FORM 10-K

REGENERX BIOPHARMACEUTICALS INC - RGRX

Filed: April 02, 2007 (period: December 31, 2006)

Annual report with a comprehensive overview of the company

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2006

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: 0-15070

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 Exchange Act 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 111 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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

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, 2006, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $56,826,597. 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, 2006.

The number of shares outstanding of the registrant's common stock, as of March 31, 2006 was 46,553,527.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the following documents are incorporated by reference in this Report on Form 10-K:

1) The registrant's definitive Proxy Statement for its Annual Meeting of Stockholders to be filed not later than 120 days after the close of the fiscal year (incorporated into Part III).

PART I

Item 1. Business.

General

RegeneRx Biopharmaceuticals, Inc. (the "Company", "We", "Us", "Our"), is a biopharmaceutical company focused on the discovery and development of novel molecules to accelerate tissue and organ repair. Currently, we are developing Thymosin beta 4 ("Tß4™), a 43 amino acid peptide as the basis for our technology platform. Current research suggests that Tß4 may prove efficacious for multiple medical indications; therefore, we are developing several Tß4-based therapeutic drug candidates. We hold nearly sixty world-wide patents and patent applications related to dermal, ophthalmic, and internal wounds and tissue repair, cardiac and neurological injuries, and septic shock. We are currently sponsoring, in parallel, three Phase II dermal wound healing clinical trials that are targeted for full enrollment during 2007, with data reported during the second half of the year. Under our Phase II Investigational New Drug Application ("IND"), Sigma-Tau, one of our major shareholders see "Material Agreements" below, is conducting one of these three Phase II clinical trials in the EU and has assumed all associated costs. Additionally, we have commenced pre-clinical studies, targeted at cardiac and ophthalmic indications and submitted INDs to the U.S. Food and Drug Administration ("FDA") for the initiation of these clinical trials during the first quarter of 2007.

We utilize an outsourcing business strategy in order to effectively control costs while focusing on the clinical development of Tß4-based products. We use this model for certain research and development, clinical trials, and manufacturing operations, as well as other functions critical to our mission. 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, formulate and manufacture each drug candidate. It also includes utilizing third party contract research organizations to perform pre-clinical and/or clinical studies in accordance with our designed protocols.

Primary Commercial Development Focus—Thymosin Beta 4

General. Originally isolated from the thymus gland, Tß4 is a chemically synthesized copy of a natural human peptide that circulates in the blood and plays a vital role 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. Tß4 is not a growth factor. Moreover, numerous scientific papers published by independent researchers have identified several important biological activities involving Tß4 that make it unique.

Tß4 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 Tß4 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 (angeogenisis) and other tissues. These studies were the first to document the important role of Tß4 in wound healing.

Tß4 also reduces inflammation and stimulates the formation of collagen and laminin-5 (both substances central to healthy tissues). In combination, these various mechanisms of action work together to play a vital role in the healing of injured or damaged tissues.

Tß4 has also been shown to prevent apoptosis (programmed cell death) in both the cornea (eye) and myocardium (heart). Further, Tß4 is active both topically and systemically to accelerate wound healing in the cornea and skin of laboratory animals. 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 Tß4 to be an important compound having many potential medical applications. Tß4 therefore is the basis of a *technology platform* from which we intend to develop unique medical products and investigate its broad clinical potential.

Product Development. With time, we have learned more about Tß4's therapeutic potential and its underlying mechanisms of action, and have expanded our clinical development program beyond the chronic dermal wound indications initially targeted. Tß4's role in healing dermal wounds was initially established by the NIH. These data compelled management to license Tß4 from the NIH, discussed in *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 animal studies that suggested Tß4 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 that suggested Tß4 may prevent damage of myocardium (heart tissue) just after a myocardial infarction (heart attack) in rats.

These foundational research efforts have confirmed our current clinical development program for chronic dermal wounds, ophthalmic injuries and acute myocardial infarctions (heart attack). Management and our Board are focused on proving human efficacy of Tß4 in these areas and while we are not currently entertaining the initiation of additional clinical programs. However, we monitor all of the continuing scientific research surrounding Tß4 to confirm our planned clinical efforts and to evaluate additional indications we might target at a later date. For instance, Nature published a second myocardial study performed by the collective efforts of scientists from University College – London, Massachusetts General Hospital, and Baylor University that identified Tß4 as the triggering factor to stimulate adult myocardial stem cells to mature into cardiovascular tissue (Nature Online, November 17, 2006.) This study also provided evidence to suggest Tß4's therapeutic potential in the areas of pulmonary edema and congestive heart failure. All of these results provide significant evidence to suggest that Tß4's collective mechanisms of action and its anti-apoptotic properties in particular, could provide therapeutic relief in other ischemic conditions such as stroke or other ischemic events.

Clinical Development. In December of 2002, we received an IND, from the U.S. Food and Drug Administration ("FDA") allowing us to begin Phase I human clinical trials. The Phase I study was successfully completed in September of 2003. In November 2004, January 2005 and February 2005, we were cleared to initiate our first three dermal Phase II wound healing clinical trials using topically administered Tß4. The first Phase II trial is to treat patients with chronic pressure ulcers, more commonly referred to as bed sores. The second trial is for patients with epidermolysis bullosa

("EB"), a genetic defect manifest by the presences of fragile skin and other tissues that can blister at the slightest trauma or friction. The third Phase II trial is targeting patients with venous stasis ulcers that result from poor blood circulation. The venous stasis trial is being conducted and paid for by Sigma-Tau, our partner in Europe, pursuant to our U.S. IND. Of our three current Phase II trials, EB has been designated as an "orphan" indication due to the prevalence in the U.S. of less than 200,000. We expect these trials to be completed in 2007. For additional information regarding the regulatory approval process for RegeneRx's products, see "-- Government Regulation" below.

In 2005, based on the reported pre-clinical results indicating Tß4's ability to accelerate corneal wound healing in the eye and Tß4's protective properties after a heart attack in animals, we decided to expand our clinical program to include these two medical indications. We are currently planning a clinical trial to treat corneal wounds resulting from treatment of diabetic patients who undergo vitrectomy surgery. As a class, diabetic patients often do not readily heal. During 2006 we held a pre-IND meeting with the FDA and subsequently filed an IND in the 1st quarter of 2007 to initiate a Phase II clinical trial for this indication. We have also conducted a series of preclinical studies and are planning clinical trials (Phase I and Phase II) in patients with acute myocardial infarctions (heart attacks). In 2006 we had a pre-IND meeting with the FDA and also filed an IND for this indication in the 1st quarter of 2007 for Phase Ia and Ib clinical trials.

We may also explore other Tß4-based products to treat other indications including those that involve inflammatory processes, post surgical healing, septic shock, cystic fibrosis and wound healing in patients undergoing steroidal therapy, among others.

RegeneRx has placed development of Tß4 for wound healing as its highest product development priority. All of RegeneRx's efforts to develop additional applications will likely require substantial additional capital or a strategic alliance or other partnership arrangement with a firm providing the capital and/or necessary expertise. For additional information regarding RegeneRx's efforts to commercialize Thymosin beta 4, see "Proprietary Rights" below.

Manufacturing

We use an outside contract manufacturer to produce bulk Tß4 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. We, therefore, 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 to meet Company-established specifications.

We also use outside contract manufacturers to formulate bulk Tß4 into a final pharmaceutical product. We have finished the formulation and development work for the pharmaceutical products used in our three Phase II chronic dermal wound studies currently underway. We have completed the formulation of a sterile, systemically administered pharmaceutical product we plan on using in our proposed acute myocardial infarction ("AMI") (heart attack) study. And, we have completed formulation of a sterile eye drop that we will use in our proposed ophthalmic ("DV") study. Additional work is underway to manufacture sufficient quantities of both non-GMP and GMP products to complete the various pre-clinical, Phase I and Phase II studies envisioned for MI and the DV studies; and, we are dependent on individual suppliers in each instance.

While we have ordered enough bulk Tß4 to complete production of all pharmaceutical products envisioned for our near-term studies, there can be no assurance that scheduled deliveries will meet our quality, yield or timing expectations. Failure to obtain bulk Tß4 as planned, failure to manufacture bulk Tß4 into pharmaceutical products, or the need for us to establish new relationships with alternate suppliers, would significantly impact our ability to proceed with our planned clinical development program.

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 with some success. Other companies, such as Novartis, are developing and marketing artificial skins which could compete with RegeneRx's products in certain 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.

There are numerous companies and institutions engaged in research, development and marketing of products for ophthalmic wound healing and treatment of ophthalmic disorders where Tß4 may be useful. Most specialty ophthalmic companies have various products on the market that could compete with Tß4 or be modified to compete with our products. Other companies market antibiotics and steroids to treat certain conditions within our area of focus, with varying degrees of success.

Currently, there are no approved pharmaceutical products for preventing or repairing cardiac damage resulting from an acute myocardial infarction. However, the market for a product of this type is extremely large and many pharmaceutical companies and research organizations are exploring products and technologies that may prevent such damage or improve cardiac function after an AMI Further, if RegeneRx were to successfully develop Tß4 for other cardiovascular indications such as chronic or congestive heart failure, it would be compared to 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, manufacture, labeling, storage, recordkeeping, approval, advertising, and promotion of our products. Regulation by governmental authorities in the United States and foreign countries will be a significant factor in the manufacturing and marketing of our products and in our ongoing research and product development activities. Any product developed by RegeneRx will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous pre-clinical and clinical testing and other approval procedures by the FDA and similar health authorities in foreign countries. The process of obtaining these approvals and the subsequent compliance with appropriate federal and state statutes and regulations require the expenditure of substantial resources. Any failure to obtain regulatory approvals, or any delay in obtaining such approvals, could adversely affect the development and marketing of our products and our ability to generate revenue, which in turn would negatively impact our liquidity and capital resources.

Pre-clinical testing in the laboratory must ordinarily be conducted to evaluate the potential efficacy and the safety of an investigational drug. The results of these studies 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 testing can begin. Typically, clinical evaluation involves a three-stage process. In Phase I, trials are conducted with a small number of subjects to determine the safety profile, the pattern of drug distribution and metabolism. In Phase II, trials are conducted with small groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase III, large scale, multi-center, comparative trials are generally conducted with patients afflicted with a target disease in order to provide enough data for the statistical proof of efficacy and safety required by the FDA and other regulatory authorities.

The results of the pre-clinical and clinical testing with detailed information on manufacturing are submitted to the FDA in the form of a New Drug Application, or NDA, or Biologics License Application, or BLA, for approval to commence commercial sales. In responding to an NDA or BLA, 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 products, and submit an NDA or BLA to the Agency, 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, it may require, among other things, post-marketing testing, including potentially expensive Phase IV studies, 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 or a BLA 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, current Good Manufacturing Practices, and computer information system validation standards. Before approval of a BLA, 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 Tß4 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 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 ("OOPD") Another such incentive 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 (or BLA) for a given drug for its use in treating a given rare disease may receive marketing exclusivity for that specific use. Even if a sponsor of a product for an indication for use with an Orphan Drug designation is the first to obtain FDA approval of an NDA (or BLA) 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.

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 Tß4 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 Tß4. On February 6, 2001, we executed an agreement with the NIH giving us an exclusive worldwide license from the NIH for all claims to Tß4 within the patent application. In exchange for the exclusive license, we must make certain royalty and milestone payments to the NIH. Through December 31, 2006 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 Tß4, as well as to novel peptides resulting from our research efforts. During 2006, we were issued a patent in Europe 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 ß4," 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 Tß4 research at GWU and was 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 under the research agreement to pay GWU a royalty of 4% of the net sales, if any, of specified products covered by patents issued in connection with the agreement. Pursuant to the research agreement, we have exclusive rights to patent applications filed in the United States and in Europe disclosing the use of Tß4 for the treatment of septic shock and associated syndromes, including Adult Respiratory Distress Syndrome. Two U.S. patents have been issued. The first patent, No. 5,578,570, entitled "Method of Treating Septic Shock Using Tß4," 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 numerous other patents related to Tß4 and related compounds and indications for their use.

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 $10,000, other obligations will be triggered upon the sale or license of our technology to a third party.

Defiante Farmaceutica, L.d.a. We have exclusively licensed certain European rights to Tß4 to Defiante Farmaceutica, L.d.a., a Portuguese company that is a wholly owned subsidiary of Sigma-Tau, S.p.A., a pharmaceutical company headquartered in Rome, Italy. Defiante will develop Tß4 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.

Under the Agreement, Defiante will pay us a royalty on commercial sales and we will supply all required Tß4. When we complete at least one positive Phase II clinical trial, 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 enter into various agreements with a variety of outside service providers for the manufacture and development of Tß4, formulation of drug products, the conduct of pre-clinical safety, toxicology and efficacy studies in animal models, and management/execution of clinical studies in humans. Terms of these agreements vary, in that they can last from a few months to a year plus in duration. Some agreements require initial up front payments of 25% to 50% of the total estimated cost.

Employees

In order to most cost effectively execute our clinical development efforts, we have chosen to utilize an out-sourced business strategy. Recognizing the periodic peaks and valleys of 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 testing, to clinical study management, we believe that the use of outside contractors as and when needed is more cost beneficial than trying to directly employ and maintain facilities to support these varied efforts. We currently have ten full and two part-time employees who collectively define the Company's strategy in consultation with our Board, and manage all outside relationships.

Principal Executive Offices

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 electronically file with or furnish them to the U.S. Securities and Exchange Commission.

Item 1A. Risk Factors,

Investors in RegeneRx should carefully consider the risks described below before making an investment decision. The risks described below may not be the only ones facing our company. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment. In assessing these risks, investors should also refer to the other information contained or incorporated by reference in this Annual Report on Form 10-K for the year ended December 31, 2006, including our financial statements and related notes.

Risks Related to RegeneRx's Business

RegeneRx Has A Lack Of Revenues And A History Of Losses

RegeneRx has sustained operating losses since its inception in 1982. It believes these losses will continue for the foreseeable future. To date, RegeneRx has not had revenues from operations and does not expect to in the foreseeable future. As of December 31, 2006, RegeneRx had an accumulated

deficit of $56.2 million. RegeneRx anticipates substantial and increasing operating losses over the next several years as it continues its research and development efforts and seeks to obtain regulatory approval of its products to make them commercially viable. Therefore, RegeneRx's ability to continue operations depends on its ability to access capital when necessary, cease operating losses by completing development of its products, obtain requisite regulatory approvals and ultimately commercialize such products.

There Are Uncertainties Related To The Limited Capital Resources Of RegeneRx

RegeneRx anticipates that new capital resources will be required to continue its independent development efforts. The actual amount of funds that RegeneRx will need will be determined by many factors, some of which are beyond RegeneRx's control. These factors include the success of its research and development efforts, the status of its non-clinical and clinical testing, the costs relating to securing approvals of the U.S. Food and Drug Administration and other regulatory authorities, the costs and timing of obtaining new patents, regulatory changes, competition and technological developments in the market.

Potential sources of outside capital include entering strategic business relationships, public or private sales of shares of RegeneRx's capital stock or debt or other similar arrangements. RegeneRx does not have any committed sources of outside capital at this time. It is uncertain whether RegeneRx will be able to obtain outside capital when it needs it or on terms that would be acceptable. If RegeneRx raises additional capital through strategic business relationships, such as through collaborations and licensing arrangements, the company may have to give up valuable rights to intellectual property and the value of the company's interest in the licensed products could be negatively impacted by competing strategic and financial interests of the company's collaborators or licensees. If RegeneRx raises funds by selling additional shares of its common stock or securities convertible into its common stock, the ownership interest of its existing stockholders will be diluted. If RegeneRx is unable to obtain outside capital when needed, in the amount needed, its business and future prospects would be adversely affected and it could be forced to suspend or discontinue operations.

RegeneRx Has Limited Expertise And Capacity To Conduct Pre-Clinical Testing And Trials Requiring Dependence On Other Parties

RegeneRx has only limited experience, resources, and capacity with pre-clinical testing, clinical trials, formulation, manufacturing and commercialization of drug products. As a result, RegeneRx has engaged and intends to continue engaging contract research organizations, or "CROs", to perform pre-clinical testing and clinical trials for drug candidates that are chosen for development without a collaborator. If the CROs that RegeneRx hires to perform the pre-clinical testing and clinical trials or collaborators or licensees do not meet deadlines, do not follow proper procedures, or a conflict arises between RegeneRx and their CROs, the pre-clinical testing and clinical trials may take longer than expected, may be delayed or may be terminated. If RegeneRx were forced to find a replacement entity to perform any of the pre-clinical testing or clinical trials, RegeneRx may not be able to find a suitable entity on favorable terms, or at all. Even if it were able to find another company to perform a pre-clinical test or clinical trial, the delay in the test or clinical trial may result in significant expenditures. Events such as these may result in delays in obtaining regulatory approval for drug candidates or commercializing products and could result in increased expenditures that would adversely affect RegeneRx's operating results.

In addition, for some of its drug candidates, RegeneRx plans to contract with collaborators or licensees to advance those candidates through later-stage, more expensive clinical trials, rather than invest its own resources to perform these clinical trials. Depending on the terms of the agreements with these collaborators or licensees, RegeneRx may not have any control over the conduct of these clinical trials, and in any event would be subject to the risks associated with depending on collaborators or licensees to develop these drug candidates.

RegeneRx Is Exposed To Product Development Risk

Although RegeneRx was formed in 1982, it is still in the early stages of the development of its pharmaceutical products. Presently, RegeneRx does not have any products that have received regulatory approval, does not expect to have any such products for several years and may never successfully develop or commercialize any such products. RegeneRx's proposed products are subject to numerous risks associated with the development of medical products. These risks include the possibilities that any of RegeneRx's products could be found to be ineffective or toxic, or could fail to receive necessary regulatory approvals. In addition, RegeneRx's products could face obsolescence if third parties develop superior or equivalent but less expensive products.

RegeneRx Is Subject To Government Regulation

Products that RegeneRx may develop will require regulatory approvals prior to sale. In particular, therapeutic agents and diagnostic products are subject to stringent approval, prior to commercial marketing, by the FDA in the United States and by comparable agencies in most foreign countries. The process of obtaining FDA and corresponding foreign approvals is costly and time consuming and RegeneRx cannot assure that such approvals will be granted. Any failure to obtain or any delay in obtaining such approvals could decrease the ability of RegeneRx to successfully market any products developed. Also, RegeneRx cannot predict the extent of adverse government regulation that might arise from future legislative or administrative action.

RegeneRx Is Heavily Reliant On Its World-Wide License From The National Institute Of Health ("NIH")

RegeneRx received an exclusive world-wide license to intellectual property discovered at the 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 RegeneRx to pay a minimum annual royalty to the NIH plus certain other royalties upon the sale of products created by the intellectual property granted under the license. RegeneRx relies on this license for a significant portion of its business. The loss of this license would adversely affect RegeneRx's ability to conduct its operations, which would have a material adverse affect on its financial conditions and results of operations.

RegeneRx Is Developing A Technology Platform Primarily Based On A Single Compound Which Has Yet To Be Proven Effective

RegeneRx's current primary business focus is the development of Thymosin beta 4, and its analogues and fragments, for the treatment of non-healing wounds and other conditions. While RegeneRx has in the past explored and may in the future explore the use of other compounds for the treatment of other medical conditions, it presently has no immediate plans to develop products for such purposes. This lack of product diversification would have a material adverse affect on RegeneRx if it is unsuccessful in its efforts to commercialize Thymosin beta 4 in some manner, possibly resulting in the termination of its current line of business.

RegeneRx Depends On Third Parties For Supply Of Raw Materials

RegeneRx depends on outside vendors for the supply of Thymosin beta 4. While there are numerous vendors that can manufacture Thymosin beta 4 to RegeneRx's specifications, RegeneRx's ability to obtain Thymosin beta 4 at an affordable cost or timely manner could be affected by various factors outside RegeneRx's control, including the availability of certain chemicals necessary for manufacturing Thymosin beta 4. If RegeneRx is unable to obtain sufficient supplies of Thymosin beta 4 in a timely fashion, our clinical development program will be adversely impacted.

RegeneRx Relies Upon Dr. Goldstein, Mr. Finkelstein, And Other Key Personnel

RegeneRx's success will depend to a large extent on the abilities and continued service of Dr. Goldstein and Mr. Finkelstein. The loss of Dr. Goldstein or Mr. Finkelstein could prevent or significantly delay the achievement of RegeneRx's goals. RegeneRx has employment agreements with Dr. Goldstein and Mr. Finkelstein. RegeneRx does not maintain, however, a key man life insurance policy with respect to Dr. Goldstein or Mr. Finkelstein. As RegeneRx grows, it will need to add additional management and other personnel. Competition for qualified personnel in RegeneRx's industry is intense, and RegeneRx's success will depend on its ability to attract and retain highly skilled personnel. RegeneRx cannot assure you that its efforts to obtain or retain such personnel will be successful.

RegeneRx Is Subject To Competition From Companies With Greater Resources

RegeneRx is engaged in a business that is highly competitive. Research and development activities for the development of drugs to treat indications within RegeneRx's 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 those of RegeneRx, and that have extensive experience in conducting research and development activities and clinical testing 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 RegeneRx's products 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. Additionally, most large pharmaceutical companies and many smaller biomedical companies are vigorously pursuing therapeutics to treat patients after heart attacks and other cardiovascular indications.

RegeneRx May Be Unable To Obtain Adequate Product Liability Insurance

RegeneRx's business exposes it to the risk of product liability claims that are inherent in the testing, manufacturing, and marketing of drugs. RegeneRx's liability exposure for human clinical trials for Thymosin beta 4 is dependent on its ability to obtain sufficient product liability insurance or to collaborate with corporate partners that have adequate insurance. In addition, the use of RegeneRx's products, when and if developed and sold, will expose RegeneRx to the risk of product liability claims. Although RegeneRx intends to obtain product liability insurance coverage, it cannot guarantee that product liability insurance will continue to be available to it on acceptable terms, or at all, or that its coverage will be sufficient to cover all claims against it. A product liability claim, even

one without merit or for which RegeneRx has substantial coverage, could result in significant legal defense costs, thereby potentially exposing RegeneRx to expenses significantly in excess of its revenues.

RegeneRx May Be Unable To Obtain Product Reimbursement By Third Parties

In addition to obtaining regulatory approval, the successful commercialization of certain of RegeneRx's products may depend on its 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 challenging 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 significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for RegeneRx's products, if and when developed. The cost containment measures that healthcare providers are instituting and any healthcare reform could affect RegeneRx's ability to sell its products and may have a material adverse effect on its operations. RegeneRx cannot assure that reimbursement in the United States or foreign countries will be available for any of RegeneRx's products, 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, its products. The lack or inadequacy of third-party reimbursements for certain of RegeneRx's products decreases the potential profitability of its operations. RegeneRx 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 its business.

Clinical Trials Could Be Delayed Or Fail To Show Efficacy Resulting In Additional Cost Or Failure To Commercialize Our Technology Platform.

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 RegeneRx's clinical trials. In addition, it may take longer than RegeneRx projects to achieve study endpoints and complete data analysis for a trial. RegeneRx may not complete its clinical trials when or as projected or commence or complete clinical trials involving any of its other product candidates as projected or may not conduct them successfully.

RegeneRx relies on academic institutions, physician practices and clinical research organizations to conduct, supervise, or monitor some or all aspects of clinical trials involving our product candidates. RegeneRx has less control over the timing and other aspects of these clinical trials than if it conducted the monitoring and supervision entirely on its 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. RegeneRx also relies on clinical research organizations to perform much of its data management and analysis. They may not provide these services as required or in a timely manner.

If RegeneRx fails to complete or if it experiences material delays in completing the Phase II trials as currently planned, or it otherwise fails to commence or complete, or experience delays in, any of its other present or planned clinical trials, RegeneRx's ability to conduct its business as currently planned could materially suffer. Development costs will increase if RegeneRx experiences any future delays in its clinical trials or if RegeneRx needs to perform more or larger clinical trials than it currently plans. If the delays or costs are significant, RegeneRx's financial results and its ability to commercialize its product candidates will be adversely affected.

Risks Related To RegeneRx Intellectual Property

RegeneRx May Be Unable To Obtain And Protect Its Intellectual Property Rights

RegeneRx's success also will depend in substantial part on its 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, RegeneRx has rights to two U.S. patents relating to the treatment of septic shock. RegeneRx also owns patents related to the use of Thymosin beta 4 among other thymic peptides, for the stimulation of hair growth.

Pursuant to an exclusive world-wide license from the NIH, RegeneRx now has exclusive rights under a patent application filed by the NIH for the use of Thymosin beta 4 in the treatment of non-healing wounds. While this patent has issued in certain countries, RegeneRx cannot guarantee whether or when the patent will be issued or as to the scope of the patent issued in other countries. If no additional patent issues from the NIH's application, RegeneRx's ability to commercialize Thymosin beta 4 as a wound-healing treatment could be substantially limited.

RegeneRx cannot assure you that any patent applications filed by RegeneRx, or by others under which RegeneRx has rights, will result in patents being issued in the United States or foreign countries. In addition, RegeneRx cannot guarantee that patents that have been or will be issued will afford meaningful protection for RegeneRx's products. Competitors may develop products similar to RegeneRx's that do not conflict with RegeneRx's patents. Others may challenge RegeneRx's patents and, as a result, RegeneRx's patents could be narrowed or invalidated. RegeneRx cannot assure that it will be able to afford the legal costs associated with defending or enforcing any of its patents.

Changes To United States Patent Laws May Devalue RegeneRx's Patent Portfolio

The value of RegeneRx's patents depends in part to their duration. A shorter period of patent protection could lesson the value of RegeneRx's 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 RegeneRx's period of patent exclusivity and may decrease the revenues that RegeneRx might derive from the patents.

International Patent Protection Is Uncertain And Costly

Biotechnology and pharmaceutical patent law outside the United States is even more uncertain and costly than in the United States and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as United States laws. For example, certain countries do not grant patent claims that are directed to the treatment of humans. RegeneRx may participate in opposition proceedings to determine the validity of its foreign patents or its competitors' foreign patents, which could result in substantial costs and diversion of RegeneRx's efforts.

Risks Related To Our Securities

RegeneRx Common Stock Price And Volume Is Volatile

The price of RegeneRx's stock can be volatile, which makes it difficult for stockholders to predict the value of their shares or buy or sell shares at any given time. During the year ended December 31, 2006, RegeneRx's closing stock price has ranged from $1.79 to $3.41. A variety of factors may affect the market price of RegeneRx's common stock including, but not limited to:

- results of testing and clinical trials;
- commercial success of approved products;
- corporate partnerships;
- technological innovations by RegeneRx or competitors;
- changes in laws and government regulations;
- changes in key personnel at the company;
- developments concerning proprietary rights, including patents and litigation matters;
- public perception relating to the commercial value or safety of any of RegeneRx's products;
- future sales of RegeneRx common stock;
- future issuance of RegeneRx common stock causing dilution;
- variations in RegeneRx financial performance;
- general trends related to the biopharmaceutical and biotechnological industries; and
- general conditions in the stock market.

RegeneRx's common stock is currently traded on the American Stock Exchange. During the year ended December 31, 2006, the average volume of RegeneRx common stock trade was 15,543 shares per day.

RegeneRx Has Never Paid Dividends On Its Common Stock

Since its inception in 1982, RegeneRx has not paid cash dividends on its common stock and does not intend to pay cash dividends in the foreseeable future due to RegeneRx's limited funds for operations. Therefore, any return on your investment would come only from an increase in the value of the stock.

RegeneRx Controlled By Management And A Small Number Of Stockholders

As of December 31, 2006, RegeneRx's executive officers, directors and 5% or greater stockholders together controlled approximately 49% of the outstanding shares of RegeneRx's common stock, RegeneRx's sole class of outstanding voting securities. These stockholders, acting together, are in a position to influence and possibly control most matters submitted for approval by RegeneRx's stockholders, including the election of directors and the consideration of mergers or other proposed transactions in which stockholders might otherwise receive a premium for their shares over then current market prices.

There Is A Potential For Future Dilution To Existing Stockholders

Currently, RegeneRx is authorized to issue up to 100,000,000 shares of its common stock, and as of December 31, 2006, there were issued and outstanding 46,096,477 shares of RegeneRx's common stock. The authorized but unissued shares may be issued by RegeneRx in such transactions and at such times as its Board of Directors considers appropriate, whether in public or private offerings, as stock splits or dividends or in connection with mergers and acquisitions or otherwise. Any such issuance 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.

RegeneRx May Be Unable To Maintain The Standards For Listing On The American Stock Exchange

RegeneRx common stock is currently listed on the American Stock Exchange. There are several requirements that RegeneRx must satisfy in order for its common stock to continue to be listed on the American Stock Exchange. In the future, RegeneRx may not comply with all of these listing requirements, which might result in the delisting of its common stock. Delisting from the American Stock Exchange could adversely affect the liquidity and the price of RegeneRx's common stock and could have a long-term adverse impact on its ability to raise future capital through a sale of shares of its common stock.

If it were to be delisted, RegeneRx common stock would be traded on an electronic bulletin board established for securities that are not traded on a national securities exchange, NASDAQ or traded in quotations published by the National Quotation Bureau, Inc., commonly referred to as the "pink sheets." If this occurs, it could be difficult to sell RegeneRx securities or obtain the same level of market information as to the price of shares of its common stock as is currently available.

The Exercise Of Options And Warrants And Other Issuances Of Shares Of Common Stock Will Likely Have A Dilutive Effect On RegeneRx's Stock Price.

As of March 31, 2007, there were outstanding options to purchase an aggregate of 3,332,500 shares of RegeneRx common stock at prices ranging from $0.28 per share to $3.82 per share, of which options to purchase approximately 1,647,083 shares were exercisable as of such date. As of March 30, 2007, there were outstanding warrants to purchase 3,522,544 shares of RegeneRx common stock, at a weighted average exercise price of $3.26.

The exercise of options and warrants at prices below the market price of RegeneRx common stock could adversely affect the price of shares of RegeneRx common stock. Additional dilution may result from the issuance of shares of RegeneRx capital stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

The issuance of additional shares of RegeneRx common stock could be dilutive to stockholders if they do not invest in future offerings. Moreover, to the extent that RegeneRx issues options or warrants to purchase its common stock in the future and those options or warrants are exercised or RegeneRx issues restricted stock, stockholders may experience further dilution. Holders of shares of RegeneRx 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.

RegeneRx's Certificate Of Incorporation And Delaware Law Contain Provisions That Could Discourage A Takeover And Entrench Management.

RegeneRx's certificate of incorporation provides its board of directors the power to issue shares of preferred stock without stockholder approval. This preferred stock could have voting rights, including voting rights that could be superior to that of RegeneRx's common stock. In addition, Section 203 of the Delaware General Corporation Law contains provisions that impose restrictions on stockholder action to acquire control of RegeneRx. The effect of these provisions of its certificate of incorporation and Delaware law make it more difficult to remove management and could discourage third parties from seeking to obtain control, even though the price at which such third parties seek to acquire RegeneRx common stock is in excess of the market price for its stock.

Item lB. Unresolved Staff Comments.

None

Item 2. Properties.

Our corporate headquarters are located in Bethesda, Maryland where we lease office space in a high-rise office building. Our thirty-six (36) month lease commenced in January 2005 and has an optional twenty-four (24) month extension.

Item 3. Legal Proceedings.

None

Item 4. Submission of Matters to a Vote of Security Holders.

None

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Securities.

On March 28, 2005, our common stock began trading on the American Stock Exchange under the symbol RGN. Prior to that date and since March 2001, our common stock traded on the OTC Bulletin Board under the symbol RGRX. We also have outstanding classes of warrants to purchase our common stock for which there is no public market.

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

	2006		2005	
	High	Low	High	Low
First Quarter	$3.41	$2.85	$4.85	$2.75
Second Quarter	$3.05	$2.52	$4.20	$2.60
Third Quarter	$2.75	$1.79	$4.25	$3.05
Fourth Quarter	$2.96	$1.97	$3.65	$2.90

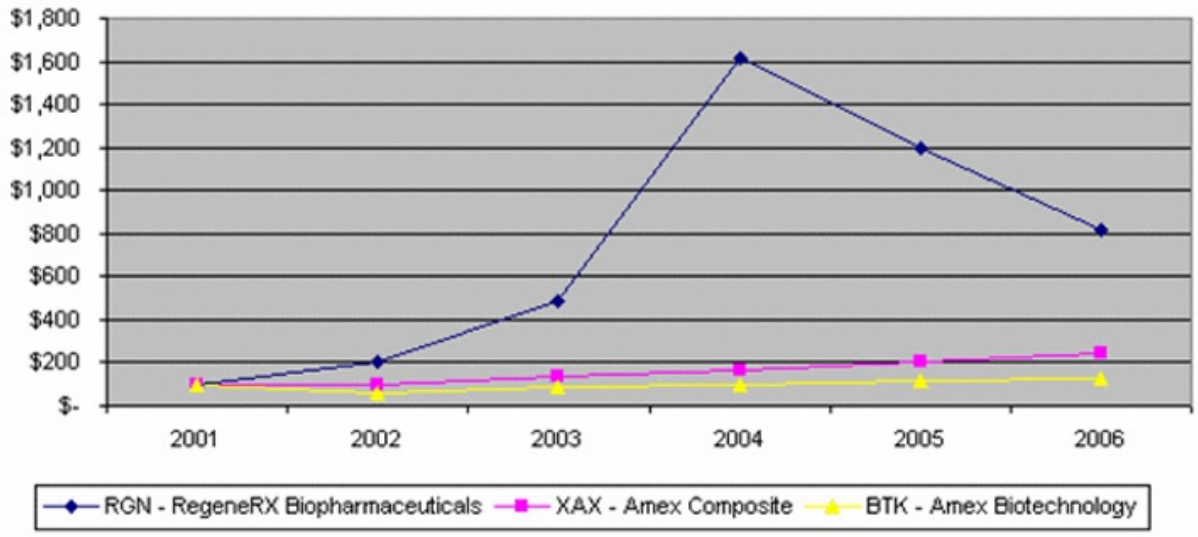
As of March 14, 2007, there were approximately 986 holders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Corporation (or "DTC"). All of the shares of Common Stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners 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.

For information regarding securities authorized for issuance under equity compensation plans, see our proxy statement for the 2007 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of the Company's fiscal year.

Performance Graph

We show below the cumulative total return to our stockholders during the period from December 31, 2001 through December 31, 2006 in comparison to the cumulative return on the Amex Composite Index and the Amex Biotechnology Index during that same period. [1] The results assume that $100 was invested on December 31, 2001.



	2001	2002	2003	2004	2005	2006
RGN—RegeneRX Biopharmaceuticals	$100	$200	$484	$1,620	$1,200	$820
XAX—Amex Composite	100	97	138	169	208	243
BTK—Amex Biotechnology	100	58	84	94	117	130

(1) The total return on investment (change in year end stock price plus reinvested dividends) assumes $100 invested on December 31, 2001 in our common stock, the Amex Composite Index and the Amex Biotechnology Index. The Amex Biotechnology Index is comprised of Affymetrix Inc., Amgen Inc., Amylin Pharmaceuticals Inc., Biogen Idec Inc., Celgene Corporation, Cephalon Inc., Celera Group, Genentech Inc., Genzyme Corp., Gilead Sciences Inc., Human Genome Sciences Inc., Imclone Systems Inc., InterMune Inc., Invitrogen Corp., MedImmune, Inc., Millipore Corp., Millenium Pharmaceuticals Inc., Nektar Therapeutic, PDL Biopharma Inc., Vertex Pharmaceuticals Inc.

The information under "Performance Graph" is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any filing of RegeneRx under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this 10-K and irrespective of any general incorporation language in those filings.

Item 6. Selected Financial Data.

The selected consolidated financial data set forth below with respect to RegeneRx's Statements of Operations for the fiscal years ended December 31, 2006, 2005 and 2004 with respect to RegeneRx's Balance Sheets at December 31, 2006 and 2005 are derived from the audited Financial Statements of RegeneRx, which are included elsewhere in this Form 10-K. Statements of Operations data for the fiscal years ended December 31, 2003 and 2002 and Balance Sheet data at December 31, 2004, 2003 and 2002 are derived from audited Financial Statements of RegeneRx not included herein. The selected financial data set forth below is qualified in its entirety by, and should be read in conjunction with, the Financial Statements, the related Notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Form 10-K.

	For the years ended December 31,				
	2006	2005	2004	2003	2002
Revenue	$ 272,491	$ —	$ —	$ —	$ —
Loss from operations	$ (8,266,981)	$ (5,454,851)	$ (3,326,399)	$ (1,659,875)	$ (1,404,547)
Basic and diluted loss per share	$ (0.21)	$ (0.15)	$ (0.10)	$ (0.06)	$ (0.05)

	As of December 31,				
	2006	2005	2004	2003	2002
Working capital	$ 16,187,188	$ 6,939,195	$ 2,412,917	$ 890,166	$ 379,100
Total assets	$ 17,501,625	$ 7,724,634	$ 3,288,501	$ 1,109,818	$ 546,933
Accumulated deficit	$(56,227,421)	$(47,960,440)	$(42,505,589)	$(39,179,190)	$(37,519,315)
Total stockholders' equity	$ 16,252,335	$ 7,010,507	$ 2,708,579	$ 916,770	$ 309,787

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation.

This report contains forward-looking statements concerning matters that involve risks and uncertainties. Statements made in this Item that are not purely historical, including statements about us, our respective clinical trials, research programs, product pipelines, current and potential corporate partnerships, licenses and intellectual property, the adequacy of capital reserves and anticipated operating results and cash expenditures, are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended and Section 27A of the Securities Act of 1933, as amended. Words such as "believes," "likely," "may," and "plans" are intended to identify forward–looking statements, although not all forward-looking statements contain these words. These forward-looking statements concern matters that involve risks and uncertainties that could cause actual results to differ materially from those projected, including risks associated with the success of research and product development programs, the issuance and validity of patents, the development and protection of proprietary technologies, the ability to raise capital, operating expense levels and the ability to establish and retain corporate partnerships, our history of operating losses and the risks set forth under Part II, Item 1A., "Risk Factors." We do not undertake any obligation to update forward-looking statements. The following should be read in conjunction with our financial statements included elsewhere herein and in other documents filed by us from time to time with the Securities and Exchange Commission.

Results of Operations. As a company focused on the research and clinical development efforts necessary to bring pharmaceutical products to the market, our operations are currently generating losses. Those losses are generally the net result of research and development efforts, and general and administrative costs, offset by investment income. Additionally, in 2006 we received income of approximately $270,000 from a grant awarded by the FDA's Office of Orphan Drugs and we anticipate a similar amount of grant income in 2007. This income helps to offset some of the costs we incur for our epidermolysis bullosa trial. These annual net losses have increased from $3.3 million in 2004 to $5.4 million in 2005 and $8.3 million in 2006. We anticipate our net losses will increase in the near term as we continue to expand and advance our clinical development activity.

For the three years ended December 31, 2006, we reported annually increasing expenditures in the area of research and development. These increases directly reflect the increased research and development activities that we have undertaken as our clinical development has progressed over the

three year period. In 2004 we were focused primarily on pre-clinical and Phase I clinical activities in our dermal wound healing indications. During 2005, some of these preclinical activities continued into the first half of the year, clinical drug formulation was performed, and Phase II clinical trials commenced in the later half of the year. During 2006 we continued to manage our Phase II clinical dermal trials and expanded our clinical development program into the cardiac and ophthalmic areas. Specifically, drug formulation, protocol development, contractor and site qualification, etc., 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 one and a half full-time equivalent employees in 2004 to 7 full-time equivalent employees by the end of 2006. Coincident with our expanding development was the need to supply increasingly larger amounts of Tß4, along with a significant increase in outsourced contract activity. All of these expanding efforts increased our research and development costs from $2.2 million in 2004 to $3.2 million in 2005 and $6.4 million in 2006, approximately a three-fold increase. Included in these total research and development costs were non-cash equity compensation costs for our research and development personnel of approximately $0.09 million, $0.04 million and $0.3 million in 2004, 2005 and 2006, respectively. (See Note 2 to the financial statements for a full description of our accounting for the costs of non-cash equity compensation and how that accounting has changed during this time period.)

General and administrative expenses include legal costs to protect our patent portfolio, non-cash equity compensation of our administrative personnel, along with the general compliance and administrative costs necessary to operate a publicly-traded entity. In 2004, we had two full-time administrative employees. During 2005, we hired a chief financial officer which increased our administrative headcount to three. Additionally, in 2005 we were listed on the American Stock Exchange and generally enhanced our supporting infrastructure to accommodate all of our additional employees and expanded research activities. As a result, general and administrative costs increased from $1.2 million in 2004 to $2.5 million in 2005 and to $2.7 million in 2006. Included in those costs were patent legal costs of approximately $0.0 million, $0.9 million and $0.6 million, in 2004, 2005 and 2006, respectively. Non-cash equity compensation expenses for our administrative personnel were $0.0 million, $0.2 million and $0.5 million in 2004, 2005 and 2006, respectively. With the exception of some additional costs to comply with section 404 requirements of Sarbanes Oxley, which we do not believe will be material, and additional non-cash equity compensation costs, we do not anticipate a significant change in our current level of general and administrative expenses.

Liquidity and Capital Resources. Since inception we have financed our operations through the sale of equity securities. At December 31, 2006 we had $17.0 million in cash, cash equivalents and short-term investments. Although no assurance can be given, we believe that our current cash and investment balances will be sufficient to meet our operating needs through the second quarter of 2008. However, those activities will not be sufficient to bring our drug candidates to market and we, therefore, believe new capital resources will be required in the coming months to continue our independent development efforts. Accordingly, we may entertain the possibility of raising additional capital to preserve our liquidity, depending on a number of conditions, including conditions in the capital markets. We regularly consider the conditions of capital markets, dilution, stockholder value and tax consequences of each type of financing. Certain of the financing options available to us may have negative consequences to stockholders such as dilution. Given the volatile nature of the capital markets, decisions to raise capital may require actions that would impose a negative consequence in order to reduce or minimize a more significant negative consequence to stockholders.

Contractual obligations. Our contractual obligations as of December 31, 2006, presented in the following chart consist of an office facility lease which ends in January 2008 and obligations to purchase Tß4. We anticipate that a new lease will be more expensive than our current lease due to an increased rate per square foot and possibly leasing additional square feet. While we can not accurately predict these future expenses at this time, we do not anticipate that the increased costs will be material to our future operating results.

	Payments due by period:		
	Total	Under 1 year	1 - 3 years
Operating lease	$ 72,740	$ 72,740	$ —
Purchase obligations	1,280,000	1,280,000	—
	$1,352,740	$1,352,740	$ —

We also have approximately $2 million in other contractual obligations due within one year and related to our research and development efforts. These obligations, however, are contingent on future events, e.g. the rate of patient accrual in our clinical trials. This amount represents the remaining contractual amounts due under various contracts, although all of these contracts could be cancelled by us, in which case we would only be liable to the vendors for work performed to the date of cancellation.

Critical Accounting Policies. We prepare our financial statements in conformity with accounting principles generally accepted in the United States. Such accounting principles require that our management make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Our actual results could differ materially from those estimates. The items in our financial statements that have required us to make significant estimates and judgments are as follows:

- Share-based payment – Effective January 1, 2006, we adopted the fair value recognition provisions of FASB Statement 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 SAB 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.

- Clinical trial costs – We accrue estimated costs for clinical studies conducted by contract research organizations and participating hospitals. These costs are a significant component of research and development expenses. We accrue costs for clinical studies 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.

Off Balance Sheet Arrangements. We have no material off-balance sheet arrangements other than those that are discussed above.

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 mortgage 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, 2006, cash, cash equivalents and short-term investments were $17.0 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, 2006, the decline in fair value would not be material.

Item 8. Financial Statements and Supplementary Data.

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

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

We have audited the accompanying balance sheets of RegeneRx Biopharmaceuticals, Inc. as of December 31, 2006 and 2005, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 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 mistatment. 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, 2006 and 2005, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 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 20, 2007

RegeneRx Biopharmaceuticals, Inc.
Balance Sheets

	December 31, 2006	December 31, 2005
ASSETS		
Current assets		
Cash and cash equivalents	$ 13,052,308	$ 4,896,143
Short-term investments	4,000,000	2,679,693
Accounts receivable	272,491	—
Due from related party	—	4,592
Prepaid expenses and other current assets	111,679	72,894
Total current assets	17,436,478	7,653,322
Fixed assets, net of accumulated depreciation of $41,030 and $22,918	53,398	54,234
Other non-current assets	11,749	17,078
Total assets	$ 17,501,625	$ 7,724,634
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 362,402	$ 187,666
Accrued expenses	886,888	526,461
Total current liabilities	1,249,290	714,127
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; 46,096,477 and 37,629,024 issued and outstanding	46,096	37,629
Additional paid-in capital	72,433,660	54,936,362
Accumulated other comprehensive loss	—	(3,044)
Accumulated deficit	(56,227,421)	(47,960,440)
Total stockholders' equity	16,252,335	7,010,507
Total liabilities and stockholders' equity	$ 17,501,625	$ 7,724,634

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Operations

	Years ended December 31,		
	2006	2005	2004
Revenues	$ 272,491	$ —	$ —
Operating expenses:			
Research and development	6,396,524	3,155,735	2,184,314
General and administrative	2,665,652	2,513,792	1,158,450
Total operating expenses	9,062,176	5,669,527	3,342,764
Loss from operations	(8,789,685)	(5,669,527)	(3,342,764)
Interest income	522,704	214,676	16,365
Net loss	$ (8,266,981)	$ (5,454,851)	$ (3,326,399)
Basic and diluted net loss per common share	$ (0.21)	$ (0.15)	$ (0.10)
Weighted average number of common shares outstanding	40,116,367	36,843,609	32,909,753

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Changes in Stockholders' Equity
Years ended December 31, 2006, 2005 and 2004

	Common stock					
	Shares	Amount	Additional Paid-in capital	Accumulated Deficit	Accumulated other Comprehensive Income/(loss)	Total stockholders' equity
Balance, December 31, 2003	30,098,968	$30,099	$40,065,861	$(39,179,190)	$ —	$ 916,770
Issuance of common stock, net of offering costs of $78,293	2,778,197	2,778	3,428,646	—	—	3,431,424
Issuance of common stock upon exercise of warrants	1,675,191	1,675	1,574,676	—	—	1,576,351
Issuance of common stock upon exercise of options	25,000	25	2,100	—	—	2,125
Share-based compensation expense	—	—	108,308	—	—	108,308
Net loss	—	—	—	(3,326,399)	—	(3,326,399)
Unrealized loss on available for sale securities	—	—	—	—	—	—
Total comprehensive loss	—	—	—	—	—	(3,326,399)
Balance, December 31, 2004	34,577,356	34,577	45,179,591	(42,505,589)	—	2,708,579
Issuance of common stock, net of offering costs of $97,035	2,958,923	2,959	9,516,505	—	—	9,519,464
Issuance of common stock upon exercise of warrants	72,745	73	6,427	—	—	6,500
Issuance of common stock upon exercise of options	20,000	20	9,280	—	—	9,300
Share-based compensation expense	—	—	224,559	—	—	224,559
Net loss	—	—	—	(5,454,851)	—	(5,454,851)
Unrealized loss on available for sale securities	—	—	—	—	(3,044)	(3,044)
Total comprehensive loss						(5,457,895)
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
Issuance of common stock upon exercise of options	—	—	—	—	—	—
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

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

RegeneRx Biopharmaceuticals, Inc.
Statements of Cash Flows

	Year ended December 31,		
	2006	2005	2004
Operating activities:			
Net loss	$ (8,266,981)	$(5,454,851)	$(3,326,399)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	18,112	15,626	4,175
Write-off of deferred patent costs		597,043	—
Non-cash share-based compensation	795,003	224,559	108,308
Changes in operating assets and liabilities:			
Accounts receivable	(272,491)	—	—
Prepaid expenses and other current assets	(38,785)	(42,556)	6,090
Due from related party	4,592	7,765	14,540
Other non-current assets	5,329	(17,078)	—
Accounts payable	174,736	(218,332)	256,031
Accrued expenses	360,427	428,420	(13,739)
Net cash used in operating activities	(7,220,058)	(4,459,404)	(2,950,994)
Investing activities:			
Purchase of short-term, available-for-sale investments	(5,580,424)	(6,382,737)	—
Proceeds from sales/maturities of short-term investments	4,263,161	3,700,000	—
Purchase of fixed assets	(17,276)	(64,564)	(1,598)
Increase in patent costs	—	(306,676)	(202,937)
Net cash used in investing activities	(1,334,539)	(3,053,977)	(204,535)
Financing activities:			
Stock subscription receivable	—	(5,000,000)	—
Proceeds from stock subscription receivable	—	5,000,000	—
Net proceeds from issuance of common stock	15,936,512	9,519,464	3,431,424
Preceeds from exercise of warrants	774,250	6,500	1,576,351
Proceeds from exercise of options	—	9,300	2,125
Net cash provided by financing activities	16,710,762	9,535,264	5,009,900
Net increase in cash and cash equivalents	8,156,165	2,021,883	1,854,371
Cash and cash equivalents:			
Beginning of period	4,896,143	2,874,260	1,019,889
End of period	$13,052,308	$ 4,896,143	$ 2,874,260
Supplemental disclosure of significant noncash investing and financing activities:			
Deferred offering costs included in accrued expenses	$ —	$ —	$ 75,884
Patent costs included in accounts payable	$ —	$ —	$ 68,698

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 Tß4. 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 Tß4-based products 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 and/or cosmetic products 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 Tß4. We expect that our existing capital resources will be sufficient to fund our projected operations into the second 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, 2006 consist primarily of 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 its 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 $18,112 $12,918 and $2,387 for the years ended December 31, 2006, 2005 and 2004, 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, 2006 or 2004. A write-off of $597,043 was recorded in the year ended December 31, 2005 for the unamortized balance of deferred patent costs.

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 clinical and preclinical study 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,		
	2006	2005	2004
Outstanding stock options	2,685,000	2,470,000	1,565,000
Warrants	3,979,594	1,546,815	1,253,574
Total potential common shares excluded from diluted net loss per share computation	6,664,594	4,016,815	2,818,574

Share-Based Compensation. Prior to January 1, 2006, we accounted for share-based compensation plans under the recognition and measurement provisions of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees" and the related interpretations, as permitted by SFAS No. 123, "Accounting for Stock-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 fiscal 2006

includes: (a) compensation cost for all equity-based payments granted prior to, but not vested as of, January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and (ii) compensation cost for all equity-based payments granted subsequent to January 1, 2006, based on the grant-date fair value, estimated in accordance with the provisions of SFAS No. 123R. Results of prior periods have not been restated. A summary of compensation expense related to stock options follows:

	Years ended December 31,		
	2006	2005	2004
Employees	$452,571	$ —	$ —
Non-employees	342,432	224,559	108,308
Total compensation expense	$795,003	$224,559	$108,308
Research and development	$293,297	$ 45,251	$ 91,697
General and administrative	501,706	179,308	16,611
Total compensation expense	$795,003	$224,559	$108,308

As a result of the adoption of SFAS No. 123R effective January 1, 2006, the Company's net loss for the year ended December 31, 2006 was $452,571 higher than if the Company had not adopted SFAS No. 123R. Basic and diluted net loss per share for the year ended December 31, 2006 was $0.01 higher than if the Company had not adopted SFAS No. 123R.

The following table illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS 123R to stock-based compensation for the years ended December 31, 2004 and 2005. The reported and pro forma net loss and net loss per common share for the year ended December 31, 2006 are the same because stock-based compensation is calculated under the provisions of SFAS 123R. The amounts for the year ended December 31, 2006 are included in the following table only to provide net loss and net loss per common share for a comparative presentation to the period of the previous year. The pro forma disclosure for the years ended December 31, 2004 and 2005 utilized the Black-Scholes option-pricing formula to estimate the value of the respective options with such value recognized as expense over the options' vesting periods.

	Years ended December 31,		
	2006	2005	2004
Pro forma net loss:			
As reported	$(8,266,981)	$(5,454,851)	$(3,326,399)
Total employee non-cash stock compensation expense determined under fair value based method for all awards	—	(324,429)	(77,384)
Pro forma net loss:	$(8,266,981)	$(5,779,280)	$(3,403,783)
Net loss per common share:			
Basic and diluted—as reported	$ (0.21)	$ (0.15)	$ (0.10)
Basic and diluted—pro forma	$ (0.21)	$ (0.16)	$ (0.10)

The weighted average fair value of the options at the date of grant during 2006, 2005 and 2004 was $2.47, $3.12 and $0.47, respectively. The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions for stock options granted during the years ended December 31, 2006, 2005 and 2004:

	2006	2005	2004
Dividend yield	0.0%	0.0%	0.0%
Risk free rate of return	4.3 - 5.0%	3.9 - 4.3%	2.7%
Expected life in years	6.0 - 6.5	6.0 - 6.8	5.0
Volatility	100 - 333%	400 - 450%	47.0%

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 2006 to the methodology used to determine the assumptions.

We based our estimate of expected volatility for the twelve months ended December 31, 2006 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, 2006 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. The Company recorded total share-based compensation expense for all share-based awards of $795,003 during the year ended December 31, 2006.

At December 31, 2006, total compensation cost related to non-vested stock options not yet recognized was approximately $2,145,000, which is expected to be recognized over the next 1.6 years on a weighted average basis.

Reclassifications. Certain amounts presented in the prior year financial statements have been reclassified to conform with current year presentation.

Effect of new accounting standards. In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation ("FIN") No. 48, "Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109" ("FIN 48"). FIN 48 prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the effect, if any, the adoption of FIN 48 will have on its financial statements.

3. CASH, CASH EQUIVALENTS & SHORT-TERM INVESTMENTS

The following is a summary of the Company's available-for-sale investments at December 31, 2006 and 2005, all of which are due within one year:

	Net amortized cost	Unrealized gain	Unrealized loss	Estimated fair value
December 31, 2006				
Money market securities	$ 151,731	$ —	$ —	$ 151,731
Corporate notes	13,330,341	—	—	13,330,341
Municipal bonds	3,000,000	—	—	3,000,000
				$16,482,072
Reported as:				
Cash and cash equivalents				$12,482,072
Short-term investments				4,000,000
				$16,482,072
December 31, 2005				
Corporate notes	$ 7,330,818	$ —	$ (3,044)	$ 7,327,774
Reported as:				
Cash and cash equivalents				$ 4,648,081
Short-term investments				2,679,693
				$ 7,327,774

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 Tß4 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 Tß4, 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, L.d.a., ("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 Tß4 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 Tß4-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 shareholder.

5. RELATED PARTY TRANSACTIONS

Prior to 2004, we made advances to officers, a practice which has now been discontinued. As of December 31, 2006 and 2005, the Company had advances to an officer of $0 and $4,592. The advances were non-interest bearing and due on demand.

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 $28,000, $48,000 and $48,000 during the years ended December 31, 2006, 2005 and 2004.

As described in Note 4, we entered into an agreement to use Tß4 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,	
	2006	2005
Contract/clinical research organizations	$450,066	$357,651
Professional fees	373,800	29,044
Vacation	33,687	25,000
401(k) contributions	17,294	—
Other	7,166	9,516
Employee bonuses	4,875	92,500
Board fees	—	12,750
	$886,888	$526,461

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 $11,414, $5,157 and $0 for the years ended December 31, 2006, 2005 and 2004, 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 shareholders (other than the acquiring entity) will be issued a significant number of new shares which would encumber an acquisition.

Sales of Common Stock. 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.

During 2005 we sold 2,958,923 shares of our common stock for an average price of $3.25 per share, generating approximately $9.6 million in gross proceeds. In addition, we issued 366,653 warrants to purchase our common stock at an average price of $4.06 per share. These warrants are exercisable until January 2008.

During 2004 we sold 2,778,197 shares of our common stock for an average price of $1.26 per share, generating approximately $3.5 million in gross proceeds. In connection with these sales, we issued 694,552 warrants to purchase our common stock at an average price of $1.86 per share. These warrants are exercisable until December 2007.

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, 2006, 2005 and 2004:

		Options outstanding		
	Shares available for grant	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2003	1,285,000	1,225,000	$0.08 - $1.07	$ 0.34
Grants	(365,000)	365,000	0.86 - 1.54	1.25
Exercises		(25,000)	0	0.08
Cancellations	—	—	—	—
Newly authorized	700,000			
December 31, 2004	1,620,000	1,565,000	0.28 - 1.54	$ 0.54
Grants	(925,000)	925,000	3.10 - 3.82	3.20
Exercises	—	(20,000)	0.40 - 0.53	0.47
Cancellations	—	—	—	—
Newly authorized	—	—	—	—
December 31, 2005	695,000	2,470,000	0.28 - 3.21	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 - $3.21	$ 1.66

	For the years ended December 31,		
	2006	2005	2004
Weighted average estimated fair value of options granted, based on the assumptions in the Black-Scholes valuation model	$ 2.47	$ 3.14	$ 0.47
Intrinsic value of options exercised	$ —	$ 33,000	$103,125
Estimated fair value of shares vested, based on the fair value assigned to the shares at the time of grant	$752,058	$238,583	$128,100

For various price ranges, weighted average characteristics of outstanding and exercisable options as of December 31, 2006 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	5.2	$ 0.38	1,196,250	5.1	$ 0.35
$1.07 - $1.54	255,000	7.3	$ 1.46	175,000	7.3	$ 1.44
$2.59 - $3.82	1,140,000	8.4	$ 3.15	192,500	8.3	$ 3.20
	2,685,000			1,563,750		
Intrinsic value of in-the-money options, using the December 31, 2006 closing price of $2.05	$2,302,200			$2,145,037		

Warrants to Purchase Common Stock

The following table summarizes our warrant activity for 2005 and 2004:

	Warrants outstanding		
	Number of shares	Exercise price range	Weighted average exercise price
December 31, 2003	2,206,797	$ 0.10 to $ 1.25	$ 0.73
Grants	694,552	1.50 - 4.06	1.86
Exercises	(1,647,775)	0.10 - 1.50	0.95
Cancellations	—	—	—
December 31, 2004	1,253,574	0.10 - 1.50	1.05
Grants	366,653	4.06	4.06
Exercises	(73,412)	0.10 - 0.41	0.13
Cancellations	—	—	—
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

9. INCOME TAXES

Significant components of the Company's deferred tax assets at December 31, 2006 and 2005 are shown below, in thousands. A valuation allowance of approximately $20.1 million and $17.6 million has been recognized to offset the net deferred tax assets as of December 31, 2006 and 2005, respectively, as realization of such assets is uncertain. The valuation allowance increased by approximately $2.5 million in 2006 compared to 2005, primarily due to an increase in the Company's net operating loss.

	December 31,	
	2006	2005
Deferred tax assets:		
Net operating loss carryforwards	18,423,000	16,569,000
Research and development tax credit carryforward	1,174,000	842,000
Charitable contribution carryforward	35,000	2,000
Accrued vacation	11,000	8,000
Amortization	7,000	8,000
Other	436,000	128,000
	20,086,000	17,557,000
Less—valuation allowance	(20,083,000)	(17,557,000)
Net deferred tax asset	3,000	—
Deferred tax liabilities:		
Depreciation	(3,000)	—
Net deferred tax amounts	$ —	$ —

At December 31, 2006, we had net operating loss carryforwards for income tax purposes of approximately $47.7 million and research and development tax credit carryforwards of approximately $1.2 million. The carryforwards, if not utilized, will expire in increments through 2026. Utilization of the net operating losses and credits may 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 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, 2006, 2005 and 2004, due to the following:

	December 31,		
	2006	2005	2004
Tax benefit at statutory rate	$(2,811,000)	$(1,855,000)	$(1,089,000)
State taxes	(382,000)	(252,000)	(148,000)
Permanent M-1s	(32,000)	(140,000)	—
Expired net operating loss carryforwards	1,033,000	795,000	199,000
Expired research and development tax credit carryforward	64,000	72,000	—
Research and development tax credit carryforward	(398,000)	(210,000)	2,000
Change in valuation allowance	2,526,000	1,590,000	1,036,000
	$ —	$ —	$ —

10. COMMITMENTS

Lease. Our rent expense, related solely to office space, for 2006, 2005 and 2004 was $77,886 $65,967 and $45,949, respectively. We are committed under an office space lease that expires on December 31, 2007, and which will require a minimum lease payment of $72,740 to be made during 2007.

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, 2006 these obligations, if triggered, could amount to $745,000.

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, 2006. 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
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)
2005				
Revenue	$ —	$ —	$ —	$ —
Net Loss	$ (898,363)	$ (983,410)	$(1,379,427)	$(2,193,651)
Basic and diluted loss per share	$ (0.03)	$ (0.03)	$ (0.04)	$ (0.06)

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.

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

None.

Item 9A. Controls and Procedures.

As of the end of the period covered by this report, based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) each of the chief executive and chief financial officers of the Company has concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in its Exchange Act reports is recorded, processed, summarized and reported within the applicable time periods specified by the SEC's rules and forms.

There were no changes in our internal controls over financial reporting during the three months ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

Item 9B. Other Information.

All information required to be disclosed in a Current Report on Form 8-K during the fourth quarter of 2006 has been reported.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required under this item is incorporated herein by reference from the proxy statement for the 2007 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of the Company's fiscal year.

Item 11. Executive Compensation.

Information required under this item is incorporated herein by reference from the proxy statement for the 2007 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of the Company's fiscal year.

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

Information required under this item is incorporated herein by reference from the proxy statement for the 2007 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of the Company's fiscal year.

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

No information is required under this item.

Item 14. Principal Accounting Fees and Services.

Information required under this item is incorporated herein by reference from the proxy statement for the 2007 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of the Company's fiscal year.

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	Amendment to 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 30,2006 (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 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 March 7, 2006)

4.9	Form of Warrant	Exhibit 4.1 to the Company's Current Report on Form 8-K (filed December 18, 2006)
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 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 99.1 to the Company's Current Report on Form 8-K (filed on January 6, 2005)
10.13	Form of Securities Purchase Agreement	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed on March 7, 2006)
10.14	Form of Securities Purchase Agreement	Exhibit 10.1 to the Company's Current Report on Form 8-K (filed on December 18, 2006)
10.15	Form of Registration Rights Agreement	Exhibit 10.2 to the Company's Current Report on Form 8-K (filed on December 18, 2006)
23.1	Consent of Reznick Group, PC	Filed herewith
31.1 & 31.2	Certifications dated April 2, 2007	Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32.1 & 32.2	Certifications dated April 2, 2007	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.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

RegeneRx Biopharmaceuticals, Inc.
(Registrant)

Date: April 2, 2007

/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 Securities Exchange Act of 1934, 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 grants Power of Attorney to J.J. Finkelstein to sign on each of their behalf for the purposes of filing any further amendments to this report:

Signature	Title	Date
/s/Allan L. Goldstein Allan L. Goldstein	Chairman of the Board, Chief Scientific Advisor, and Director	April 2, 2007
/s/J.J. Finkelstein J.J. Finkelstein	President, Chief Executive Officer, and Director (Principal Executive Officer)	April 2, 2007
/s/C. Neil Lyons C. Neil Lyons	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	April 2, 2007

/s/Richard J. Hindin Richard J. Hindin	Secretary and Director	April 2, 2007
/s/Joseph C. McNay Joseph C. McNay	Director	April 2, 2007
/s/Mauro Bove Mauro Bove	Director	April 2, 2007
/s/L. Thompson Bowles L. Thompson Bowles	Director	April 2, 2007

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 and related prospectuses (Registration Nos. 333-122386, 333-125861 and 333-140415) of RegeneRx Biopharmaceuticals, Inc. of our report dated March 20, 2007 with respect to the 2005 and 2006 financial statements of RegeneRx Biopharmaceuticals included in this Annual Report (Form 10-K).

/s/ Reznick Group, P.C.

Bethesda, MD
March 30, 2007

EXHIBIT 31.1

CERTIFICATION

I, J.J. Finkelstein certify that:

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

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

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

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

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

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

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

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

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

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

Date: April 2, 2007

/s/ J.J. Finkelstein

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

EXHIBIT 31.2

CERTIFICATION

I, C. Neil Lyons certify that:

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

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

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

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

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

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

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

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

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

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

Date: April 2, 2007

/s/ C. Neil Lyons

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

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of RegeneRx Biopharmaceuticals, Inc. (the "Company") on Form 10-K for the period ending December 31, 2006, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, J.J. Finkelstein, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: April 2, 2007

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

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of RegeneRx Biopharmaceuticals, Inc. (the "Company") on Form 10-K for the period ending December 31, 2006, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, C. Neil Lyons, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: April 2, 2007

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