination to recognize the full fair value of assets acquired and liabilities assumed in the transaction (whether a full or partial acquisition); establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed; requires expensing of most transaction and restructuring costs; and requires the acquirer to disclose to investors and other users all of the information needed to evaluate and understand the nature and financial effect of the business combination. SFAS No. 141(R) applies to all transactions or other events in which the Company obtains control of one or more businesses, including those sometimes referred to as "true mergers" or "mergers of equals" and combinations achieved without the transfer of consideration, for example, by contract alone or through the lapse of minority veto rights. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements — an amendment of Accounting Research Bulletin No. 51" ("SFAS No. 160"). SFAS No. 160 requires reporting entities to present noncontrolling (minority) interests as equity (as opposed to as a liability or mezzanine equity) and provides guidance on the accounting for transactions between an entity and noncontrolling interests. SFAS No. 160 applies prospectively as of January 1, 2009, except for the presentation and disclosure requirements which will be applied retrospectively for all periods presented.

Results of Operations

Comparison of years ended December 31, 2007 and 2006

Revenues. For the year ended December 31, 2007, our revenue decreased by approximately $32,000 or 12%, to approximately $240,000, versus approximately $272,000 in 2006. Our revenue in 2007 consisted entirely of costs recoverable as revenue through our grant from the NIH for the orphan indication EB, which amounted to $32,000 less than they were in 2006. The reduced level of costs recoverable was primarily due to the fact that in 2006 the recoverable costs were a combination of both CRO and site initiation expenses as well as patient treatment expenses. In 2007 the majority of sites had previously been initiated so the costs were primarily a function of patient care and ongoing trial management. We have approximately $32,000 remaining to be claimed under this grant and expect to claim those costs during 2008.

Expenses — Research and development. For the year ended December 31, 2007, our R&D, expenditures increased by approximately $2.5 million, or 39%, to approximately $8.9 million, versus approximately $6.4 million in 2006. Outsourced R&D expenditures, those costs incurred to make and formulate our drug candidates and manage our pre-clinical and clinical activities, accounted for approximately $1,800,000 of the overall increase, rising 37% to approximately $6.7 million. Outsource R&D expenditures included increases of approximately $1,000,000 related to our ophthalmic trial, $400,000 for the purchase of Tβ4, $200,000 for our Phase I parenteral trial, $200,000 for research projects and $100,000 for clinical drug supply. These increases were offset by a ($100,000) decrease in expenses related to two of our Phase II dermal trials.

In addition, cash and non-cash compensation expenses and employee benefits, increased by approximately $600,000, or 50%, in 2007 to a total of approximately $1,800,000, including approximately $422,000 of non-cash compensation expense. This increase is in line with our weighted average increase in full time equivalent ("FTE") employees, which increased 52% during the same period. During 2007 we hired a Director of Product Manufacturing to oversee non-GMP and GMP manufacturing of our various drug formulations, and a clinical research associate to oversee our clinical site operations. These new employees in combination with a full year's worth of employment of R&D personnel hired mid-2006 account for the FTE increase.

In addition, other miscellaneous R&D costs increased by approximately $100,000, or 28%, in 2007 to a total of approximately $400,000. This increase is attributable primarily to increases in costs associated with outside consulting, overhead allocations and travel, which each increased by approximately $35,000, $45,000 and $20,000, respectively. Outside consulting costs rose as we expanded our clinical programs and we placed certain research experts on retainer to advise us on our clinical development. Overhead allocations rose as a function of the increase in our R&D personnel relative to our general and administrative personnel. This yielded a higher allocation of our core infrastructure costs to R&D. Finally, with an increase in the number of clinical sites, the expansion of our clinical programs, and the addition of a clinical research associate who travels frequently, our travel costs have increased.

Expenses — General and administrative. For the year ended December 31, 2007, our G&A, expenses increased by approximately $532,000, or 20%, to approximately $3.2 million, versus approximately $2.7 million in 2006. The majority, approximately $500,000, of the increase was attributable to increased outside professional fees. These increased costs were due to increased costs to maintain our increasing intellectual property portfolio. Cash and non-cash compensation expenses and employee benefits increased in 2007 by approximately $190,000, or 17%, to a total of approximately $1,300,000, including $612,000 of non-cash compensation expense. Approximately $110,000 of this increase in compensation expense is due to the increase in non-cash compensation expenses recognized as a result of the issuance of stock options in the first quarter of 2007. The remaining increase in compensation expense of $80,000 is attributable to a cost of living increase in salaries of 4% and slightly higher discretionary and non-discretionary bonus payments in 2007. All other G&A costs in 2007 decreased by approximately $158,000, or 24%, due primarily to a reduction in outside investor relation services.

Comparison of years ended December 31, 2006 and 2005

Revenues. For the year ended December 31, 2006, our revenues totaled approximately $272,000. We did not have revenues in 2005. In 2006, we were awarded a grant from the NIH for our orphan indication EB. Consequently, we were able to claim reimbursement for qualifying costs incurred under this grant during 2006 which amounted to $272,000. Those qualifying costs were incurred from May 15, 2006 through December 31, 2006 and related to trial management by our CRO, site initiations and patient care.

Expenses — Research and development. For the year ended December 31, 2006, our R&D expenditures increased by approximately $3.2 million, or 103%, to approximately $6.4 million, versus approximately $3.2 million in 2005. This increase resulted from the increased R&D activities that we undertook in 2006 as clinical development progressed. During 2005, some pre-clinical activities were active in the first half of the year, clinical drug formulation activities concluded on our dermal gel product candidate, and Phase II clinical dermal trials commenced in the later half of the year. During 2006 we continued to manage our Phase II clinical dermal trials throughout the year and expanded our clinical development program into the cardiac and ophthalmic areas. Specifically, drug formulation, protocol development, contractor selection, and site qualification were commenced during 2006 for our planned myocardial infarction and ophthalmic wound healing trials. To manage these expanding research efforts, we increased our research staffing from a weighted average 2.5 FTEs in 2005 to 5.1 FTEs in 2006, a 103% increase. Coincident with our expanded development was the need to supply increasingly larger amounts of Tβ4, along with a significant increase in outsourced contract activity. All of these expanded efforts increased our research and development costs.

Expenses — General and administrative. For the year ended December 31, 2006, our G&A expenditures increased by approximately $152,000, or 6%, to approximately $2.7 million. During April of 2005, we hired a chief financial officer, which increased our weighted-average FTEs from 2.7 to 3.0 in 2006, a 10% increase. We also implemented employee benefits in 2006 in order to help attract employees. The resulting increase in payroll and benefits cash expenses for these items, along with the annual cost of living increase amounted to approximately $129,000, or 26%, over 2005. As a direct result of our implementation of SFAS 123r, non-cash equity compensation expense increased by approximately $314,000 to approximately $502,000 in 2006. Offsetting these increases was a decrease in the amount of legal fees expended in support of our patent portfolio of approximately ($383,000). All other costs of a general and administrative nature for 2006 increased by approximately $92,000, or 6%.

Liquidity and Capital Resources

We had cash, cash equivalents and short-term investments totaling $8.2 million and $17.0 million for the years ending December 31, 2007 and 2006, respectively. The decrease in 2007 is primarily due to the fact that we had just completed a sale of common stock at the end of 2006 and used the proceeds from that transaction to finance operations throughout 2007. In February 2008 we concluded a $5 million private placement of common stock with affiliates of Sigma-Tau (see Note 12 to the Notes to the Financial Statements for more details).

Cash Flows

Net Cash Used in Operating Activities. Net cash used in operating activities was approximately $8.8 million and $7.2 million for the years ended December 31, 2007 and 2006, respectively. Our net loss in 2007 was approximately $2.4 million higher than our net cash used in operating activities in the same period. Our net loss in 2006 was approximately $1.1 million higher than our net cash used in operating activities in the same period. The $1.3 million increase in 2007 of our net operating loss over net cash used in operations was due primarily to the following: (i) we purchased and expensed approximately $900,000 of Tβ4 at the end of 2007 and paid for that purchase in the first quarter of 2008, (ii) our non-cash compensation expenses for 2007 were approximately $240,000 more than 2006 and (iii) we recorded approximately $190,000 more in grant revenue in 2007 than we received in cash.

Net Cash Used in Investing Activities. Net cash used in investing activities was $600,000 and $1.3 million for the years ended December 31, 2007 and 2006, respectively. In both years the level of fixed asset investment was less than $20,000, leaving the net remainder attributable to investments in and 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 2006 than in 2007 as a result of our cash management activity.

Net Cash Provided by Financing Activities. Net cash provided by financing activities totaled approximately $46,000 and $16.7 million for the years ended December 31, 2007 and 2006, respectively. The amounts provided in 2007 relate solely to the exercise of warrants. In 2006, we completed two issuances of common stock that netted approximately $16 million after deducting the costs of the transactions. In 2006, we also received proceeds of $774,000 upon the exercise of warrants.

Future Funding Requirements

The expenditures that will be necessary to execute our business plan are subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. As of December 31, 2007, we have three proprietary product candidates in clinical trials, development of which is primarily accomplished through cancellable third-party contracts. We are committed under an office space lease that expires on December 31, 2009 that requires monthly rental payments of $7,072 scheduled to increase by 3% in calendar 2009. We expect our R&D expenses to trend higher as our product candidates advance through the various stages of clinical development. 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.

We have not commercialized any of our product candidates to date and, since our inception we have primarily financed our operations through the issuance of common stock and common stock warrants in private and public financings. Since a number of significant budgeted items are discretionary and based on our capital resources as of the date of this report and including the proceeds of a $5 million private placement of common stock with affiliates of Sigma-Tau (see Note 12 in the Notes to the Financial Statements for more details), we believe that we have adequate resources to fund our operations through the fourth quarter of 2008, without considering the benefits of any potential future milestone payments that we may receive under our current collaborations, see "Material Agreements in Item 1. Business." However, there can be no assurance that we will be able to attain such milestones and generate any such payments. Accordingly, we expect to continue to seek funding through public and private financings in the future. However, as a result of the uncertainties discussed above, among others, we are unable to estimate the duration and completion costs of our research and development projects.

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 recently closed a private placement of $5 million in common stock and warrants to purchase common stock involving certain of our existing investors, 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 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 investments in marketable securities, which are composed primarily of investment-grade corporate bonds, U.S. government agency debt securities and asset-backed 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, 2007, cash, cash equivalents and short-term investments were $8.3 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, 2007, 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. Controls and Procedures.

Disclosure controls and procedures are 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. 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.

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 the year ended December 31, 2007. 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, 2007.

Item 9A(T). 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 Rule 13a-15(f). 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, 2007.

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.

There were no changes in our internal control over financial reporting during the three months ended December 31, 2007, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information.

On March 27, 2008, we received a warning letter from the American Stock Exchange, or Amex citing a minor violation, in connection with our recently announced private placement of securities completed on February 29, 2008, of Section 301 of the Amex Company Guide, which provides that a listed company may not issue, or authorize its transfer agent or registrar to issue or register, additional securities of a listed class until it has filed an application for the listing of such additional securities and received notification from Amex that the securities have been approved for listing. We filed an application on March 21, 2008, for the listing of the additional securities referenced in the notification from Amex. As of the date hereof, we had not yet received approval to list the additional shares although we expect to receive such approval upon completion of the application review by Amex within approximately two weeks.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our Board of Directors consists of six directors. Our bylaws allow for not less than three and not more than seven directors. Directors are elected annually to serve one-year terms.

The following sets forth, with respect to each director and executive officer, his name and age, the year in which he first joined our Board, if applicable, and his principal occupation and business experience during the past five years.

Name	Age	Principal Occupation/Position Held	Director since
Allan Goldstein.....	70	Chairman of the Department of Biochemistry and Molecular Biology, The George Washington University School of Medicine and Health Sciences. Founder of RegeneRx, Chairman of the Board and Chief Scientific Advisor	1982
J.J. Finkelstein.....	55	President and Chief Executive Officer of RegeneRx	2002
Rick Hindin.....	65	Principle stockholder, Chicken Out Rotisserie Inc.	2002
Joseph McNay.....	74	Chairman, Chief Investment Officer and Managing Principal of Essex Investment Management Company, LLC	1987
Mauro Bove	52	Head of Corporate & Business Development and Director of Sigma-Tau Finanziaria S.p.A., and certain Sigma-Tau affiliates	2004
Thompson Bowles	76	Retired, thoracic surgeon and former Dean of Medicine and Professor of Surgery at The George Washington University School of Medicine and Health Sciences	2006
David Crockford.....	62	Vice President Clinical and Regulatory Affairs of RegeneRx	N/A
C. Neil Lyons.....	50	Chief Financial Officer of RegeneRx, certified public accountant	N/A

Dr. Goldstein has served as the Chairman of our Board of Directors and our Chief Scientific Advisor since he founded our company in 1982. Dr. Goldstein has since 1978 served as a Professor of Biochemistry and Chairman of the Department of Biochemistry and Molecular Biology at the George Washington University School of Medicine and Health Sciences ("George Washington"). Dr. Goldstein is a recognized expert in the field of immunology and protein chemistry, having authored more than 428 scientific articles in professional journals. He is also the inventor on over 15 U.S. Patents. Dr. Goldstein discovered several important compounds, including Tα1 and Tβ4, that are either in clinical trials and/or marketed in certain countries around the world. Dr. Goldstein has served on the Board of Trustees of the Sabin Vaccine Institute since 2000 and on the Board of Trustees of the Richard B. and Lynne V. Cheney Cardiovascular Institute since 2006. Dr. Goldstein has also done pioneering work in the area of medical education, developing distance learning programs offered through "Frontiers in Medicine," a medical education series that Dr. Goldstein developed and utilized in connection with his work at George Washington.

Mr. Finkelstein has served as our President and Chief Executive Officer and a member of our Board of Directors since 2002. Mr. Finkelstein also served as our Chief Executive Officer from 1984 to 1989 and as the Vice Chairman of our Board of Directors from 1989 to 1991. Mr. Finkelstein has worked as an executive officer and consultant in the bioscience industry for the past 25 years, including serving from 1989 to 1996 as chief executive officer of Cryomedical Sciences, Inc., a publicly-traded medical device company. Mr. Finkelstein has significant experience in developing early-stage companies. He has been responsible for the regulatory approval and marketing of several medical devices in the U.S. and abroad and has raised more than $80 million in capital to finance these ventures. Mr. Finkelstein has served on the executive committee of the Board of Directors of the Technology Council of Maryland since 2006 and MdBio, Inc. since 1998, non-profit entities that support bioscience development and education in the State of Maryland. Mr. Finkelstein received a business degree from the University of Texas where he majored in finance.

Mr. Hindin has served as a member of our Board of Directors since 2002 and as our Secretary since 2004. Mr. Hindin is the principal stockholder of Chicken Out Rotisserie, Inc., which operates 21 restaurants in four states and the District of Columbia. In 1967, Mr. Hindin co-founded Britches of Georgetown, Inc., a clothing retailer specializing in the sale of upscale men's and women's apparel and accessories. Mr. Hindin has served since 1987 as a member and since 1989 as the chairman of the board of directors of The Institute for Advanced Studies in Aging & Geriatric Medicine, IASIA, a non-profit corporation that specializes in disseminating medical information to the public as well as providing the pharmaceutical industry with an independent source for testing vaccines and drugs for the elderly. Since 1990, Mr. Hindin has also served as Chairman of the Board of Hinsilblon Laboratories Ltd., a company based in Cape Coral, Florida which sells odor neutralization products and delivery systems. Since 1987, Mr. Hindin has also served as President of Adworks Inc, a Washington D.C.-based advertising and marketing consulting agency.

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

Mr. Bove has served as a member of our Board of Directors since 2004. Mr. Bove is currently the Head of Corporate & Business Development and serves on the board of Sigma-Tau Finanziaria S.p.A., a leading international pharmaceutical company, and certain Sigma-Tau affiliates, positions he has held for more than five years. Mr. Bove has also held a number of senior positions in business, licensing and corporate development within Sigma-Tau, which has subsidiaries in most European countries and the United States. Mr. Bove has more than 20 years of business and management experience within the pharmaceutical industry. Mr. Bove obtained his law degree at the University of Parma, Italy, in 1980. In 1985, he attended the Academy of American and International Laws at the International and Comparative Law Center, Dallas, Texas. Sigma-Tau Finanziaria and affiliates are our largest stockholder.

Dr. Bowles has served as a member of our Board of Directors since 2006. He retired from his career as a thoracic surgeon in 1988. Dr. Bowles served as Dean of Medicine and Professor of Surgery at The George Washington University ("GWU") School of Medicine and Health Sciences from 1976 to 1988 and as Vice President for Medical Affairs and Executive Dean of the GWU Medical Center from 1988 to 1992. Dr. Bowles previously served as President of the National Board of Medical Examiners, the medical accrediting organization, from 1992 to 2000. He has also been a member of the National Academy of Sciences Institute of Medicine since 1988 and currently serves as a member of several other national medical societies including: The American College of Surgeons, The American Association for Thoracic Surgery, The Society of Thoracic Surgeons, The American College of Chest Physicians, The American Gerontological Society, The Society of Medical Administrators, The College of Physicians of Philadelphia, and The Washington Academy of surgeons. Dr. Bowles has served on the editorial board of a number of medical journals, including the Journal of Medical Education and continued on as chairman of its newly revised updated version, Academic Medicine. Dr. Bowles has been President of the District of Columbia's medical licensing board called the Healing Arts Commission (1977-1979), and was a member of the National Library of Medicine's Board of Regents (1982-1986), chairman (1984-1986), member of the Special Medical Advisory Group of Veterans Administration (now Dept. of Veterans Affairs) 1984-1992, chairman 1992-1994. Dr. Bowles was also chairman of the National Committee on Foreign Medical Education and Accreditation, 1994-1996. Dr. Bowles received his medical degree from Duke University and his Ph.D. from New York University.

Mr. Crockford has served as our Vice President of Clinical and Regulatory Affairs, since March 1, 2005 and was a consultant to the Company from 2000 until his appointment as Vice President.. He has more than 25 years of experience in the biotechnology and pharmaceutical industries. During his career as a clinical and regulatory affairs professional, Mr. Crockford established strategic plans, implemented and obtained marketing approval for 18 drug products, including one of the first human growth hormone preparations sold in the U.S., 17 in vitro diagnostic tests, and an intraoperative medical device to detect and treat cancer. Mr. Crockford's other clinical and regulatory achievements include the cost-effective and timely development of a number of innovative investigational drugs. Mr. Crockford has a number of publications and is an inventor or co-inventor on more than a dozen patents.

Mr. Lyons has served as our Chief Financial Officer and Treasurer since 2005, providing seasoned leadership in the areas of finance and administration. With more than 25 years of experience, Mr. Lyons has developed expertise related to operations, finance, SEC regulations, complex transactions, strategy, information systems and corporate governance. From 1979 to 1990, Mr. Lyons practiced with Deloitte, providing assurance and advisory services to several public companies in the Washington, D.C. metro area. Following that, Mr. Lyons served as a senior financial executive with HFS, Inc. (a major Department of Defense contractor) from 1990 to 1996, with Bell Atlantic from 1996 to 1998, with SkyBridge LP (an international satellite broadband start-up affiliated with Alcatel) from 1998 to 2003, and consulting with area businesses regarding the initial implementations of the Sarbanes-Oxley Act from 2003 to 2005. Mr. Lyons is a certified public accountant ("CPA") and received a Bachelor of Science degree, magna cum laude, from Florida Southern College where he majored in accounting.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of our common stock, to report to the SEC their initial ownership of our common stock and any subsequent changes in that ownership. Specific due dates for these reports have been established by the SEC and we are required to disclose any late filings or failures to file.

To our knowledge, based solely on our review of the copies of such reports furnished to us, or written representations that no filings were necessary, we believe that during the past fiscal year our officers, directors and greater than ten percent (10%) beneficial owners complied with all filing requirements.

Corporate Governance

The Board expects all directors, as well as our officers and employees, to act ethically at all times and to adhere to the policies outlined in our Corporate Code of Conduct and Ethics. The Board also expects the Principal Executive Officer (our Chief Executive Officer or CEO), and the Principal Financial Officer (our Chief Financial Officer or CFO) to adhere to our Code of Ethics for the Principal Executive Officer and Principal Financial Officer. These documents, as well as our charters for standing committees of our Board can be found at www.regenerx.com. These documents are also available in print to any security holder who requests it by contacting our Investor Relations department at RegeneRx Biopharmaceuticals, Inc., 3 Bethesda Metro Center, Suite 630, Bethesda, Maryland 20814, or by phone at 301-280-1992, or by e-mail to info@regenerx.com.

Communication with the Board of Directors

We have established procedures for our security holders to communicate directly with the Board on a confidential basis. Security holders who wish to communicate with the Board or with a particular director may send a letter to the Secretary of the Company at 3 Bethesda Metro Center, Suite 630, Bethesda, Maryland 20814. The mailing envelope must contain a clear notation indicating that the enclosed letter is a "Security Holder-Board Communication" or "Security Holder-Director Communication." All such letters must identify the author as a security holder and clearly state whether the intended recipients are all members of the Board or just certain specified individual directors. The Secretary will make copies of all such letters and circulate them to the directors addressed. If a security holder wishes the communication to be confidential, such security holder must clearly indicate on the envelope that the communication is "confidential." The Secretary will then forward such communication, unopened, to the individual indicated.

Audit Committee Matters

The Audit Committee of the Board consists of Messrs. Hindin, McNay and Bowles, with Mr. Hindin acting as the Chair. Mr. Hindin was appointed the Chair of the Audit Committee on July 26, 2006. The Audit Committee meets no less than quarterly with management and the independent registered public accounting firm, both jointly and separately, has sole authority to hire and fire our independent registered public accounting firm, and reviews our financial reporting process on behalf of the Board. The Audit Committee operates under a formal written charter available on the Company's website at www.regenerx.com.

Each member of the Audit Committee is an independent member director in accordance with both Section 121A of the American Stock Exchange Company Guide, and Rule 10A-3 of the Exchange Act. Furthermore, the Board has determined that Messrs. Hindin and McNay qualify as "audit committee financial experts" as defined under SEC rules.

The Audit Committee pre-approves all audit and non-audit engagement fees, and terms and services. On an ongoing basis, management communicates specific projects and categories of services for which advance approval of the Audit Committee is required. The Audit Committee reviews these requests and advises management and the independent auditors if the Audit Committee pre-approves the engagement of the independent auditors for such projects and services. On a periodic basis, the independent auditors report to the Audit Committee the actual spending for such projects and services compared to the approved amounts.

Item 11. Executive Compensation.

The following table shows for the fiscal years ended December 31, 2007 and 2006, compensation awarded to or paid to, or earned by, our CEO and the next two highest paid executive officers during 2007 (the "Named Executive Officers").

Name and Principal Position...	Year	Salary (1)	Bonus (2)	Option Awards (3)	Non-Equity Incentive Plan Compensation (4)	All Other Compensation (5)	Total
J.J. Finkelstein,.....	2007	$ 299,520	$ 22,464	$ 116,808	$ 22,464	17,322	$ 478,578
Chief Executive Officer	2006	288,000	15,000	72,500	—	15,990	391,490
Neil Lyons, ...	2007	194,432	11,798	145,424	11,798	8,094	371,546
Chief Financial Officer	2006	182,053	9,454	118,840	—	7,268	317,615
David Crockford, ...	2007	202,792	12,246	120,574	12,246	11,425	359,283
VP Clinical and Regulatory Affairs	2006	192,708	9,813	72,500	—	10,552	285,573

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

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

(3) These amounts reflect expense recognized by us for a portion of the current and prior year option awards to our named executive officers, or NEOs, adjusted to assume no forfeitures of the awards. Reference is made to Note 2 "Summary of Significant Accounting Policies" in this Form 10-K for the period ended December 31, 2007, which identifies assumptions made in the valuation of option awards in accordance with SFAS 123R.

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

(5) Primarily reflects our match of executive compensation deferrals into our 401(k) plan, along with supplemental life and disability insurance premiums. None of the individual items exceeded $10,000.

Outstanding Equity Awards at December 31, 2007

The following information outlines outstanding equity awards held by the named executive officers as of December 31, 2007. All of these outstanding equity awards are in the form of stock option awards and none of our named executive officers hold any stock awards. All stock option awards reflected in the table below were granted from our Amended and Restated 2000 Stock Option and Incentive Plan.

	Option Awards				
Name and Principal Position	Option Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($/sh)	Option Expiration Date
J.J. Finkelstein,.....	1/1/2002 (1)	500,000		$ 0.33	1/1/2012
Chief Executive Officer	4/1/2005 (2)	50,000	50,000	3.21	4/1/2015
	3/15/2007 (2)	—	125,000	2.34	3/15/2014
Neil Lyons, ...	4/7/2005 (3)	66,667	133,333	3.10	4/7/2015
Chief Financial Officer	3/15/2007 (2)	—	75,000	2.34	3/15/2014
David Crockford, ...	7/1/2003 (4)	15,000		1.07	7/1/2013
VP Clinical and Regulatory Affairs	1/1/2004 (5)	56,250	68,750	0.86	1/1/2014
	4/1/2005 (5)	25,000	75,000	3.21	4/1/2015
	5/25/2005 (5)	6,250	18,750	3.82	5/25/2015
	1/16/2007 (2)	—	50,000	2.15	1/16/2014
	3/15/2007 (2)	—	75,000	2.34	3/15/2014

(1) The options vest and become exercisable in equal installments on the first three anniversaries of the grant date.

(2) The options vest and become exercisable in equal installments on the first four anniversaries of the grant date.

(3) The options vest and become exercisable in equal installments on the first six anniversaries of the grant date.

(4) The options fully vested upon issuance.

(5) The options vest and become exercisable on the first five anniversaries of the grant date in the following order: 10%, 15%, 20%, 25%, 30%.

Employment Agreements

We have entered into employment contracts with each of our named executive officers, including J.J. Finkelstein, David Crockford, and Neil Lyons our President and Chief Executive Officer; Vice President of Clinical and Regulatory Affairs; and Chief Financial Officer, respectively. Mr. Finkelstein's employment agreement was entered into January 1, 2002 and had an initial term of three years. The agreement is automatically extended for successive one-year terms unless we or Mr. Finkelstein elect not to extend the agreement. Messrs. Crockford and Lyons' employment agreements were entered into on March 1, 2005 and April 12, 2007, respectively, and both have initial terms of one year and are automatically extended for successive one-year terms unless we or Messrs. Crockford and Lyons elect not to extend the agreement. Pursuant to their respective employment agreements, Messrs. Finkelstein, Crockford and Lyons are entitled to participate in and receive all standard employee benefits and to participate in all of our applicable incentive plans, including stock option, stock, bonus, savings and retirement plans.

At any time during the terms of Messrs. Finkelstein, Crockford and Lyons' employment agreements, the Board may terminate their employment with or without cause. If Mr. Finkelstein is terminated without cause, then we are obligated to pay him a lump sum payment in an amount equal to his then annual base salary (less federal and state tax withholding) as severance pay. If Mr. Crockford is terminated without cause, then we are obligated to pay him a lump sum payment in an amount equal to 9 months of his then annual base salary (less federal and state tax withholding) as severance pay. If Mr. Lyons is terminated without cause, then we are obligated to pay him a lump sum payment in an amount equal to 6 months of his then annual base salary (less federal and state tax withholding) as severance pay. For both Mr. Crockford and Mr. Lyons their severance benefit increases to 100% of their then annual base salary after their third anniversary dates which will occur in March and April 2008, respectively. If their respective termination is for cause, then Messrs. Finkelstein, Crockford and Lyons are not entitled to receive any payment under their employment agreements beyond the date of their termination. For purposes of each employment agreement, "cause" is defined as: (i) refusal, failure or neglect to perform the material duties of his employment under this Agreement (other than by reason of the Executive's physical or mental illness or impairment); (ii) committing willful dishonesty, fraud, embezzlement or misconduct with respect to the business or affairs of the Company; (iii) indictment or conviction of a felony or of any crime involving dishonesty or moral turpitude; or (iv) the executive's refusal to abide by or comply with the directives of the Board or Chief Executive Officer (as applicable), so long as those directives are lawful and ethical.

Potential Payments Upon Termination or Change in Control

If employment had been terminated on December 31, 2007 without cause for any of our named executive officers, the individual would have been entitled to severance of six months in the case of Mr. Lyons, nine months in the case of Mr. Crockford, and one year in the case of Mr. Finkelstein. After Messrs Crockford and Lyons attain their third anniversary dates with us, which will be in March and April 2008, respectively, they too will be eligible for a one year severance benefit. Additionally, if the individual terminates his employment for any reason within 12 months after a change of control event, we are obligated to pay the individual a lump sum severance payment of like amount. For purposes of the employment agreements, change of control is defined as any of the following events: (a) the dissolution or liquidation of the Company; (b) the sale of all or substantially all of the assets of the Company to an unrelated person or entity; (c) a merger, reorganization or consolidation in which the holders of the Company's outstanding voting power immediately prior to such transaction do not own a majority of the outstanding voting power of the surviving or resulting entity immediately upon completion of such transaction; (d) the sale of all of the outstanding securities of the Company to an unrelated person or entity; (e) if any "individual, firm, corporation, or other entity, or any group (as defined in Section 13(d) of the Exchange Act) other than (1) a trustee or other fiduciary holding securities of the Company under an employee benefit plan of the Company or (2) the executive becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of (A) the outstanding shares of common stock of the Company, or (B) the combined voting power of the Company's then-outstanding securities entitled to vote generally in the election of directors; or (f) any other transaction in which the owners of the Company's outstanding voting power prior to such transaction do not own at least a majority of the outstanding voting power of the relevant entity after the transaction, in each case, regardless of the form thereof.

Our named executive officers are also entitled to continuation of health and welfare benefits for their respective severance period. The following table sets forth our potential payments upon termination or change in control as of December 31, 2007.

Name	Lump Sum Cash Severance Payment	Continuing Health and Welfare Benefits
J.J. Finkelstein	$ 299,520	$ 8,322
David Crockford	153,075	10,413
Neil Lyons	98,319	8,382
Severance entitlement after third anniversary date:		
David Crockford	210,223	13,884
Neil Lyons	202,537	16,764

Equity Compensation Plan Information

The following table gives information about our Common Stock that may be issued upon the exercise of options, warrants and rights under all existing equity compensation plans as of December 31, 2007.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column)
Equity compensation plans approved by stockholders	3,545,000	$ 1.80	620,000
Equity compensation plans not approved by stockholders	—	—	—
Total	3,545,000	$ 1.80	620,000

2007 Director Compensation

The following table provides the compensation paid to our directors, including annual board and committee retainer fees, and meeting attendance fees for the fiscal year ended December 31 2007. Information related to Mr. Finkelstein's compensation is detailed in the "Compensation of Named Executive Officers" section in this Annual Report on Form 10–K. Mr. Finkelstein does not receive any additional compensation for his services as a director.

Name	Fees earned or paid in cash	Option awards (2)	All other compensation	Total
Employee Director:				
Allan Goldstein	$ —	$ 99,084	$ 203,840 (3)	$ 302,924
Non-employee Directors:				
Richard Hindin	42,000	59,692	—	101,692
Thompson Bowles	20,650	89,980	—	110,630
Joseph McNay	19,450	59,692	—	79,142
Mauro Bove	18,300	59,692	—	77,992

(1) In 2007, each non-employee director was eligible to receive an annual cash retainer fee of $13,500 per year. In addition, the chairman of the Audit Committee and the chairman of the Compensation Committee, each receive an annual retainer of $10,000 for the committee chairmanship. In 2007 Mr. Hindin served as the chairman of both committees. Board members were eligible to receive $1,250 for each Board meeting at which the director was present in person, and $400 for each meeting the director participated by telephone. Board members are also eligible to receive $500 for each committee meeting attended, whether in person or by telephone.

(2) These amounts reflect expense recognized by us in 2007 for a portion of the current and prior year option awards to directors, adjusted to assume no forfeiture of the awards. Reference is made to Note 2 "Summary of Significant Accounting Policies" in this Annual Report on Form 10–K for the period ended December 31, 2007 which identifies assumptions made in the valuation of option awards in accordance with SFAS No. 123R. Beginning in 2007 and annually thereafter, our independent directors are eligible to receive a stock option to purchase 15,000 shares of our Common Stock. For 2007, those awards were granted on March 15, 2007. Starting with the 2008 Annual Meeting of Stockholders, those options will be granted upon re-election to the Board. These options vest annually over a four year period, in equal amounts, at each subsequent anniversary date of the grant. Newly elected independent directors will receive an option to purchase 35,000 shares of the Company's Common Stock upon appointment to our Board. At December 31, 2007 Messrs. Hindin, McNay and Bove each held 190,000 unexercised stock options, Dr. Bowles held 115,000 unexercised stock options, and Dr. Goldstein held 475,000 unexercised stock options.

(3) In addition to being Chairman of our Board, Dr. Goldstein also serves as the Company's Chief Scientific Advisor. In this capacity, Dr. Goldstein received compensation of $182,000 for 2007 and participates in the Company's bonus program. For 2007, Dr. Goldstein received a bonus of $10,920 based on the achievement of corporate performance goals and a discretionary cash bonus of $10,920. Dr. Goldstein is also entitled to receive his annual salary as severance, which was $182,000 at December 31, 2007. Dr. Goldstein is not entitled to receive any continuing health and welfare benefits as part of our severance obligation to him.

2000 Stock Option and Incentive Plan, as amended.

The 2000 Stock Option and Incentive Plan was approved 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 is to be determined by the Board but shall never 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. Presently, the authorized shares reserved for issuance under the plan is 4,200,000. We currently anticipate issuing new shares to fill any and all options that are exercised.

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

The following table shows, as of March 17, 2008, the beneficial ownership of the Company's common stock by (a) each security holder known to us to beneficially own more than 5% of our Common Stock, (b) each of our directors, (c) each of our Named Executive Officers, and (d) all of our directors and executive officers as a group.

In general, "Beneficial Ownership" refers to shares that an individual or entity has the power to vote or dispose of, and any rights to acquire Common Stock that are currently exercisable or will become exercisable within 60 days of March 17, 2008 ("Acquirable Within 60 Days.") Unless otherwise indicated, each person named below holds sole investment and voting power, other than the powers that may be shared with the person's spouse under applicable law. The Percent of Common Stock Outstanding represents the respective Beneficial Ownership amount as compared to the total of the Company's outstanding stock on March 17, 2008 which was 51,553,527 plus the respective individual's amount of shares Acquirable Within 60 Days.

Name of Beneficial Owner	Beneficial Ownership			
	Common Stock	Acquirable within 60 days	Total	Percent of class
Directors:				
J.J. Finkelstein	1,451,638	606,250	2,057,888 (1)	3.9%
Allan Goldstein	1,805,446	393,750	2,199,196	4.2%
Rick Hindin	1,592,710	160,000	1,752,710	3.4%
Joseph McNay	1,339,111	160,000	1,499,111	2.9%
Mauro Bove	—	160,000	160,000	*
Thompson Bowles	—	70,416	70,416	*
Executive officers who are not Directors:				
David Crockford	—	185,000	185,000	*
Neil Lyons	10,000	118,749	128,749	*
All directors, and executive officers as a group (8 persons)	6,198,905	1,854,165	8,053,070	15.1%
More than 5% stockholders:				
Sigma-Tau Finanziaria, S.p.A.	21,257,385	1,880,837	23,138,222 (2)	43.3%

* – less than 1%.

(1) Consists of (i) 1,413,138 shares owned directly by Mr. Finkelstein over which he has sole voting and dispositive powers; and (ii) 8,500 shares held by Mr. Finkelstein's minor daughter with respect to which Mr. Finkelstein shares voting and dispositive powers.

(2) Consists of (i) 984,615 shares and 246,154 shares underlying warrants owned by Sigma–Tau and (ii) 20,272,770 shares and 1,634,683 shares underlying warrants owned by affiliates of Sigma–Tau, including 12,011,185 shares and 589,481 shares underlying warrants owned by Defiante Farmaceutica LDA, 3,705,600 shares and 522,601 shares underlying warrants owned by Inverlochy Consultodoria & Servicos LDA, and 4,555,985 shares and 522,601 shares underlying warrants owned by Chaumiere–Consultadoria & Servicos SDC Unipessoal LDA.

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

On February 29, 2008, we closed agreements with two affiliates of Sigma–Tau, who are both accredited investors, with respect to the sale of 5,000,000 shares of our common stock at a price per share of $1.00 for gross proceeds of $5,000,000. In connection with the offering, we also issued warrants to purchase an additional 1,000,000 shares of common stock with an exercise price of $1.60 per share. Under the terms of the offering, we may, in our sole discretion, repurchase the shares subject to the offering 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. Our repurchase right terminates after December 31, 2010. In addition, the purchasers have agreed to vote the shares subject to the offering, and any additional shares issued pursuant to the exercise of the warrants, with our 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 offering, one-third is scheduled to vest on December 31, 2008, and one-third is scheduled to vest on December 31, 2009. However, should we repurchase all of the shares subject to the offering prior to December 31, 2009, any unvested warrants would terminate as of the date we complete the repurchase.

On December 13, 2007, we approved amending the terms of certain warrants held by Sigma–Tau and other investors which were scheduled to expire between December 31, 2007 and January 7, 2008 to extend the expiration date of each Warrant to March 31, 2008 and to eliminate the cashless exercise provisions of these Warrants. None of the Warrant Holders paid any additional consideration for these amendments.

Each of the foregoing transactions were approved unanimously by the Board of Directors following disclosure of the transactions, including the related party benefits, if any.

Item 14. Principal Accounting Fees and Services.

Fees paid to the Reznick Group, P.C., our independent registered public accounting firm, for the last two fiscal years ended December 31 were as follows:

	2007	2006
Audit fees	$ 46,000	$ 43,000
Audit–related fees	2,850	3,750
Tax fees	7,000	—
All other fees	10,000	—

Audit fees include fees for our annual financial statement audit, along with fees associated with the review of our quarterly financial statements.

Audit–related fees include fees for reviews and consents necessary to engage in equity transactions that we have, from time to time, executed.

Tax fees include the preparation and filing of our corporate federal and state income tax returns.

All other fees include an executive compensation survey

All audit related services, tax services and other services were pre-approved by the Audit Committee, which concluded that the provision of such services by Reznick Group, P.C. was compatible with the maintenance of that firm's independence in the conduct of its auditing functions.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Exhibit No.	Description of Exhibit	Reference*
3.1	Restated Certificate of Incorporation of the Company	Exhibit 3.1 to Registration Statement No. 33-9370, Amendment No. 1 (filed November 26, 1986)
3.2	Certificate of Amendment of Restated Certificate of Incorporation of Company	Exhibit 3.2 to the Company's Transitional Report on Form 10–K, File No. 0–15070 (filed March 18, 1991)
3.3	Amendment to Restated Certificate of Incorporation of Company	Exhibit 3.3 to the Company's Form 10–KSB, File No. 0–15070 (filed April 2, 2001)
3.4	Amended and Restated Bylaws of Company	Exhibit 3.4 to the Company's Quarterly Report on Form 10–Q for the quarter ended June 30,2007 (filed August 14, 2006)
4.1	Form of Stock Certificate	Exhibit 4.1 to Registration Statement No. 33–9370, Amendment No. 1 (filed November 26, 1986)
4.2	Rights Agreement, dated as of April 29, 1994, between the Company and American Stock Transfer & Trust Company, as Rights Agent	Exhibit 1 to the Company's Current Report on Form 8–K, File No. 0–15070 (filed May 2, 1994)
4.3	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, File No. 1–15070 (filed March 31, 2006)
4.4	Warrant Agreement, dated March 12, 1997	Exhibit 4.3 to the Company's Annual Report on Form 10–K, File No. 0–15070 (filed March 31, 1997)
4.5	Warrant Agreement, dated January 23, 2004	Exhibit 4.4 to the Company's Registration Statement on Form SB–2, File No. 333–113417 (filed March 9, 2004)
4.6	Form of Warrant Agreement	Exhibit 4.1 to the Company's Current Report on Form 8–K (filed on January 6, 2005)
4.7	Warrant Agreement, dated December 31, 2004	Exhibit 4.2 to the Company's Current Report on Form 8–K (filed on January 6, 2005)
4.8	Form of Warrant	Exhibit 4.1 to the Company's Current Report on Form 8–K (filed on March 7, 2006)
4.9	Form of Warrant	Exhibit 4.1 to the Company's Current Report on Form 8–K (filed on December 18, 2006)
4.10	Form of Warrant	Exhibit 4.1 to the Company's Current Report on Form 8–K (filed on February 27, 2008)
10.1	Patent License Agreement — Exclusive, between the U.S. Public Health Service and the Company	Exhibit 10.1 to the Company's Form 10–KSB, File No. 0–15070 (filed April 2, 2001)**
10.2^	Amended and Restated Directors Stock Option Plan	Exhibit 10.25 to the Company's Annual Report on Form 10–K, File No. 0–15070 (filed March 26, 1993)
10.3^	Amended and Restated 2000 Stock Option and Incentive Plan	Exhibit 10.3 to the Company's Quarterly Report on Form 10–Q for the quarter ended June 30, 2006 (filed August 14, 2006)

10.4^	Unit Purchase Agreement dated March 12, 1997	Exhibit 10.25 to the Company's Annual Report on Form 10–K, File No. 0–15070 (filed March 31, 1997)
10.5	Registration Rights Agreement, dated March 12, 1997	Exhibit 10.26 to the Company's Annual Report of Form 10–K, File No. 0–15070 (filed March 31, 1997)
10.6	Lease Agreement dated April 5, 2002 between the Company and HQ Global Workplaces, Inc.	Exhibit 10.7 to the Company's Annual Report on Form 10–KSB, File No. 0–15070 (filed March 31, 2003)
10.7^	Employment Agreement	Exhibit 10.8 to the Company's Registration Statement on Form SB–2, File No. 333–113417 (filed March 9, 2004)
10.8^	Employment Agreement	Exhibit 10.9 to the Company's Registration Statement on Form SB–2, File No. 333–113417 (filed March 9, 2004)
10.9	License and Supply Agreement	Exhibit 10.10 to the Company's Registration Statement on Form SB–2, File No. 333–113417 (filed March 9, 2004)**
10.10	Securities Purchase Agreement	Exhibit 10.11 to the Company's Registration Statement on Form SB–2, File No. 333–113417 (filed March 9, 2004)
10.11	Master Services Agreement	Exhibit 10.12 to the Company's Registration Statement on Form SB–2, Amendment No. 1, File No. 333–113417 (filed April 23, 2004)
10.12	Form of Purchase Agreement	Exhibit 99.2 to the Company's Current Report on Form 8–K (filed on January 6, 2005)
10.13	Form of Stock Purchase Agreement	Exhibit 99.2 to the Company's Current Report on Form 8–K (filed on June 23, 2005)
10.14	Form of Securities Purchase Agreement	Exhibit 10.1 to the Company's Current Report on Form 8–K (filed on March 7, 2006)
10.15	Form of Securities Purchase Agreement	Exhibit 10.1 to the Company's Current Report on Form 8–K (filed on December 18, 2006)
10.16	Form of Registration Rights Agreement	Exhibit 10.2 to the Company's Current Report on Form 8–K (filed on December 18, 2006)
10.17	Form of Securities Purchase Agreement	Exhibit 10.1 to the Company's Current Report on Form 8–K (filed on March 7, 2006)
10.18	Amendment No. 1 to Employment Agreement of C. Neil Lyons	Exhibit 10.1 to the Company's Current Report on Form 8–K (filed on December 17, 2007)
10.19	Form of Securities Purchase Agreement	Exhibit 10.1 to the Company's Current Report on Form 8–K (filed on December 18, 2007)
10.20	Form of Registration Rights Agreement	Exhibit 10.2 to the Company's Current Report on Form 8–K (filed on December 18, 2007)
10.21	Form of Amendment to Investor Warrant	Exhibit 99.1 to the Company's Current Report on Form 8–K (filed on January 7, 2008)
10.22	Form of Amendment to Placement Agent Warrant	Exhibit 99.2 to the Company's Current Report on Form 8–K (filed on January 7, 2008)

10.23	Form of Securities Purchase Agreement	Exhibit 99.1 to the Company's Current Report on Form 8–K (filed on February 27, 2008)
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith
31.1 & 31.2	Certifications dated March 28, 2008	Certifications Pursuant to Section 302 of the Sarbanes–Oxley Act of 2002 (filed herewith)
32.1 & 32.2	Certifications dated March 28, 2008	Certifications 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.

** Portions of this document have been omitted pursuant to a request for confidential treatment.

^ Compensatory plan, contract or arrangement.

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. as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity, and cash flows for each of the years ended December 31, 2007 and 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of RegeneRx Biopharmaceuticals, Inc. as of December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the years ended December 31, 2007 and 2006, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the financial statements, the Company adopted Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, as of January 1, 2006

/s/ Reznick Group, P.C.

Bethesda, Maryland
March 27, 2008

RegeneRx Biopharmaceuticals, Inc.
Balance Sheets

	December 31, 2007	December 31, 2006
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,696,878	$ 13,052,308
Short-term investments	4,579,592	4,000,000
Accounts receivable	26,951	272,491
Prepaid expenses and other current assets	268,244	111,679
Total current assets	8,571,665	17,436,478
Fixed assets, net of accumulated depreciation of $62,227 and $41,030	44,435	53,398
Other non-current assets	5,693	11,749
Total assets	$ 8,621,793	$ 17,501,625
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 273,561	$ 362,402
Accrued expenses	2,195,508	886,888
Total current liabilities	2,469,069	1,249,290
Commitments	—	—
Stockholders' equity		
Preferred stock, $.001 par value per share, 1,000,000 authorized; no shares issued	—	—
Common stock, par value $.001 per share, 100,000,000 shares authorized; 46,553,527 and 46,096,477 issued and outstanding	46,554	46,096
Additional paid-in capital	73,513,292	72,433,660
Accumulated other comprehensive loss	(1,543)	—
Accumulated deficit	(67,405,579)	(56,227,421)
Total stockholders' equity	6,152,724	16,252,335
Total liabilities and stockholders' equity	$ 8,621,793	$ 17,501,625

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Operations

	Years ended December 31,	
	2007	2006
Revenues	$ 240,324	$ 272,491
Operating expenses:		
Research and development	8,887,255	6,396,524
General and administrative	3,197,685	2,665,652
Total operating expenses	12,084,940	9,062,176
Loss from operations	(11,844,616)	(8,789,685)
Interest income	666,458	522,704
Net loss	$ (11,178,158)	$ (8,266,981)
Basic and diluted net loss per common share	$ (0.24)	$ (0.21)
Weighted average number of common shares outstanding	46,465,982	40,116,367

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Changes in Stockholders' Equity
Years ended December 31, 2007 and 2006

	Common stock		Additional	Accumulated	Accumulated other Comprehensive	Total stockholders'
	Shares	Amount	Paid-in capital	Deficit	Income/(loss)	equity
Balance, December 31, 2005	37,629,024	$ 37,629	$ 54,936,362	$ (47,960,440)	$ (3,044)	$ 7,010,507
Issuance of common stock, net of offering costs of $896,889	7,897,509	7,897	15,928,615	—	—	15,936,512
Issuance of common stock upon exercise of warrants	569,944	570	773,680	—	—	774,250
Share-based compensation expense	—	—	795,003	—	—	795,003
Net loss	—	—	—	(8,266,981)	—	(8,266,981)
Unrealized gain on available for sale securities	—	—	—	—	3,044	3,044
Total comprehensive loss						(8,263,937)
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

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Cash Flows

	For the Years Ended December 31	
	2007	2006
Operating activities:		
Net loss	$ (11,178,158)	$ (8,266,981)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21,197	18,112
Non-cash share-based compensation	1,034,384	795,003
Changes in operating assets and liabilities:		
Accounts receivable	245,540	(272,491)
Prepaid expenses and other current assets	(156,565)	(38,785)
Due from related party	—	4,592
Other non-current assets	6,056	5,329
Accounts payable	(88,841)	174,736
Accrued expenses	1,308,620	360,427
Net cash used in operating activities	(8,807,767)	(7,220,058)
Investing activities:		
Purchase of short-term, available-for-sale investments	(20,681,135)	(5,580,424)
Proceeds from sales/maturities of short-term investments	20,100,000	4,263,161
Purchase of fixed assets	(12,234)	(17,276)
Net cash used in investing activities	(593,369)	(1,334,539)
Financing activities:		
Net proceeds from issuance of common stock	—	15,936,512
Preceeds from exercise of warrants	45,706	774,250
Net cash provided by financing activities	45,706	16,710,762
Net increase (decrease) in cash and cash equivalents	(9,355,430)	8,156,165
Cash and cash equivalents:		
Beginning of period	13,052,308	4,896,143
End of period	$ 3,696,878	$ 13,052,308

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. We view our operations and manage our business as one segment, the development and marketing of Thymosin Beta 4 ("Tβ4") –based product candidates. Factors used to identify our single operating segment include the financial information available for evaluation by the chief operating decision maker in making decisions about how to allocate resources and assess performance.

Management Plans to Address Operating Conditions. 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. To achieve profitability we must successfully conduct pre–clinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture and market those pharmaceutical 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.

We have incurred negative cash flows from operations since inception, and 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. We expect that our existing capital resources, including those received after December 31, 2007 as more fully described in Note 12, will be sufficient to fund our projected operations into the fourth quarter of 2008. However, substantial additional resources will be needed before we will be able to achieve sustained profitability. Consequently, we continually evaluate alternative sources of financing and/or sharing 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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Financial Statement Preparation The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses during the reporting period. 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 purchased.

Short–term Investments. In accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Debt and Equity Securities," short–term investments are classified as available–for–sale. We define short–term investments as income–yielding securities that can be readily converted to cash. These securities are carried at fair value, with unrealized gains and losses reported as accumulated other comprehensive income. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in calculating interest income. Realized gains and losses and declines in securities judged to be other than temporary are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on available–for–sale securities are included in interest income. Investments held as of December 31, 2007 consist of corporate notes and municipal or state bonds.

Fair Value of Financial Instruments. Cash and cash equivalents, accounts receivable, accounts payable and accrued expenses are carried at cost, which management believes approximates fair value due to the short–term maturity of these instruments. Short–term investments are carried at fair value.

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, debt that is rated investment grade.

Fixed Assets. Fixed assets consist of office furniture and equipment, and are 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 $21,197 and $18,112 for the years ended December 31, 2007 and 2006, respectively.

Long–lived Assets. In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long–Lived Assets," we review the recoverability of long–lived and finite–lived intangible assets when circumstances indicate that the carrying amount of assets may not be recoverable. This evaluation is based on various analyses including undiscounted cash flow projections. In the event undiscounted cash flow projections indicate an impairment, we would record an impairment loss, if any, based on the fair value of the assets. We did not record any impairments or write–offs of long–lived assets in the years ended December 31, 2007 or 2006.

Derivative Financial Instruments. We do not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks.

In connection with the sale of equity instruments, we may issue freestanding options or warrants. Additionally, we may issue options or warrants to non–employees in connection with consulting or other services they provide. In the event we issue options or warrants with terms that provide for net–cash settlement under circumstances that may be deemed to be outside of our control, we may be required to account for these securities as derivative financial instrument liabilities, rather than as equity.

Derivative financial instruments are required to be initially measured at their fair value. For derivative financial instruments that shall be accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re–valued at each reporting date, with changes in the fair value reported as charges or credits to income.

To the extent that the fair value of the freestanding derivative instrument liability exceeds the total proceeds received, an immediate charge to income is required to be recognized, in order to initially record the derivative instrument liability at its fair value.

We review the classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, at the end of each reporting period. Derivative instrument liabilities are required to be classified in the balance sheet as current or non–current based on whether or not net–cash settlement of the derivative instrument could be required within 12 months of the balance sheet date. We currently do not have any derivative instruments that are required to be bifurcated and recorded as liabilities.

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 options or warrants.

The Agreements usually require us to pay penalties for any time delay in filing the required registration statements, or in the registration statements becoming effective, beyond dates specified in the Agreement. 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 we have not recognized 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.

Government Grants. We receive non–refundable grants under available government programs. Government grants towards current expenditures are recorded as revenue when there is reasonable assurance that we have complied with all conditions necessary to receive the grants, collectibility is reasonably assured, and as the expenditures are incurred.

Research and Development. Research and development costs, which consist of primarily of costs associated with external pre–clinical study and clinical trial fees, manufacturing costs and other related expenses, are expensed as incurred.

Clinical Trial Expenses. We accrue clinical trial expenses based on work performed. We rely on estimates of total costs incurred based on enrollment of subjects, completion of studies and other events. We follow this method because reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. Accrued clinical costs are subject to revisions as clinical trials progress, and any revisions are recorded in the period in which the facts that give rise to the revisions become known.

Patent Costs. Legal costs related to filing and protecting patent applications are expensed to general and administrative as incurred as recoverability of such expenditures is uncertain.

Income Taxes. In accordance with SFAS No. 109, "Accounting for Income Taxes," a deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities as measured by enacted tax rates which will be in effect when these differences reverse. We provide a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

Comprehensive Income. In accordance with SFAS No. 130, "Reporting Comprehensive Loss," all components of comprehensive loss, including net loss, are reported in the financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non–owner sources.

Net Loss Per Share. Basic and diluted net loss per share are presented in conformity with SFAS No. 128, "Earnings per Share," for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per share has been computed using the weighted–average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture.

We have excluded all outstanding stock options and warrants from the calculation of basic and diluted net loss per share because these securities are antidilutive for all years presented. Securities that could potentially dilute basic net loss per share in the future, and that were not included in the calculation of diluted net loss per share, are as follows:

	December 31,	
	2007	2006
Outstanding stock options	3,545,000	2,685,000
Warrants	3,522,544	3,979,594
Total potential common shares excluded from diluted net loss per share computation	7,067,544	6,664,594

Share–Based Compensation. Effective January 1, 2006 we adopted the fair value provisions of SFAS No. 123 (revised 2005), "Share–Based Payment" (or "FAS 123R"), using the modified–prospective transition method. Under the modified prospective transition method, compensation cost recognized in periods subsequent to 2005 includes: (i) compensation cost for all equity–based payments granted prior to, but not vested as of, January 1, 2006, and (ii) compensation cost for all equity–based payments granted subsequent to January 1, 2006, all based on the grant–date fair value, estimated in accordance with the provisions of SFAS No. 123R. Transactions with nonemployees in which consideration is received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable in accordance with EITF 96–18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods and Services.

A summary of compensation expense related to stock options follows:

	Years ended December 31,	
	2007	2006
Employees	$ 649,227	$ 452,571
Non–employees	385,157	342,432
Total compensation expense	$ 1,034,384	$ 795,003
Research and development	$ 422,721	$ 293,297
General and administrative	611,663	501,706
Total compensation expense	$ 1,034,384	$ 795,003

The fair value of each option is estimated on the date of grant using the Black–Scholes option–pricing model with the following range of assumptions for stock options granted during the years ended December 31, 2007 and 2006:

	2007	2006
Dividend yield	0.0%	0.0%
Risk free rate of return	3.9 – 5.1%	4.3 – 5.0%
Expected life in years	3.0 – 5.0	6.0 – 6.5
Volatility	68 – 75%	100 – 333%

We use the Black–Scholes option pricing model (the "Black–Scholes Model") for the purpose of determining the estimated fair value of stock–based payment awards on the date of grant under SFAS 123R. The Black–Scholes Model requires the input of certain assumptions that involve judgment. Because our stock options have characteristics significantly different from those of traded options, and because changes in the input assumptions can materially affect the fair value estimate, existing models may not provide reliable measures of fair value of our stock options. We will continue to assess the assumptions and methodologies used to calculate estimated fair value of stock–based compensation. If circumstances change, and additional data becomes available over time, we may change our assumptions and methodologies, which may materially impact our fair value determination.

The fair value of our options was estimated using the Black–Scholes Model. This model requires the input of assumptions regarding a number of complex and subjective variables that will usually have a significant impact on the fair value estimate. These variables include, but are not limited to, the volatility of our stock price and employee exercise behaviors. The assumptions and variables used for the current period grants were developed based on SFAS 123R and SEC guidance contained in SAB 107. There were no material changes made during 2007 to the methodology used to determine the assumptions.

We based our estimate of expected volatility for the twelve months ended December 31, 2007 on the sequential historical monthly trading data of our common stock for a period equal to the expected life of the options granted. The selection of the historical volatility approach was based on available data indicating our historical volatility is as equally representative of our future stock price trends as is implied volatility. We have no reason to believe the future volatility of our stock price is likely to differ from its past volatility.

The risk–free interest rate assumption is based upon implied yields of U.S. Treasury zero–coupon bonds on the date of grant having a remaining term equal to the expected life of the options granted. The dividend yield is based on our historical and expected dividend payouts.

The expected life of our stock options is based upon historical exercise and cancellation activity of our previous stock–based grants with a ten–year contractual term.

Stock–based compensation expense recognized in our Statement of Operations for the twelve months ended December 31, 2007 is based on options ultimately expected to vest, and has been reduced for estimated forfeitures. These estimates were based upon historical experience. Compensation expense related to share–based awards, which is recognized on a straight–line basis over the vesting period, is included in research and development and in general and administrative expenses in the accompanying statements of operations.

At December 31, 2007, total compensation cost related to non–vested stock options not yet recognized was approximately $2,035,000, which is expected to be recognized over the next 1.4 years on a weighted average basis.

Effect of new accounting standards. In September 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement 109" ("FIN 48"). This statement clarifies the criteria that an individual tax position must satisfy for some or all of the benefits of that position to be recognized in a company's financial statements. FIN 48 prescribes a recognition threshold of more–likely–than–not, and a measurement attribute for all tax positions taken or expected to be taken on a tax return, in order for those tax positions to be recognized in the financial statements. Effective January 1, 2007, we adopted the provisions of FIN 48, and determined that the impact had no material effect on our financial statements.

In September 2006, and February 2007 the FASB issued FASB Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("FAS 157"), and Statement of Financial Accounting Standards 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 are effective for fiscal years beginning after November 15, 2007. We do not anticipate the adoption of these standards will 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 is effective for fiscal years beginning after December 15, 2007. Historically we expense nonrefundable advance payments when paid. We have determined that there were approximately $35,000 in qualifying transactions requiring capitalization in accordance with EITF 07–03 as of January 1, 2008. In order to adopt the provisions of this statement, we will recognize a cumulative–effect adjustment to retained earnings as of that date.

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS No. 141(R)"). SFAS 141(R) requires the acquiring entity in a business combination to recognize the full fair value of assets acquired and liabilities assumed in the transaction (whether a full or partial acquisition); establishes the acquisition–date fair value as the measurement objective for all assets acquired and liabilities assumed; requires expensing of most transaction and restructuring costs; and requires the acquirer to disclose to investors and other users all of the information needed to evaluate and understand the nature and financial effect of the business combination. SFAS No. 141(R) applies to all transactions or other events in which the Company obtains control of one or more businesses, including those sometimes referred to as "true mergers" or "mergers of equals" and combinations achieved without the transfer of consideration, for example, by contract alone or through the lapse of minority veto rights. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements—an amendment of Accounting Research Bulletin No. 51" ("SFAS No. 160"). SFAS No. 160 requires reporting entities to present noncontrolling (minority) interests as equity (as opposed to as a liability or mezzanine equity) and provides guidance on the accounting for transactions between an entity and noncontrolling interests. SFAS No. 160 applies prospectively as of January 1, 2009, except for the presentation and disclosure requirements which will be applied retrospectively for all periods presented.

3. CASH, CASH EQUIVALENTS & SHORT–TERM INVESTMENTS

The following is a summary of the Company's available–for–sale investments at December 31, 2007 and 2006, all of which are due within one year:

	Net amortized cost	Unrealized gain	Unrealized loss	Estimated fair value
December 31, 2007				
Corporate notes	$ 2,581,135	$ —	$ (1,543)	$ 2,579,592
Municipal Bonds	2,000,000	—	—	2,000,000
				$ 4,579,592
Reported as:				
Short-term investments	$ 4,581,135		$ (1,543)	4,579,592
				$ 4,579,592
December 31, 2006				
Corporate notes	$ 13,330,341	$ —	$ —	$ 13,330,341
Municipal bonds	3,000,000	—	—	3,000,000
				$ 16,330,341
Reported as:				
Cash and cash equivalents				$ 12,330,341
Short-term investments				4,000,000
				$ 16,330,341

4. LICENSES, AND INTELLECTUAL PROPERTY

On February 6, 2001, we executed an agreement with the National Institutes of Health ("NIH") giving us an exclusive worldwide license for all claims to Tβ4 within their broadly–defined patent application. In exchange for this exclusive license, we must make certain royalty and milestone payments to the NIH. Through December 31, 2005 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 the exclusive right to use Tβ4 to conduct research and development activities in Europe, to Defiante. Under the Agreement, we will receive fees and royalty payments based on a percentage of sales of Tβ4–related products by Defiante, as defined. The term of the Agreement is the later of the expiration of any patents developed under the Agreement, any marketing rights, or 2016. Sigma–Tau is our largest stockholder.

5. RELATED PARTY TRANSACTIONS

In September 2003, we entered into a consulting agreement with one of our outside directors for general business strategy and financial advice. This agreement was terminated during 2006. Under this agreement we incurred expenses of $0 and $28,000 during the years ended December 31, 2007 and 2006, respectively.

As described in Note 4, we entered into an agreement to use Tβ4 to conduct research and development activities in Europe with Defiante.

6. COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

Accrued expenses consist of the following:

	December 31, 2007	December 31, 2006
Contract/clinical research organizations	$ 1,915,132	$ 450,066
Professional fees/Lawyer fees	148,962	373,800
Employee bonuses	83,002	4,875
Vacation	43,745	33,687
Other	4,667	7,166
401(k) contributions	—	17,294
	$ 2,195,508	$ 886,888

7. EMPLOYEE BENEFIT PLANS

We have a defined contribution retirement plan that complies with Section 401(k) of the Internal Revenue 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 $47,873 and $11,414 for the years ended December 31, 2007 and 2006, respectively.

8. STOCKHOLDERS' EQUITY

Shareholders Rights Plan. Our Board of Directors adopted a Rights Agreement, dated April 29, 1994, as amended, as a tool to prevent an unsolicited take over. In general, if an entity acquires more than a 25% ownership interest in our 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 which would encumber an acquisition.

Sales of Common Stock.

During 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, generating approximately $45,706 in gross proceeds.

During 2006 we sold 7,897,509 shares of our common stock for an average price of $2.13 per share, generating approximately $16.8 million in gross proceeds. In connection with these sales, we issued 3,059,736 warrants to purchase our common stock at an average price of $3.14 per share. These warrants are exercisable until 2011.

2000 Stock Option and Incentive Plan, as amended. The 2000 Stock Option and Incentive Plan was approved 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 is to be determined by the Board but shall never 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. Presently, the authorized shares reserved for issuance under the plan is 4,200,000. We currently anticipate issuing new shares to fill any and all options that are exercised.

A summary of the status of the Company's stock option plan is presented below for the years ended December 31, 2007 and 2006:

		Options outstanding		
	Shares available for grant	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2005	695,000	2,470,000	$ 0.28 - 3.82	$ 1.54
Grants	(215,000)	215,000	2.50 - 3.16	2.94
Exercises	—	—	—	—
Cancellations	—	—	—	—
Newly authorized	1,000,000	—	—	—
December 31, 2006	1,480,000	2,685,000	0.28 - 3.82	1.66
Grants	(860,000)	860,000	—	2.24
Exercises	—	—	—	—
Cancellations	—	—	—	—
December 31, 2007	620,000	3,545,000	$ 0.28 - $3.82	$ 1.80

	For the years ended December 31,	
	2007	2006
Weighted average estimated fair value of options granted, based on the assumptions in the Black-Scholes valuation model	$ 1.37	$ 2.47
Intrinsic value of options exercised	$ —	$ —
Estimated fair value of shares vested, based on the fair value assigned to the shares at the time of grant	$ 3,500	$ 752,058

For various price ranges, weighted average characteristics of outstanding and exercisable options as of December 31, 2007 were as follows:

	Outstanding options			Exerciseable options		
Range of exercise prices	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	4.2	$ 0.38	1,221,250	4.1	$ 0.36
$ 1.07 - $1.93	280,000	6.2	$ 1.50	261,250	6.3	$ 1.47
$ 2.02 - $2.68	900,000	6.4	$ 2.27	11,750	8.7	$ 2.54
$ 3.00 - $3.82	1,075,000	7.4	$ 3.19	434,583	7.3	$ 3.19
	3,545,000			1,928,833		
Intrinsic value of in-the-money options, using the December 31, 2007 closing price of $1.00.	$ 796,200			$ 786,575		

Warrants to Purchase Common Stock

The following table summarizes our warrant activity for 2006 and 2007:

	Warrants outstanding		
	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2005	1,546,815	$ 0.10 - $4.06	$ 1.80
Grants	3,059,736	2.75 - 4.06	3.14
Exercises	(578,272)	0.10 - 1.50	1.36
Cancellations	(48,685)	1.50	1.50
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

9. INCOME TAXES

Significant components of the Company's deferred tax assets at December 31, 2007 and 2006 are shown below, in thousands. A valuation allowance of approximately $23.0 million and $20.1 million has been recognized to offset the net deferred tax assets as of December 31, 2007 and 2006, respectively, as realization of such assets is uncertain. The valuation allowance increased by approximately $2.8 million in 2007 compared to 2006, primarily due to an increase in the Company's net operating loss.

	December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carryforwards	20,491,000	18,423,000
Research and development tax credit carryforward	1,649,000	1,174,000
Charitable contribution carryforward	42,000	35,000
Accrued vacation	8,000	11,000
Accrued expenses	93,000	—
Amortization	6,000	7,000
Other	677,000	436,000
	22,966,000	20,086,000
Less - valuation allowance	(22,963,000)	(20,083,000)
Net deferred tax asset	3,000	3,000
Deferred tax liabilities:		
Depreciation	(3,000)	(3,000)
Net deferred tax amounts	$ —	$ —

At December 31, 2007, we had net operating loss carryforwards for income tax purposes of approximately $53.1 million, which are available to offset future federal and state taxable income, if any; and, research and development tax credit carryforwards of approximately $1.7 million. The carryforwards, if not utilized, will expire in increments through 2027. Section 382 of the Internal Revenue Code limits the utilization of net operating losses when ownership changes, as defined by that section, are greater than 50%. The effects, if any, of potential ownership changes have not been analyzed by the Company. Management believes that in the event that there have been significant ownership changes, these would not have an impact on the financial statements. Utilization of the net operating losses and credits may also be subject to an annual limitation as provided by the Internal Revenue Code of 1986, and there can be no guarantee that such NOLs and tax credits will ever be fully utilized. As a result of these uncertainties and cumulative losses, we have recorded a full valuation allowance against our net deferred tax assets as we believe it is more likely than not that the assets will not be realizable.

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2007 and 2006, due to the following:

	December 31, 2007	December 31, 2006
Tax benefit at statutory rate	$ (3,800,000)	$ (2,811,000)
State taxes	(516,000)	(382,000)
Permanent M-1s	673,000	(32,000)
Expired net operating loss carryforwards	1,378,000	1,033,000
Expired research and development tax credit carryforward	80,000	64,000
Research and development tax credit carryforward	(695,000)	(398,000)
Change in valuation allowance	2,880,000	2,526,000
	$ —	$ —

10. COMMITMENTS

Lease. Our rent expense, related solely to office space, for 2007 and 2006 was $83,361 and $77,886, respectively. We are committed under an office space lease that expires on December 31, 2009 that requires monthly rental payments of $7,072 scheduled to increase by 3% in calendar 2009.

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, 2007 these obligations, if triggered, could amount to $781,000.

11. QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

The following table sets forth unaudited quarterly statement of operations data for each of the eight quarters in the two year period ended December 31, 2007. In the opinion of management, this information has been prepared on the same basis as the audited financial statements appearing elsewhere in this Form 10-K, and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to present fairly the unaudited quarterly results of operations.

	Q1	Q2	Q3	Q4
2007				
Revenue	$ —	$ —	$ 213,373	$ 26,951
Net Loss	$ (3,002,767)	$ (2,552,671)	$ (2,081,702)	$ (3,541,018)
Basic and diluted loss per share	$ (6.00)	$ (0.05)	$ (0.04)	$ (0.08)
2006				
Revenue	$ —	$ —	$ —	$ 272,491
Net Loss	$ (1,324,903)	$ (3,437,157)	$ (1,935,573)	$ (1,569,348)
Basic and diluted loss per share	$ (0.03)	$ (0.09)	$ (0.05)	$ (0.04)

The loss per share was calculated for each three-month period on a stand-alone basis. As a result, the sum of the loss per share for the four quarters does not equal the loss per share for the respective twelve-month period.

12. SUBSEQUENT EVENT

On February 29, 2008 we sold 5,000,000 shares of the Company's common stock at a price per share of $1.00 (the "Shares") to affiliates of Sigma-Tau, for gross proceeds of $5,000,000 (the "Offering"). In connection with the Offering, we have also agreed to issue warrants to purchase an additional 1,000,000 shares of its common stock with an exercise price of $1.60 per share (the "Warrants"). There were no discounts or brokerage fees associated with the Offering.

Under the terms of the Offering, we may, in our 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. Our 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, with our Board of Directors until December 31, 2010. The Warrants have a term of three years. One-third of the Warrants will vest upon the closing of the Offering, one-third is scheduled to vest on December 31, 2008, and one-third is scheduled to vest on December 31, 2009. However, should we repurchase all of the Shares prior to December 31, 2009, any unvested Warrants would terminate as of the date of repurchase.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

RegeneRx Biopharmaceuticals, Inc.
(Registrant)

Date: March 28, 2008

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

/s/C. Neil Lyons
C. Neil Lyons
Chief Financial Officer

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 amendments to this report, and to file the same, with 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.:

Signature	Title	Date
/s/Allan L. Goldstein Allan L. Goldstein	Chairman of the Board, Chief Scientific Advisor, and Director	March 28, 2008
/s/J.J. Finkelstein J.J. Finkelstein	President, Chief Executive Officer, and Director (Principal) Executive Officer	March 28, 2008
/s/C. Neil Lyons C. Neil Lyons	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 28, 2008
/s/Richard J. Hindin Richard J. Hindin	Secretary and Director	March 28, 2008
/s/Joseph C. McNay Joseph C. McNay	Director	March 28, 2008
/s/Mauro Bove Mauro Bove	Director	March 28, 2008
/s/L. Thompson Bowles L. Thompson Bowles	Director	March 28, 2008

REGENERX

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