UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

Amendment No. 2

(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, 2003

OR

o **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 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**13-3444607**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No)*
777 Old Saw Mill River Road, Tarrytown, New York	**10591-6707**
(Address of principal executive offices)	*(Zip code)*

(914) 347-7000

(Registrant's telephone number, including area code)

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

None

(Title of Class)

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

Common Stock — par value $.001 per share

(Title of Class)

Preferred Share Purchase Rights expiring October 18, 2006

(Title of Class)

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 o

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☑ No o

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2003, was $546,128,000.

Indicate the number of shares outstanding of each of Registrant's classes of common stock as of February 29, 2004:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	2,365,873

Common Stock, $.001 par value	53,197,081

DOCUMENTS INCORPORATED BY REFERENCE:

The Registrant's definitive proxy statement filed in connection with solicitation of proxies for its 2004 Annual Meeting of Shareholders is incorporated by reference into Part III of this Form 10-K/A. Exhibit index is located on pages 40 to 42 of this filing.

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EXPLANATORY NOTE:

This Amendment No. 2 on Form 10-K/A ("Amendment No. 2") to the Annual Report on Form 10-K of Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2003, as previously amended by Amendment No. 1 on Form 10-K/A ("Amendment No. 1") filed on March 19, 2004, is being filed to (i) include the audited financial statements of Amgen-Regeneron Partners, an entity which is 50% owned by Regeneron, as of and for the year ended December 31, 2001 and the accompanying audit report of Ernst & Young LLP, independent auditors and (ii) include as Exhibit 23.2 a consent of Ernst & Young LLP. In addition, the audit report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, on page F-2 has been updated to include new descriptive language required under standards adopted by the Public Company Accounting Oversight Board since Amendment No. 1 was filed. In all other respects, the text of this Amendment No. 2, including the financial statements filed as part of this report, remains unchanged from Amendment No. 1.

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PART I

Item 1. *Business*

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

General

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. Our clinical and preclinical pipeline includes product candidates for the treatment of cancer, diseases of the eye, rheumatoid arthritis and other inflammatory conditions, allergies, asthma, obesity, and other diseases and disorders. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to combine our strong foundation in basic scientific research and discovery-enabling technology with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. Our efforts have yielded a diverse and growing pipeline of product candidates that have the potential to address a variety of unmet medical needs. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. These platforms are designed to discover specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Below is a summary of our clinical programs.

- **VEGF TRAP:** Protein-based product candidate designed to bind Vascular Endothelial Growth Factor (called VEGF, also known as Vascular Permeability Factor or VPF) and its relative, Placental Growth Factor (called PLGF), and prevent their interaction with cell surface receptors. VEGF (and to a less validated degree PLGF) is required for the growth of blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage. In 2001, we initiated a dose-escalation Phase I clinical trial designed to assess the safety and tolerability of the VEGF Trap in subjects with advanced solid tumor malignancies. This trial continues to test increasing doses of VEGF Trap delivered by subcutaneous injection as per the protocol and is expected to be completed in the first half of 2004. A second phase, expected to begin in the first half of 2004, will test higher doses of the VEGF Trap delivered intravenously. We are also evaluating the VEGF Trap for the potential treatment of certain eye diseases and in March 2004, announced the initiation of a Phase I study of the VEGF Trap in patients with the neovascular or "wet" form of age-related macular degeneration.

  In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals Inc. to jointly develop and commercialize the VEGF Trap in multiple oncology, ophthalmology, and possibly other indications throughout the world with the exception of Japan, where product rights remain with us. Aventis made a non- refundable up-front payment of $80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for $45.0 million. Under the collaboration agreement, we and Aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap. Aventis

has agreed to make a $25.0 million payment to us upon achievement of an early-stage clinical milestone. We may also receive up to $360.0 million in additional milestone payments upon receipt of specified marketing approvals for up to eight VEGF Trap indications in Europe or the United States. Regeneron has agreed to continue to manufacture clinical supplies of the VEGF Trap at our plant in Rensselaer, New York. Aventis has agreed to be responsible for providing commercial scale manufacturing capacity for the VEGF Trap.

Under the collaboration agreement, agreed upon development expenses incurred by both companies during the term of the agreement will be funded by Aventis. If the collaboration becomes profitable, we will reimburse Aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits, or at a faster rate at our option. In 2004, we and Aventis plan to invest approximately $100 million to support the development of the VEGF Trap. The broad based development program will include multiple Phase I studies to evaluate the VEGF Trap in combination with other therapies in various cancer indications, Phase II single-agent studies of the VEGF Trap in separate cancer indications, and multiple Phase I studies of the VEGF Trap in certain eye diseases.

- **INTERLEUKIN-1 TRAP (IL-1 Trap):** Protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. IL-1 is thought to play an important role in rheumatoid arthritis and other inflammatory diseases. In October 2003, we announced that the IL-1 Trap demonstrated evidence of clinical activity and safety in patients with rheumatoid arthritis (RA) in a Phase II dose-ranging study in approximately 200 patients. Patients treated with the highest dose, 100 milligrams of the IL-1 Trap, exhibited non-statistically significant improvements in the proportion of American College of Rheumatology (ACR) 20 responses versus placebo, the primary endpoint of the trial. Patients treated with the IL-1 Trap also exhibited improvements in secondary endpoints of the trial. The IL-1 Trap was generally well tolerated and was not associated with any drug-related serious adverse events.

  On February 27, 2004, Regeneron announced plans to initiate a Phase IIb study of the IL-1 Trap in patients with rheumatoid arthritis in the second half of 2004. The Phase IIb study will be conducted in a larger patient population, testing higher doses and for a longer period of time than in the previous Phase II trial. In addition, we intend to conduct studies of the IL-1 Trap in a variety of other inflammatory diseases where interleukin-1 is believed to play a critical role. We are currently working on new product formulations that would allow delivery of higher doses of IL-1 Trap either through subcutaneous or intravenous administration and plan to conduct patient tolerability studies in the first half of 2004.

  Since March 2003, we have been collaborating with Novartis Pharma AG on the development of the IL-1 Trap. On February 27, 2004, we announced that Novartis had provided notice of its intention not to proceed with the joint development of the IL-1 Trap. Under the terms of the collaboration agreement, Novartis remains obligated to fund agreed upon pre-Phase III IL-1 Trap development expenses during the nine-month notice period before its voluntary termination becomes effective. Novartis and we retain rights under the collaboration agreement to elect to collaborate on the development and commercialization of other IL-1 antagonists being developed independently by the other party that are in earlier stages of development than the IL-1 Trap.

- **INTERLEUKIN-4/ INTERLEUKIN-13 TRAP (IL-4/13 Trap):** Protein-based product candidate designed to bind both the interleukin-4 and interleukin-13 (called IL-4 and IL-13) cytokines and prevent their interaction with cell surface receptors. IL-4 and IL-13 are thought to play a major role in diseases such as asthma, allergic disorders, and other inflammatory diseases. In October 2002, we initiated a Phase I trial for the IL-4/13 Trap in adult subjects with mild to moderate asthma. This placebo-controlled, double-blind, dose escalation study is designed to assess the safety and tolerability of the IL-4/13 Trap. The trial is expected to be completed in the first quarter of 2004 and we anticipate presenting the results at a scientific conference in the second quarter of 2004. We are also evaluating the potential use of the IL-4/13 Trap in other therapeutic indications.

- **AXOKINE®:** Protein-based product candidate designed to act on the brain region regulating appetite and energy expenditure. AXOKINE is being developed for the treatment of obesity. In March 2003, we reported data from the 12-month treatment period of our initial Phase III pivotal trial of AXOKINE. The double-blind treatment period in this study is being followed by a twelve-month open-label extension phase, during which all study subjects receive AXOKINE. The extension phase is expected to be completed in the first quarter of 2004. We are currently conducting research on improving the formulation and delivery of AXOKINE and evaluating its commercial potential. We do not expect to initiate any Phase III clinical trials of AXOKINE in 2004.

Our Areas of Focus

Anti-Angiogenesis/Angiogenesis in Cancer and Other Settings: VEGF Trap and the Angiopoietins

Research. A plentiful blood supply is required to nourish every tissue and organ of the body. Diseases such as diabetes and atherosclerosis wreak their havoc, in part, by destroying blood vessels (arteries, veins, and capillaries) and compromising blood flow. Decreases in blood flow (known as ischemia) can result in non-healing skin ulcers and gangrene, painful limbs that cannot tolerate exercise, loss of vision, and heart attacks. In other cases, disease processes can damage blood vessels by breaking down vessel walls, resulting in defective and leaky vessels. Leaking vessels can lead to swelling and edema, as occurs in brain tumors following ischemic stroke, in diabetic retinopathy, and in arthritis and other inflammatory diseases. Finally, some disease processes, such as tumor growth, depend on the induction of new blood vessels.

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. Thus, building new vessels, by a process known as angiogenesis, can improve circulation to ischemic limbs and the heart, aid in healing skin ulcers or other chronic wounds, and in establishing tissue grafts. Reciprocally, blocking tumor-induced angiogenesis can blunt tumor growth. In addition, repairing leaky vessels can reverse swelling and edema.

Vascular Endothelial Growth Factor was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor specifically expressed on blood vessel cells. In 1994, we discovered a second family of angiogenic growth factors, termed the Angiopoietins, and we have received patents covering the members of this family. The Angiopoietins include naturally occurring positive and negative regulators of angiogenesis, as described in numerous scientific manuscripts published by our scientists and their collaborators. The Angiopoietins are being evaluated in preclinical research by us and our academic collaborators.

Our studies have revealed that VEGF and the Angiopoietins normally function in a coordinated and collaborative manner during blood vessel growth. Thus, for example, the growth of new blood vessels to nourish ischemic tissue appears to require both these agents. In addition, Angiopoietin-1 seems to play a critical role in stabilizing the blood vessel wall, and in animal models administration of this growth factor can prevent or repair leaky vessels. In terms of blocking vessel growth, manipulation of both VEGF and Angiopoietins seems to be of value.

The approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was further validated in February 2004, when the U.S. Food and Drug Administration (or FDA) approved Genentech, Inc.'s VEGF inhibitor, Avastin™. Avastin is an antibody product designed to inhibit VEGF and interfere with the blood supply to cancerous tumors. We exploited our Trap technology (which is described below) to develop a protein-based blocker of VEGF, referred to as the VEGF Trap.

Oncology. Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually lead a cell to become cancerous; however, a common feature of cancer cells is that they need to get nutrients and remove waste products, just as normal cells do. The vascular system is designed to supply nutrients and remove waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels. VEGF is secreted by many tumors to stimulate the growth of new blood vessels to support the tumor. Countering the effects of VEGF, thus blocking the blood supply to tumors, has been shown to provide therapeutic benefits.

Diseases of the Eye. Age-Related Macular Degeneration (AMD) and Diabetic Retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. VEGF both stimulates angiogenesis and increases vascular permeability, has been shown to be a major pathogenic factor in both DR and AMD, and is believed to be involved in other medical problems affecting the eyes. Counteracting the effects of VEGF may provide a significant therapeutic benefit to patients suffering from these disorders.

AMD is a leading cause of severe visual loss in people over the age of 55 in developed countries. It is estimated that, in the U.S., 6% of individuals aged 65-74 and 20% of those older than 75 are affected with AMD. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as Diabetic Macular Edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

Clinical Development — VEGF Trap. In November 2001, we initiated a Phase I clinical trial designed to assess the safety and tolerability of the VEGF Trap in subjects with solid tumor malignancies. The Phase I trial is an open-label study in subjects with advanced tumors and is evaluating the VEGF Trap at increasing dose levels. The ongoing study is being conducted at three clinical sites in the United States, and the trial is expected to be completed in the first half of 2004. A second phase, expected to begin in the first half of 2004, will test higher doses of the VEGF Trap delivered intravenously. We are also evaluating the VEGF Trap for the potential treatment of certain diseases of the eye and in March 2004, announced the initiation of a Phase I study of the VEGF Trap in patients with the neovascular or “wet” form of age-related macular degeneration.

In September 2003, we entered into a Collaboration Agreement with Aventis to jointly develop and commercialize the VEGF Trap in multiple oncology, ophthalmology, and possibly other indications throughout the world with the exception of Japan, where product rights remain with us. In 2004, we and Aventis plan to invest approximately $100 million to support the development of the VEGF Trap. The broad based development program will include multiple Phase I studies to evaluate the VEGF Trap in combination with other therapies in various cancer indications, Phase II single-agent studies of the VEGF Trap in separate cancer indications, and multiple Phase I studies of the VEGF Trap in certain eye diseases.

Trap Technology and Additional Traps

Research. Our research on ciliary neurotrophic factor, or CNTF, led to the discovery that CNTF, although it is a neurotrophic factor, belongs to the “superfamily” of signaling molecules called cytokines. Cytokines are soluble proteins secreted by the cells of the body. In many cases, cytokines act as messengers to help regulate immune and inflammatory responses. In excess, cytokines can be harmful and have been linked to a variety of diseases. Blocking cytokines and growth factors is a proven therapeutic approach with a number of medicines or product candidates already approved or in clinical development. The cytokine superfamily includes factors such as erythropoietin, thrombopoietin, granulocyte-colony stimulating factor, and the interleukins (or ILs).

During the 1990s, our scientists made a number of breakthroughs in understanding how receptors work for an entire family of cytokines, which had broad relevance for many other families of cytokines and growth factors. Based on these findings, we developed a new class of protein-based antagonists, termed Traps, which could be designed to target and block specific cytokines and growth factors implicated in human disease. Examples include the VEGF Trap (designed to block VEGF and PLGF), the IL-1 Trap (designed to block both IL-1 alpha and IL-1 beta), the IL-4 Trap (designed to block IL-4), the IL-6 Trap (designed to block IL-6), the IL-18 Trap (designed to block IL-18), and the IL-4/13 Trap (designed to block IL-4 and IL-13).

In preclinical studies, these Traps are more potent than other growth factor and cytokine antagonists, potentially allowing lower levels of these drug candidates to be used. Moreover, because these Traps are comprised entirely of natural human-derived protein sequences, they may be less likely to induce an immune reaction in humans. Because pathological levels of certain cytokines and growth factors seem to contribute to a variety of diseases, our Traps have the potential to be important therapeutic agents.

We have clinical programs underway for our IL-1 Trap and IL-4/13 Trap (see below) and research programs underway for an IL-6 Trap and an IL-18 Trap. IL-6 has been implicated in the pathology and progression of multiple myeloma, certain solid tumors, AIDS, lymphomas (both AIDS-related and non-AIDS-related), osteoporosis, and other conditions. IL-18 is thought to contribute to a number of inflammatory and immunological diseases and disorders. We also have patents covering additional Traps for IL-2, IL-3, IL-5, IL-15, and others, which are being studied in earlier stage research programs. Our research also includes molecular and cellular research to improve or modify Trap technology, process development efforts to produce experimental and clinical research supplies, and in vivo and in vitro studies to further understand and demonstrate the efficacy of the Traps.

Clinical Development.

IL-1 Trap. Rheumatoid arthritis is a chronic disease in which the immune system attacks the tissue that lines and cushions joints. Over time, the cartilage, bone, and ligaments of the joint erode, leading to progressive joint deformity and joint destruction, generally in the hand, wrist, knee, and foot. Joints become painful and swollen and motion is limited. Over two million people, 1% of the U.S. population, are estimated to have rheumatoid arthritis, and 10% of those eventually become disabled. Women account for roughly two-thirds of these patients.

In July 2002, we announced the initiation of a dose-ranging Phase II study of the IL-1 Trap in subjects with rheumatoid arthritis. This trial enrolled approximately 200 subjects who received weekly self-injections of one of three fixed doses of IL-1 Trap or placebo for 12 weeks, followed by 10 weeks of off-treatment follow-up. In October 2003, we announced that in this trial the IL-1 Trap demonstrated evidence of clinical activity and safety. Patients treated with the highest dose, 100 milligrams of the IL-1 Trap, exhibited non-statistically significant improvements in the proportion of American College of Rheumatology (ACR) 20 responses versus placebo, the primary endpoint of the trial. Patients treated with the IL-1 Trap also exhibited improvements in secondary endpoints of the trial. The IL-1 Trap was generally well tolerated and was not associated with any drug-related serious adverse events.

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Since March 2003, we have been collaborating with Novartis Pharma AG on the development of the IL-1 Trap. On February 27, 2004, we announced that Novartis had provided notice of its intention not to proceed with the joint development of the IL-1 Trap. Under the terms of the collaboration agreement, Novartis remains obligated to fund agreed upon pre-Phase III IL-1 Trap development expenses during the nine-month notice period before its voluntary termination becomes effective. Novartis and we retain rights under the collaboration agreement to elect to collaborate on the development and commercialization of other IL-1 antagonists being developed independently by the other party that are in earlier stages of development than the IL-1 Trap.

IL-4/13 Trap. One in 13 Americans suffers from allergies and one in 18 suffers from asthma. The number of people afflicted with these diseases has been growing at a fast rate. It is believed that IL-4 and IL-13 play a role in these diseases. These two cytokines are essential to the normal functioning of the immune system, creating a vital communication link between white blood cells. In the case of asthma and allergies, however, it is thought that excess levels of IL-4 and IL-13 causes overactivity of the immune system, which contributes to disease initiation and progression.

Antagonists for IL-4 and IL-13 may be therapeutically useful in a number of allergy and asthma-related conditions, including as an adjunct to vaccines where blocking IL-4 and IL-13 may help to elicit more of the desired type of immune response to the vaccine. We have developed both an IL-4 Trap and an IL-4/13 Trap,

which is a single molecule that can block both interleukin-4 and interleukin-13. In October 2002, we initiated a placebo-controlled, double-blind, dose escalation Phase I clinical trial designed to assess the safety and tolerability of the IL-4/13 Trap in subjects with mild to moderate asthma. The trial is expected to be completed in the first quarter of 2004. We are also evaluating the potential use of the IL-4/13 Trap in other therapeutic indications.

Obesity and Metabolic Diseases

Food intake and metabolism are regulated by complex interactions between diverse neural and hormonal signals that serve to maintain an optimal balance between energy intake, storage, and utilization. The hypothalamus, a small area at the base of the brain, is critically involved in the integration of peripheral signals which reflect nutritional status and neural outputs which regulate appetite, food seeking behaviors, and energy expenditure. Obesity and related metabolic disorders, such as type 2 diabetes, reflect a dysregulation in the systems which ordinarily tightly couple energy intake to energy expenditure. Our preclinical research program encompasses the study of both central (neuropeptide) and peripheral (hormonal) regulators of food intake and metabolism in health and disease.

Obesity is a major health problem in all developed countries. The prevalence of obesity in the United States has increased substantially during the past decade. A 1999 Congressional Report funded by the National Institutes of Health confirmed that obesity significantly increases a number of health risks, including type 2 diabetes. Obesity-related conditions, such as stroke and myocardial infarct are estimated to contribute to about 300,000 deaths yearly, ranking second only to smoking as a cause of preventable death. Several studies published in 2002 demonstrate that even modest levels of weight loss, when maintained over an extended period of time, can significantly reduce the risk of developing type 2 diabetes. Health care expenditures for obesity-related conditions now total over $200 billion a year in the United States. Current treatment of obesity consists of diet, exercise, and other lifestyle changes, and a limited number of medicines. There are several approved medicines currently indicated for the treatment of obesity, including sibutramine (Meridia®, a registered trademark of Abbott Laboratories) and orlistat (Xenical®, a registered trademark of Hoffmann-LaRoche, Inc.).

Clinical Development — AXOKINE. We are developing AXOKINE for the treatment of obesity. AXOKINE is our patented genetically re-engineered form of CNTF. In March 2003, we reported data from the 12-month treatment period of our initial Phase III pivotal trial of AXOKINE. The double-blind treatment period in this study is being followed by a twelve-month open-label extension phase, during which all study subjects receive AXOKINE. The extension phase is expected to be completed in the first quarter of 2004.

Two AXOKINE trials remain ongoing. These trials, which each include approximately 300 subjects, are evaluating the safety of intermittent treatment with AXOKINE and studying maintenance of weight loss following short-term treatment regimens. Results from these trials are expected to be available in mid-2004.

We are currently conducting research on improving the formulation and delivery of AXOKINE and evaluating its commercial potential. We do not expect to initiate any Phase III clinical trials of AXOKINE in 2004.

Muscle Atrophy and Related Disorders

Muscle atrophy occurs in many neuromuscular diseases and also when muscle is unused, as often occurs during prolonged hospital stays and during convalescence. Currently, physicians have few options to treat subjects with muscle atrophy or other muscle conditions which afflict millions of people globally. Thus, a treatment that has beneficial effects on skeletal muscle could have significant clinical benefit. Our muscle program is currently focused on conducting in vivo and in vitro experiments with the objective of demonstrating and further understanding the molecular pathways involved in muscle atrophy and hypertrophy, and discovering therapeutic candidates that can modulate these pathways. This work is being conducted in collaboration with scientists at The Procter & Gamble Company.

Cartilage Growth Factor System and Osteoarthritis

Osteoarthritis results from the wearing down of the articular cartilage surfaces that cover joints. Thus, growth factors that specifically act on cartilage cells could have utility in osteoarthritis. Our scientists have discovered a growth factor receptor system selectively expressed by cartilage cells, termed Regeneron Orphan Receptor 2 (ROR2). We have also demonstrated that this growth factor receptor system is required for normal cartilage development in mice. In addition, together with collaborators, we have demonstrated that mutations in this growth factor receptor system cause inherited defects in cartilage development in humans. Thus, this growth factor receptor system is a promising new target for cartilage diseases such as osteoarthritis, but we have not yet identified any therapeutic molecules from our research to advance to clinical development.

Fibrosis

Fibrotic diseases, such as cirrhosis, result from the excess production of fibrous extracellular matrix by certain cell types. We and our collaborators identified orphan receptors, termed Discoidin Domain Receptors 1 and 2 (DDR1 and DDR2), that are expressed by the activated cell types in fibrotic disease. Our work in this area is currently focused on determining whether selective inhibition or activation of DDR1 and DDR2 would be beneficial in the setting of fibrotic disease. Further, we are studying key signaling pathways which allow particular fibrosis-inducing cells to multiply. Inhibition of such pathways may be useful in preventing the development of fibrosis. These research activities are being conducted in collaboration with scientists at Procter & Gamble.

G-Protein Coupled Receptors

G-Protein Coupled Receptors have historically been among the most useful targets for pharmaceuticals. We use a genomics approach to discover new G-Protein Coupled Receptors and then we characterize these receptors in our disease models by examining their expression. Early stage research work on selected G-Protein Coupled Receptors is being conducted in collaboration with scientists at Procter & Gamble.

Technology Platforms

Our ability to discover and develop product candidates for a wide variety of serious medical conditions results from the leveraging of our powerful technology platforms, many of which were developed or enhanced by us. Although the primary use of these technology platforms is for our own research and development programs, we are also exploring the possibilities of exploiting these technologies commercially through, for example, direct licensing or sale of technology, or the establishment of research collaborations to discover and develop drug targets. In December 2002, we entered into an agreement with Serono S.A. to use excess capacity from our Velocigene™ technology platform to provide Serono with knock-out and transgenic mammalian models of gene function. Under the agreement, which was amended as of January 1, 2004 to expand the scope of services available under the Velocigene platform, Serono will pay us up to $4.0 million annually for up to five years.

Targeted Genomics™. In contrast to basic genomics approaches, which attempt to identify every gene in a cell or genome, we use Targeted Genomics approaches to identify specific genes likely to be of therapeutic interest. These approaches do not depend on random gene sequencing, but rather on function-based approaches to specifically target the discovery of genes for growth factors, peptides, and their receptors that are most likely to have use for developing drug candidates. This technology has already led to our discovery of the Angiopoietin and Ephrin growth factor families for angiogenesis and vascular disorders, the MuSK growth factor receptor system for muscle disorders, and the Regeneron Orphan Receptor (ROR) growth factor receptor system that regulates cartilage formation.

Velocigene™. A major challenge facing the biopharmaceutical industry in the post-genomic era is the efficient assignment of function to random gene sequences to enable the identification of validated drug targets. One way to help determine the function of a gene is to generate mammalian models in which the gene is removed (referred to as “knock-out mammalian models”), or is over-produced (referred to as “transgenic mammalian models”), or in which a color-producing gene is substituted for the gene of interest (referred to as

"reporter knock-in mammalian models") to identify which cells in the model system are expressing the gene. Until recently, technical hurdles involved in the generation of mammalian models restricted the ability to produce multiple models quickly and efficiently. We have developed proprietary technology that allows for the rapid and efficient production of models on a high throughput scale, enabling rapid assignment of function to gene sequences.

Designer Protein Therapeutics™. In cases in which the natural gene product is itself not a product candidate, we utilize our Designer Protein Therapeutics platform to genetically engineer product candidates with the desired properties. We use these technologies to develop derivatives of growth factors and their receptors, which can allow for modified agonistic or antagonistic properties that may prove to be therapeutically useful. This technology platform has already produced more than 10 patented proteins, including the VEGF Trap and the IL-1 Trap, which are currently in clinical testing, and several others in preclinical development.

Our Collaborative Programs

We have entered into collaboration and licensing agreements with various companies, including Aventis, Novartis, Procter & Gamble, Amgen Inc., Sumitomo Chemical Company, Ltd., Medarex, Inc., Emisphere Technologies, Inc., and Nektar Therapeutics. In addition, we conduct many research programs in collaboration with academic partners. In the future, we may enter into additional strategic collaborations or licensing agreements focusing on one or more of our product candidates, research programs, or technology platforms. Below are summaries of our major collaborations.

Aventis. In September 2003, we entered into a collaboration agreement with Aventis to jointly develop and commercialize the VEGF Trap. Aventis made a non-refundable up-front payment of $80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for $45.0 million.

Under the collaboration agreement, we and Aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap. Aventis has agreed to make a $25.0 million payment to us upon achievement of an early-stage clinical milestone. We may also receive up to $360.0 million in additional milestone payments upon receipt of specified marketing approvals for up to eight VEGF Trap indications in Europe or the United States. Regeneron has agreed to continue to manufacture clinical supplies of the VEGF Trap at our plant in Rensselaer, New York. Aventis has agreed to be responsible for providing commercial scale manufacturing capacity for the VEGF Trap.

Under the collaboration agreement, agreed upon development expenses incurred by both companies during the term of the agreement will be funded by Aventis. If the collaboration becomes profitable, we will reimburse Aventis for 50 percent of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits, or at a faster rate at our option.

Aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse Aventis for 50 percent of the VEGF Trap development expenses will also terminate and we will retain all rights to the VEGF Trap.

Novartis. In March 2003, we entered into a collaboration agreement with Novartis to jointly develop and commercialize the IL-1 Trap. Novartis made a non-refundable up-front payment of $27.0 million and purchased 7,527,050 newly issued unregistered shares of our common stock for $48.0 million.

Development expenses incurred during 2003 were shared equally by us and Novartis. We funded our share of 2003 expenses through a loan from Novartis that will be forgiven, together with accrued interest, should certain preclinical and clinical milestones be reached, and is otherwise due and payable on July 1, 2004.

On February 27, 2004, we announced that Novartis had provided notice of its intention not to proceed with the joint development of the IL-1 Trap. Under the terms of the collaboration agreement, Novartis remains obligated to fund agreed upon pre-Phase III IL-1 Trap development expenses during the nine-month

notice period before its voluntary termination becomes effective. Novartis and we retain rights under the collaboration agreement to elect to collaborate on the development and commercialization of other IL-1 antagonists being developed independently by the other party that are in earlier stages of development than the IL-1 Trap.

Procter & Gamble. In May 1997, we entered into a long-term collaboration agreement with Procter & Gamble to discover, develop, and commercialize pharmaceutical products. In connection with the collaboration, Procter & Gamble made equity purchases of our Common Stock of $42.9 million in June 1997 and $17.1 million in August 2000. These equity purchases were in addition to a purchase by Procter & Gamble of $10.0 million of our common stock that was completed in March 1997. Procter & Gamble also agreed to provide funding in support of our research efforts related to the collaboration, of which we received $80.0 million through December 31, 2003. From 1997 to 1999, Procter & Gamble also provided research support for our AXOKINE program. As a result, Procter & Gamble will be entitled to receive a small royalty on any sales of AXOKINE.

In August 2000, Procter & Gamble made two non-recurring research progress payments to us totaling $3.5 million. Effective December 31, 2000, we and Procter & Gamble entered into a new long-term collaboration agreement, replacing the companies' 1997 agreement. The new agreement extended Procter & Gamble's obligation to fund our research under the new collaboration agreement through December 2005, with no further research obligations by either party thereafter, and focused the companies' collaborative research on therapeutic areas that are of particular interest to Procter & Gamble, including muscle atrophy and muscle diseases, fibrotic diseases, and selected G-Protein Coupled Receptors. For each of these program areas, the parties contribute research activities and necessary intellectual property rights pursuant to mutually agreed upon plans and budgets established by operating committees. During the first five years of the agreement, neither party may independently perform research on targets included in the collaboration.

We and Procter & Gamble divided rights to the programs from the 1997 collaboration agreement that are no longer part of the companies' collaboration. Procter & Gamble obtained rights to certain early stage programs. We have rights to all other research programs including exclusive rights to the VEGF Trap, the Angiopoietins, and our Orphan Receptors (RORs). Any product candidates that result from the new collaboration will continue to be jointly developed and marketed worldwide, with the companies equally sharing development costs and profits. Under the new agreement, beginning in the first quarter of 2001, research support from Procter & Gamble is $2.5 million per quarter (before adjustments for inflation) through December 2005.

The new collaboration agreement expires on the later of December 31, 2005 or the termination of research, development, or commercial activities relating to compounds that meet predefined success criteria before that date. In addition, if either party successfully develops a compound covered under the agreement to a predefined development stage during the two-year period following December 31, 2005, the parties shall meet to determine whether to reconvene joint development of the compound under the agreement. The agreement is also subject to termination if either party enters bankruptcy, breaches its material obligations, or undergoes a change of control. In addition to termination rights, our new collaboration agreement with Procter & Gamble has an "opt-out" provision, whereby a party may decline to participate further in a research or product development program. In such cases, the opting-out party generally does not have any further funding obligation and will not have any rights to the product or program in question (but may be entitled to a royalty on any product sales). If Procter & Gamble opts out of a product development program, and we do not find a new partner, we would bear the full cost of the program.

Manufacturing

We maintain an 8,000 square foot manufacturing facility in Tarrytown, New York. This facility, designed to comply with FDA current good manufacturing practices (GMP), produces preclinical and clinical supplies of our product candidates.

In 1993, we purchased our 104,000 square foot Rensselaer, New York manufacturing facility, and in 2003 completed a 19,500 square foot expansion. This facility is used to manufacture therapeutic candidates for our

own preclinical and clinical studies. We also use the facility to manufacture a product for Merck & Co., Inc. under a contract that expires in 2005. In July 2002, we leased 75,000 square feet in a building near our Rensselaer facility which is being used for the manufacture of Traps and for warehouse space. As of December 31, 2003, there were no impairment losses associated with long-lived assets.

At December 31, 2003, we employed 274 people in our manufacturing operations at these facilities.

In 1995, we entered into a long-term manufacturing agreement with Merck (called, as amended, the Merck Agreement) to produce an intermediate for a Merck pediatric vaccine at our Rensselaer facility. We agreed to modify portions of our facility for manufacture of the Merck intermediate and to assist Merck in securing regulatory approval for manufacturing in the Rensselaer facility. In December 1999, we announced that the FDA had approved us as a contract manufacturer for the Merck intermediate. Under the Merck Agreement, we are manufacturing intermediate for Merck for six years, with certain minimum order quantities each year. The Merck Agreement extends through 2005, but may be terminated at any time by Merck upon one year's notice and may be extended by mutual agreement. Merck reimbursed us for the capital costs to modify the facility and for the cost of our activities performed on behalf of Merck prior to the start of production. Merck pays an annual facility fee of $1.0 million, subject to annual adjustment for inflation, reimburses us for certain manufacturing costs, pays us a variable fee based on the quantity of intermediate supplied to Merck, and makes certain additional payments. We recognized contract manufacturing revenue related to the Merck Agreement of $10.1 million in 2003, $11.1 million in 2002, and $9.8 million in 2001.

Among the conditions for regulatory marketing approval of a medicine is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the GMP regulations of the health authority. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money, and effort in the area of production and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, are also subject to inspections by or under the authority of the FDA and by other national, federal, state, and local agencies. If our manufacturing facilities fail to comply with FDA and other regulatory requirements, we will be required to suspend manufacturing. This will have a material adverse effect on our financial condition, results of operations, and cash flow.

Competition

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Our competitors may include Genentech, Novartis, Pfizer Inc., Hoffmann-LaRoche, Abbott Laboratories, Sanofi-Synthelabo, Merck, Amgen, and others. Many of our competitors have substantially greater research, preclinical, and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also be significant if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, one or more of our competitors may achieve product commercialization earlier than we do or obtain patent protection that dominates or adversely affects our activities. Our ability to compete will depend on how fast we can develop safe and effective product candidates, complete clinical testing and approval processes, and supply commercial quantities of the product to the market. Competition among product candidates approved for sale will also be based on efficacy, safety, reliability, availability, price, patent position, and other factors.

VEGF Trap. Many companies are developing therapeutic molecules designed to block the actions of VEGF specifically and angiogenesis in general. A variety of approaches have been employed, including antibodies to VEGF, antibodies to the VEGF receptor, small molecule antagonists to the VEGF receptor tyrosine kinase, as well as multiple other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to our VEGF Trap in efficacy, side-effect profile, or form of delivery. Additionally, many of these developmental molecules may be at a more advanced stage of development than our product candidate. In particular, Genentech recently was granted approval by the FDA to market and sell Avastin™, a monoclonal antibody to VEGF. The marketing approval for Avastin may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap. This may delay or impair our ability to

successfully develop and commercialize the VEGF Trap. In addition, Eyetech Pharmaceuticals, Inc. has successfully advanced its clinical candidate for eye diseases, Macugen, through Phase II/III trials. Eyetech is collaborating with Pfizer to develop and commercialize Macugen. If they receive approval to market Macugen for eye diseases, it would be more difficult for us to enroll patients in clinical trials for the VEGF Trap in eye diseases. This may delay or impair our ability to successfully develop and commercialize the VEGF Trap.

Cytokine Traps. Marketed products for the treatment of rheumatoid arthritis and asthma are available as either oral or inhaled medicines, whereas our Cytokine Traps currently are only planned for clinical trials as injectibles. The markets for both rheumatoid arthritis and asthma are very competitive. Several new, highly successful medicines are available for these diseases. Examples include the TNF-antagonists Enbrel® (a registered trademark of Amgen), Remicade® (a registered trademark of Centocor), and Humira® (a registered trademark of Abbott) for rheumatoid arthritis, and the leukotriene-modifier Singulair® (a registered trademark of Merck), as well as various inexpensive corticosteroid medicines for asthma. The availability of highly effective FDA approved TNF-antagonists makes it more difficult to successfully develop the IL-1 Trap for the treatment of rheumatoid arthritis. It will be difficult to enroll patients with rheumatoid arthritis to participate in clinical trials of the IL-1 Trap, which may delay or impair our ability to successfully develop the drug candidate. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines.

AXOKINE. There is substantial competition in the discovery and development of treatments for obesity, as well as established, cost-effective, and emerging prescription and over-the-counter treatments for this condition. For example, Hoffmann-LaRoche and Abbott already market well-established medicines for the treatment of obesity and Amgen, Sanofi-Synthelabo, and a number of other pharmaceutical companies are developing new potential therapeutics. Sanofi-Synthelabo has a cannaboid receptor antagonist in Phase III clinical development. In March 2004, Sanofi-Synthelabo reported that patients treated with this clinical candidate demonstrated significant weight loss in completed Phase III clinical trials. Many of these medicines or therapeutic candidates appear to offer competitive advantages over AXOKINE. For example, AXOKINE currently is available only in injectible form, while the currently available marketed medicines for the treatment of obesity and Sanofi-Synthelabo's product candidate are delivered in pill (or oral dosage) forms, which generally are favored by people over injectible medicines. Therefore, even if AXOKINE is approved for sale, the fact that it must be delivered by injection may severely limit its market acceptance among patients and physicians.

Other Areas. Many pharmaceutical and biotechnology companies are attempting to discover and develop small-molecule based therapeutics, similar in at least certain respects to our program with Procter & Gamble. In these and related areas, intellectual property rights have been sought and certain rights have been granted to competitors and potential competitors of ours, and we may be at a substantial competitive disadvantage in such areas as a result of, among other things, our lack of experience, trained personnel, and expertise. A number of corporate and academic competitors are involved in the discovery and development of novel therapeutics using tyrosine kinase receptors, orphan receptors, and compounds that are the focus of other research or development programs we are now conducting. These competitors include Amgen and Genentech, as well as many others. Many firms and entities are engaged in research and development in the areas of cytokines, interleukins, angiogenesis, and muscle conditions. Some of these competitors are currently conducting advanced preclinical and clinical research programs in these areas. These and other competitors may have established substantial intellectual property and other competitive advantages.

If a competitor announces a successful clinical study involving a product that may be competitive with one of our product candidates or an approval by a regulatory agency of the marketing of a competitive product, such announcement may have a material adverse effect on our operations, or future prospects, or the price of our common stock.

We also compete with academic institutions, governmental agencies, and other public or private research organizations, which conduct research, seek patent protection, and establish collaborative arrangements for the development and marketing of products that would provide royalties for use of their technology. These

institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of the technology that they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from such institutions, agencies, and organizations.

Patents, Trademarks, and Trade Secrets

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties. Our policy is to file patent applications to protect technology, inventions, and improvements that we consider important to the development of our business. We have been granted approximately 100 U.S. patents and we have approximately 100 pending U.S. applications. We are the nonexclusive licensee of a number of additional U.S. patents and patent applications. We also rely upon trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We or our licensors or collaborators have filed patent applications on products and processes relating to AXOKINE, Cytokine Traps, VEGF Trap, and Angiopoietins, as well as other technologies and inventions in the United States and in certain foreign countries. We intend to file additional patent applications, when appropriate, relating to improvements in these technologies and other specific products and processes. We plan to aggressively prosecute, enforce, and defend our patents and other proprietary technology.

In July 2002, we announced that Amgen and Immunex Corporation (now part of Amgen) granted us a non-exclusive license to certain patents and patent applications which may be used in the development and commercialization of the IL-1 Trap. The license followed two other licensing arrangements under which we obtained a non-exclusive license to patents owned by ZymoGenetics, Inc. and Tularik Inc. for use in connection with the IL-1 Trap program. These license agreements would require us to pay royalties based on the net sales of the IL-1 Trap if and when it is approved for sale. In total, the royalty rate under these three agreements would be in the mid-single digits.

In August 2003, Merck granted us a non-exclusive license to certain patents and patent applications which may be used in the development and commercialization of AXOKINE. In consideration for the license, we issued to Merck 109,450 newly issued unregistered shares of our Common Stock and agreed to make an additional payment to Merck if the fair market value of the shares falls below a certain threshold at the time that Merck has the right to sell them. We agreed to make an additional payment upon receipt of marketing approval for a product covered by the licensed patents and pay royalties, at staggered rates in the mid-single digits, based on the net sales, if any, of products covered by the licensed patents.

Patent law relating to the patentability and scope of claims in the biotechnology field is evolving and our patent rights are subject to this additional uncertainty. Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to continue to file product and process patent applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued to or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties.

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of our product candidates. All of our product candidates will require regulatory approval before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval

requirements by the FDA and foreign authorities. Many aspects of the structure and substance of the FDA and foreign pharmaceutical regulatory practices have been reformed during recent years, and continued reform is under consideration in a number of forums. The ultimate outcome and impact of such reforms and potential reforms cannot be predicted.

The activities required before a product candidate may be marketed in the United States begin with preclinical tests. Preclinical tests include laboratory evaluations and animal studies to assess the potential safety and efficacy of the product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an Investigational New Drug Application, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase I, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase II, clinical trials are conducted with subjects afflicted with a specific disease or disorder to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. In Phase III, large-scale clinical trials are conducted with patients afflicted with the specific disease or disorder in order to provide enough data to understand the efficacy and safety profile of the product candidate, as required by the FDA. The results of the preclinical and clinical testing of a biologic product candidate are then submitted to the FDA in the form of a Biologics License Application, or BLA, for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to a BLA, the FDA may grant marketing approval, request additional information, or deny the application.

Any approval required by the FDA for any of our product candidates may not be obtained on a timely basis, or at all. The designation of a clinical trial as being of a particular phase is not necessarily indicative that such a trial will be sufficient to satisfy the parameters of a particular phase, and a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The results of preclinical studies or early stage clinical trials may not predict long-term safety or efficacy of our compounds when they are tested or used more broadly in humans.

Various federal and state statutes and regulations also govern or influence the research, manufacture, safety, labeling, storage, record keeping, marketing, transport, or other aspects of such product candidates. The lengthy process of seeking these approvals and the compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the manufacturing or marketing of our products and our ability to receive product or royalty revenue.

In addition to the foregoing, our present and future business will be subject to regulation under the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, national restrictions, and other present and potential future local, state, federal, and foreign regulations.

Employees

As of December 31, 2003, we had 644 full-time employees, of whom 110 held a Ph.D. or M.D. degree or both. We believe that we have been successful in attracting skilled and experienced personnel in a highly competitive environment; however, competition for these personnel is intense. None of our personnel are covered by collective bargaining agreements and our management considers its relations with our employees to be good.

Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission, or SEC, under the Securities Exchange Act of 1934, or the Exchange Act. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet website

that contains reports, proxy and information statements, and other information regarding issuers, including Regeneron, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at *http://www.sec.gov*.

We also intend to make available free of charge on or through our Internet website *(http://www.regn.com)* our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 2. *Properties*

We conduct our research, development, manufacturing, and administrative activities at our owned and leased facilities. We currently lease approximately 220,000 square feet, and sublease approximately 16,000 square feet, of laboratory, office, and manufacturing space in Tarrytown, New York. The sublease will convert to a direct lease with the landlord on December 31, 2005. We own a facility in Rensselaer, New York, consisting of two buildings totaling approximately 123,500 square feet of research, manufacturing, office, and warehouse space. We also lease an additional 75,000 square feet of manufacturing, office, and warehouse space in Rensselaer.

The following table summarizes the information regarding our current property leases:

Location	Square Footage	Expiration	Current Monthly Base Rental Charges(1)	Renewal Option Available
Tarrytown	146,000	December 31, 2007	$243,000	none
Tarrytown	16,000	December 31, 2007	$ 25,000	none
Tarrytown	74,000	December 31, 2009	$148,000	one 5-year term
Rensselaer	75,000	July 11, 2007	$ 23,000	two 5-year terms

(1) Excludes additional rental charges for utilities, taxes, and operating expenses, as defined.

In the future, we may lease, operate, or purchase additional facilities in which to conduct expanded research and development activities and manufacturing and commercial operations.

Item 3. *Legal Proceedings*

In May 2003, securities class action lawsuits were commenced against Regeneron and certain of its officers and directors in the United States District Court for the Southern District of New York. A consolidated amended class action complaint was filed in October 2003. The complaint, which purports to be brought on behalf of a class consisting of investors in our publicly traded securities between March 28, 2000 and March 30, 2003, alleges that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE, in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. We believe that the lawsuit is without merit and, in December 2003, we filed a motion to dismiss the lawsuit. Because we do not believe that a loss is probable, no legal reserve has been established.

From time to time we are a party to other legal proceedings in the course of our business. Currently, we do not expect any other legal proceedings to have a material adverse effect on our business or financial condition.

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

None.

Executive Officers of the Registrant

Listed below are our executive officers as of February 29, 2004. There are no family relationships between any of the executive officers and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected. At the annual meeting of the Board of Directors, which follows the Annual Meeting of Shareholders, executive officers are elected by the Board to hold office for one year and until their respective successors are elected and qualified, or until their earlier resignation or removal.

Name	Age	Position
Leonard S. Schleifer, M.D., Ph.D.	51	President, Chief Executive Officer, and Founder
George D. Yancopoulos, M.D., Ph.D.	44	Executive Vice President and Chief Scientific Officer, and President, Regeneron Research Laboratories
Murray A. Goldberg	59	Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary
Randall G. Rupp, Ph.D.	56	Senior Vice President, Manufacturing Operations
Neil Stahl, Ph.D.	47	Senior Vice President, Preclinical Development and Biomolecular Science

PART II

Item 5. *Market for Registrant's Common Equity and Related Stockholder Matters*

Our Common Stock is quoted on The Nasdaq Stock Market under the symbol "REGN." Our Class A Stock, par value $.001 per share, is not publicly quoted or traded.

The following table sets forth, for the periods indicated, the range of high and low sales prices for the Common Stock as reported by The Nasdaq Stock Market.

	High	Low
2002		
First Quarter	$30.20	$19.74
Second Quarter	25.40	12.21
Third Quarter	18.34	11.25
Fourth Quarter	22.85	12.25
2003		
First Quarter	$21.49	$ 7.40
Second Quarter	18.78	5.77
Third Quarter	22.35	12.22
Fourth Quarter	18.72	11.80

As of March 3, 2004, there were 635 shareholders of record of our Common Stock and 56 shareholders of record of our Class A Stock. The closing bid price for the Common Stock on that date was $15.00.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

The information called for with respect to equity compensation plans is incorporated by reference to the material captioned "Equity Compensation Plan Information" in our definitive proxy statement with respect to our 2004 Annual Meeting of Shareholders to be filed with the SEC.

In March 2003, we entered into a collaboration agreement with Novartis to jointly develop and commercialize the IL-1 Trap. In connection with this agreement, we sold to Novartis 7,527,050 newly issued unregistered shares of our Common Stock for a purchase price of $48.0 million. We expect to use the proceeds from the sale of the Common Stock to fund working capital and general corporate purposes.

In August 2003, Merck granted us a non-exclusive license to certain patents and patent applications which may be used in the development and commercialization of AXOKINE. As consideration for this license, we issued to Merck 109,450 newly issued unregistered shares of our Common Stock.

In September 2003, we entered into a collaboration agreement with Aventis to jointly develop and commercialize the VEGF Trap. In connection with this agreement, we sold to Aventis 2,799,552 newly issued unregistered shares of our Common Stock for a purchase price of $45.0 million. We expect to use the proceeds from the sale of the Common Stock to fund working capital and general corporate purposes.

We view each of the aforementioned issuances as transactions not involving any public offering and therefore as exempt from registration under Section 4(2) of the Securities Act of 1933.

Item 6. ***Selected Financial Data***

The selected financial data set forth below for the years ended December 31, 2003, 2002, and 2001 and at December 31, 2003 and 2002 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in this report. The selected financial data for the years ended December 31, 2000 and 1999 and at December 31, 2001, 2000, and 1999 are derived from our audited financial statements not included in this report.

	Year Ended December 31,				
	2003	2002	2001	2000	1999
	(In thousands, except per share data)				
Statement of Operations Data					
Revenues					
Contract research and development	$ 47,366	$ 10,924	$ 12,071	$ 36,478	$ 24,539
Research progress payments				6,200	
Contract manufacturing	10,131	11,064	9,902	16,598	9,960
	57,497	21,988	21,973	59,276	34,499
Expenses					
Research and development(1)	136,024	124,953	92,542	65,134	52,450
Contract manufacturing	6,676	6,483	6,509	15,566	3,612
General and administrative	14,785	12,532	9,607	8,427	6,430
	157,485	143,968	108,658	89,127	62,492
Loss from operations	(99,988)	(121,980)	(86,685)	(29,851)	(27,993)
Other income (expense)					
Investment income	4,462	9,462	13,162	8,480	5,207
Interest expense	(11,932)	(11,859)	(2,657)	(281)	(284)
	(7,470)	(2,397)	10,505	8,199	4,923
Net loss before cumulative effect of a change in accounting principle	(107,458)	(124,377)	(76,180)	(21,652)	(23,070)
Cumulative effect of adopting Staff Accounting Bulletin 101 (“SAB 101”)(2)				(1,563)	
Net loss	$(107,458)	$(124,377)	$ (76,180)	$(23,215)	$(23,070)
Net loss per share, basic and diluted:					
Net loss before cumulative effect of a change in accounting principle	$ (2.13)	$ (2.83)	$ (1.81)	$ (0.62)	$ (0.74)
Cumulative effect of adopting SAB 101				(0.04)	
Net loss per share	$ (2.13)	$ (2.83)	$ (1.81)	$ (0.66)	$ (0.74)
Pro forma amounts assuming SAB 101 is applied retroactively:					
Net loss					$(22,699)
Net loss per share, basic and diluted					$ (0.73)

(1) Includes Loss in Amgen-Regeneron Partners of $63, $27, $1,002, $4,575, and $4,159 for the years ended December 31, 2003, 2002, 2001, 2000, and 1999, respectively.

(2) See Note 2 to our audited financial statements.

	At December 31,				
	2003	2002	2001	2000	1999
	(In thousands)				
Balance Sheet Data					
Cash, cash equivalents, marketable securities, and restricted marketable securities (current and non-current)	$366,566	$295,246	$438,383	$154,370	$ 93,599
Total assets	479,555	391,574	495,397	208,274	136,999
Capital lease obligations and notes payable, long-term portion	200,000	200,000	200,150	2,069	2,731
Stockholders' equity	137,643	145,981	266,355	182,130	109,532

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

Overview

We are a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently conducting clinical programs for four product candidates, which are in various stages of development:

Product Candidate	Primary Indications	Current Phase of Clinical Development
VEGF Trap	Cancer and eye diseases	Phase I
IL-1 Trap	Rheumatoid arthritis	Phase II
IL-4/13 Trap	Asthma	Phase I
AXOKINE	Obesity	Phase III

In addition to our clinical programs, we have research programs focused on angiogenesis, metabolic diseases, muscle atrophy and related disorders, inflammatory conditions, and other diseases and disorders. We also use our Velocigene and Trap technology platforms to discover and develop new product candidates.

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through December 31, 2003, we had a cumulative loss of $531.5 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we:

- continue the clinical development of VEGF Trap, IL-1 Trap, IL-4/13 Trap, and AXOKINE,

- commercialize product candidates that receive regulatory approval, if any,

- advance new product candidates into clinical development from our existing research programs, and

- continue our research and development programs.

Our activities may expand over time and may require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter

and will depend, among other factors, on the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

As a company that does not expect to generate product revenues or profits over the next several years, management of cash flow is extremely important. The most significant use of our cash is for research and development activities, which include drug discovery, preclinical studies, clinical trials, and the manufacture of drug supplies for preclinical studies and clinical trials. In 2003, our research and development expenses totaled $136.0 million. We expect these expenses to increase 15-30% in 2004, depending on the progress of our clinical programs. The principal sources of cash to-date have been sales of common equity and convertible debt and funding from our collaborators in the form of up-front payments, research progress payments, contract research and development, purchases of our common stock, and loans. We also receive revenue from contract manufacturing.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2003 was 675 compared to 643 in 2002 and 550 in 2001. In 2004, we expect our average headcount to increase to between 730 and 750, primarily to support our VEGF Trap and IL-1 Trap clinical programs. In 2003, payroll and related costs accounted for 36% of our total operating expenses. We expect this ratio to decline in 2004, as our clinical expenses grow.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our four clinical programs, key 2003 events and 2004 plans are as follows:

Product Candidate	2003 Events	2004 Plans
VEGF Trap	• Entered into collaboration agreement with Aventis • Continued Phase I trial in cancer	• Complete Phase I subcutaneous single-agent trial in cancer • Commence Phase I intravenous single-agent trial in cancer • Commence Phase II single-agent trials in cancer • Commence several Phase I combination therapy trials in cancer • Commence multiple Phase I trials in eye diseases
IL-1 Trap	• Completed Phase IIa trial in rheumatoid arthritis	• Commence Phase IIb trial in rheumatoid arthritis • Commence Phase I trial in other indications • Evaluate IL-1 Trap in other inflammatory conditions
IL-4/13 Trap	• Conducted Phase I trial in asthma	• Complete Phase I trial in asthma • Plan for Phase II trial in asthma
AXOKINE	• Completed efficacy portion of first pivotal Phase III trial in obesity	• Complete safety extension portion of first Phase III trial • Complete intermittent treatment trials • Additional development and market research activities • No new Phase III trials planned

In September 2003, we entered into a major collaboration agreement with Aventis to collaborate on the development and commercialization of the VEGF Trap. Aventis made a non-refundable up-front payment of

$80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for $45.0 million.

Under the collaboration agreement, we and Aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap. Aventis has agreed to make a $25.0 million payment to us upon achievement of an early-stage clinical milestone. We may also receive up to $360.0 million in additional milestone payments upon receipt of specified marketing approvals for up to eight VEGF Trap indications in Europe or the United States. Regeneron has agreed to continue to manufacture clinical supplies of the VEGF Trap at our plant in Rensselaer, New York. Aventis has agreed to be responsible for providing commercial scale manufacturing capacity for the VEGF Trap.

Under the collaboration agreement, agreed upon development expenses incurred by both companies during the term of the agreement will be funded by Aventis. If the collaboration becomes profitable, we will reimburse Aventis for 50 percent of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits, or at a faster rate at our option.

Aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse Aventis for 50 percent of the VEGF Trap development expenses will also terminate and we will retain all rights to the VEGF Trap.

In March 2003, we entered into a collaboration agreement with Novartis to jointly develop and commercialize the IL-1 Trap. Novartis made a non-refundable payment of $27.0 million and purchased 7,527,050 newly issued unregistered shares of our Common Stock for $48.0 million. On February 27, 2004, we announced that Novartis had provided notice of its intention not to proceed with the joint development of the IL-1 Trap. Under the terms of the collaboration agreement, Novartis remains obligated to fund agreed upon pre-Phase III IL-1 Trap development expenses during the nine-month notice period before its voluntary termination becomes effective. Novartis and we retain rights under the collaboration agreement to elect to collaborate on the development and commercialization of other IL-1 antagonists being developed independently by the other party that are in earlier stages of development than the IL-1 Trap.

Results of Operations

Years Ended December 31, 2003 and 2002

Revenues:

Revenues in the years ended December 31, 2003 and 2002 consist of the following:

	2003	2002
	(In millions)	
Contract research & development revenue		
Novartis	$21.4	$ —
Aventis	14.3	—
Procter & Gamble	10.6	10.5
Other	1.1	0.4
Total contract research & development revenue	47.4	10.9
Contract manufacturing revenue	10.1	11.1
Total revenue	$57.5	$22.0

Our total revenue increased to $57.5 million in 2003 from $22.0 million in 2002 primarily from the recognition of $21.4 million of revenue related to our collaboration with Novartis on the IL-1 Trap and $14.3 million of revenue related to our collaboration with Aventis on the VEGF Trap. This collaboration revenue, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments. Non-refundable up-front payments

are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with SAB 104 (see Critical Accounting Policies and Significant Judgments and Estimates).

	2003 Expense Reimbursement	Up-front Payment			
		Total Payment	Amount Recognized in 2003	Deferred Revenue at December 31, 2003	Total Revenue Recognized in 2003
			(In millions)		
Novartis	$16.5	$ 27.0	$4.9	$22.1	$21.4
Aventis	10.7	80.0	3.6	76.4	14.3
Total	$27.2	$107.0	$8.5	$98.5	$35.7

Contract manufacturing revenue relates primarily to our long-term agreement with Merck, which expires in October of 2005, unless extended by mutual agreement, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Contract manufacturing revenue decreased to $10.1 million in 2003 from $11.1 million in 2002, due primarily to the receipt of a non-recurring $1.0 million payment in the third quarter of 2002 related to services we provided to Merck in prior years. Revenue and the related manufacturing expense are recognized as product is shipped, after acceptance by Merck. Included in contract manufacturing revenue in 2003 and 2002 are $1.7 million and $1.8 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. This deferred revenue is being recognized as product is shipped to Merck based on the total amount of product expected to be shipped over the life of the agreement.

Research and Development Expenses:

Research and development expenses increased to $136.0 million in 2003 from $125.0 million in 2002, due primarily to (i) a $4.5 million increase in payroll related expenses associated with an increase in research, regulatory, and manufacturing personnel, (ii) a $6.3 million increase in lab supply, outside testing, and research contract expenses, and (iii) a $9.0 million increase in facility expenses such as rent, utilities, insurance, and depreciation. These facility related increases were due primarily to the costs associated with the plant expansion in Rensselaer which was completed in 2003 and the leasing of additional warehouse and manufacturing facilities in Rensselaer and office and lab space in Tarrytown during the third quarter of 2002. These increases were partially offset by an $8.8 million decrease in clinical expenses, due primarily to the completion of the double-blind treatment portion of the AXOKINE Phase III trial for the treatment of obesity in January of 2003.

Contract Manufacturing Expenses:

Contract manufacturing expenses increased to $6.7 million in 2003, compared to $6.5 million in 2002, primarily because we shipped more product to Merck.

General and Administrative Expenses:

General and administrative expenses increased to $14.8 million in 2003 from $12.5 million in 2002, due primarily to (i) a $1.0 million increase in payroll related costs, (ii) a $0.8 million increase in professional fees, principally associated with legal expenses for general corporate matters and the collaborations with Aventis and Novartis, and (iii) a $0.5 million increase in operating expenses including rent, utilities, supplies, and insurance.

Other Income and Expense:

Investment income decreased to $4.5 million in 2003 from $9.5 million in 2002 due to lower effective interest rates on investment securities and lower levels of interest-bearing investments for most of 2003 as we funded our operations. Average investment balances decreased to $156.6 million in 2003 from $264.9 million

in 2002. Interest expense was $11.9 million in both 2003 and 2002. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Years Ended December 31, 2002 and 2001

Revenues:

Revenues in the years ended December 31, 2002 and 2001 consist of the following:

	2002	2001
	(In millions)	
Contract research & development revenue		
Procter & Gamble	$10.5	$10.4
Amgen-Regeneron Partners	—	1.2
Other	0.4	0.5
Total contract research & development revenue	10.9	12.1
Contract manufacturing revenue	11.1	9.9
Total revenue	$22.0	$22.0

Our total revenue was $22.0 million in both 2002 and 2001. Contract research and development revenue decreased to $10.9 million in 2002 from $12.1 million in 2001 as revenue from Amgen-Regeneron Partners decreased from $1.2 million in 2001 to approximately $2,000 in 2002, due to the completion of studies conducted on behalf of the partnership. Contract manufacturing revenue, related primarily to our long-term agreement with Merck, increased to $11.1 million in 2002 from $9.9 million in 2001, due primarily to the receipt of a non-recurring $1.0 million payment related to services we provided to Merck in prior years. We shipped similar quantities of product to Merck in 2002 and 2001. Revenue and the related manufacturing expense are recognized as product is shipped, after acceptance by Merck. Included in contract manufacturing revenue in both 2002 and 2001 is $1.8 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. This deferred revenue is being recognized as product is shipped based on the total amount of product expected to be shipped over the life of the agreement.

Research and Development Expenses:

Research and development expenses increased to $125.0 million in 2002 from $92.5 million in 2001, due primarily to (i) a $14.0 million increase in clinical expenses associated primarily with our AXOKINE Phase III clinical trial for the treatment of obesity and our IL-1 Trap Phase II clinical trial for the treatment of rheumatoid arthritis, (ii) an $8.7 million increase in payroll related expenses associated with an increase in research, clinical, regulatory, and manufacturing personnel, (iii) a $4.6 million increase in lab supply, outside testing, and research contract expenses, and (iv) a $5.2 million increase in facility expenses such as rent, utilities, insurance, and depreciation.

Contract Manufacturing Expenses:

Contract manufacturing expenses were $6.5 million in both 2002 and 2001 primarily because we shipped similar quantities of product to Merck each year.

General and Administrative Expenses:

General and administrative expenses increased to $12.5 million in 2002 from $9.6 million in 2001, due primarily to (i) a $1.0 million increase in payroll related costs, (ii) an $0.8 million increase in patent prosecution and legal expenses related principally to the expansion of our intellectual property portfolio, (iii) a $0.6 million increase in professional fees related to investor relations services, bank fees, and audit services, and (iv) a $0.5 million increase in operating expenses including rent, utilities, supplies, and insurance.

Other Income and Expense:

Investment income decreased to $9.5 million in 2002 from $13.2 million in 2001, due to lower effective interest rates on investment securities during the full year 2002. Average investment balances increased to $264.9 million in 2002 from $155.5 million in 2001. Interest expense increased to $11.9 million in 2002 from $2.7 million in 2001, due to interest incurred on the $200.0 million of convertible notes that we issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our agreements with Novartis, Aventis, Merck, Procter & Gamble, Serono, Amgen, Sumitomo Chemical Co., and Sumitomo Pharmaceuticals Company, Ltd., and investment income.

Years Ended December 31, 2003 and 2002

Cash Used in Operations:

At December 31, 2003, we had $366.6 million in cash, cash equivalents, marketable securities, and restricted marketable securities compared with $295.2 million at December 31, 2002. Restricted marketable securities are pledged U.S. government securities which will be sufficient upon receipt of scheduled principal and interest payments to provide for the payment in full of the interest payments on the convertible senior subordinated notes through 2004. Net cash used in operations was $6.1 million in 2003 versus $110.5 million in 2002. The decrease in cash used in operations during 2003 resulted primarily from the receipt of contract research and development revenue and non-refundable up-front payments associated with the Aventis and Novartis collaborations which began in 2003. The effect of the two agreements on net cash used in operations in 2003 was approximately $134.2 million. The majority of cash used in operations was to fund research and development, primarily related to our VEGF Trap and IL-1 Trap programs.

In September 2003, the Company entered into a collaboration agreement with Aventis to jointly develop and commercialize the VEGF Trap. Aventis made a non-refundable up-front payment of $80.0 million which was recorded to deferred revenue and is being recognized as contract research and development revenue ratably over the period over which we are obligated to perform services. In 2003, we recognized $3.6 million of revenue related to this up-front payment and we anticipate, based on current VEGF Trap product development plans, that we will recognize approximately $10.9 million of revenue over each of the next 7 years. In addition, Aventis has agreed to fund all development expenses incurred by both companies during the term of the agreement. In 2003, Aventis funded $10.7 million of our VEGF Trap development costs, of which $8.9 million was included in accounts receivable as of December 31, 2003.

In March 2003, we entered into a collaboration agreement with Novartis to jointly develop and commercialize the IL-1 Trap. Novartis made a non-refundable up-front payment of $27.0 million which was recorded to deferred revenue and is being recognized as contract research and development revenue ratably over the period over which we are obligated to perform services. In 2003, we recognized $4.9 million of revenue related to this up-front payment. Development expenses incurred during 2003 were shared equally by Regeneron and Novartis. In 2003, Novartis agreed to reimburse us for $16.5 million of our IL-1 Trap development costs, of which $3.2 million was included in accounts receivable as of December 31, 2003. On February 27, 2004, we announced that Novartis had provided notice of its intention not to proceed with the joint development of the IL-1 Trap. As a result, we will recognize $22.1 million of revenue in 2004, representing the balance of deferred revenue at December 31, 2003 related to Novartis' non-refundable up-front payment.

In 2003, we recorded a non-cash expense of $1.5 million associated with the issuance of our Common Stock in connection with a license agreement entered into with Merck.

In both 2003 and 2002, we made two semi-annual interest payments totaling $11.0 million per year on our convertible senior subordinated notes.

Cash Used in Investing Activities:

Net cash used in investing activities was $63.8 million in 2003 compared to $58.5 million in 2002. The increase is due primarily to purchases of marketable securities which exceeded sales and/or maturities of marketable securities by $10.0 million. Offsetting this increase was a $4.7 million decrease in cash payments made for capital expenditures due to the completion of the Rensselaer plant expansion in 2003.

Cash Provided by Financing Activities:

Cash provided by financing activities increased to $108.2 million in 2003 compared to $1.7 million in 2002, due primarily to the sale of stock to Aventis and Novartis in 2003 in association with the collaboration agreements. Aventis purchased 2,799,552 newly issued unregistered shares of our Common Stock for $45.0 million. Novartis purchased 7,527,050 newly issued unregistered shares of our Common Stock for $48.0 million. In addition, in accordance with our collaboration agreement with Novartis, we elected to fund our share of 2003 IL-1 Trap development expenses through a loan from Novartis that will be forgiven, together with accrued interest, should certain preclinical and clinical milestones be reached. If these milestones are not reached, the loan is due and payable on July 1, 2004. As of December 31, 2003, we have drawn $13.7 million, excluding interest, against this loan facility and we have drawn an additional $3.8 million during the first quarter of 2004 for expenses incurred during 2003.

Aventis Agreement:

Under the collaboration agreement with Aventis, we and Aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap. Aventis has agreed to make a $25.0 million payment to us upon achievement of an early-stage clinical milestone. We may also receive up to $360.0 million in additional milestone payments upon receipt of specified marketing approvals for up to eight VEGF Trap indications in Europe or the United States.

We have agreed to continue to manufacture clinical supplies of the VEGF Trap at our plant in Rensselaer, New York. Aventis has agreed to be responsible for providing commercial scale manufacturing capacity for the VEGF Trap. Under the collaboration agreement, agreed upon development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by Aventis. If the collaboration becomes profitable, we will reimburse Aventis for 50 percent of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits, or at a faster rate at our option. We have the option to conduct additional pre-Phase III studies at our own expense. In 2003, we incurred and were reimbursed by Aventis for $10.7 million in development expenses related to the VEGF Trap program. In addition to expenses incurred by us in 2003, Aventis incurred $0.1 million in development expenses related to the VEGF Trap program.

In 2004, we and Aventis plan to invest approximately $100 million to support the development of the VEGF Trap. The broad based development program will include multiple Phase I studies to evaluate the VEGF Trap in combination with other therapies in various cancer indications, Phase II single-agent studies of the VEGF Trap in separate cancer indications, and multiple Phase I studies of the VEGF Trap in certain eye diseases.

Novartis Agreement:

Pursuant to the terms of our collaboration agreement with Novartis, in 2004, Novartis will be responsible for agreed upon pre-Phase III development expenses through the expiration of the nine-month termination notice period, which ends at the end of November 2004. In addition, a loan totaling $17.5 million as of March 3, 2004 that relates to our share of 2003 development expense will be forgiven, together with accrued interest, should we meet certain milestones. Otherwise, the loan is due and payable on July 1, 2004.

Under the Novartis agreement, Novartis and we retain rights under the collaboration agreement to elect to collaborate on the development and commercialization of other IL-1 antagonists being developed independently by the other party that are in earlier stages of development than the IL-1 Trap.

Merck License Agreement:

In August 2003, Merck granted to us a non-exclusive license to certain patents and patent applications which may be used in the development and commercialization of AXOKINE. As consideration, we issued to Merck 109,450 newly issued unregistered shares of our Common Stock (the Merck Shares), valued at $1.5 million based on the fair market value of shares of our Common Stock on the agreement's effective date. The agreement requires us to make an additional payment to Merck upon receipt of marketing approval for a product covered by the licensed patents. In addition, we would be required to pay royalties, at staggered rates in the mid-single digits, based on the net sales of products covered by the licensed patents.

At any time prior to the date that Merck has the right to sell the Merck Shares under the Securities Act of 1933 (the Sales Date), we have the right to buy back the Merck Shares from Merck for a purchase price equal to the greater of (a) $1.5 million and (b) the lesser of (i) the fair market value of the shares and (ii) $1.65 million. Unless Regeneron has previously exercised its right to buy back the Merck Shares, on the Sales Date if the fair market value of the Merck Shares (the Market Price) is less than $1.5 million, we will be required to make a cash payment to Merck equal to the difference between the Market Price and $1.5 million. Conversely, if on the Sales Date the Market Price is greater than $1.65 million, Merck will be required, at its option, to either (i) make a cash payment to us equal to the difference between the Market Price and $1.65 million (the Excess Amount) or (ii) return a number of the Merck Shares to us, calculated by dividing the Excess Amount by the fair market value of a share of our Common Stock on the Sales Date. The fair market value of the shares, based on our closing Common Stock price at December 31, 2003, was $1.6 million.

Convertible Debt:

In 2001, we issued $200.0 million aggregate principal amount of convertible senior subordinated notes in a private placement and received proceeds, after deducting the initial purchasers' discount and out-of pocket expenses, of $192.7 million. The notes bear interest at 5.5% per annum, payable semi-annually and mature in 2008. The notes are convertible into shares of our Common Stock at a conversion price of approximately $30.25 per share, subject to adjustment in certain circumstances. We may redeem the notes, in whole or in part, at any time before October 17, 2004, if the closing price of our Common Stock has exceeded 150% of the conversion price then in effect for a specified period of time. Upon any such redemption, we are required to pay interest that would have been due up through October 17, 2004. We may also redeem some or all of the notes at any time on or after October 17, 2004, if the closing price of our Common Stock has exceeded 140% of the conversion price then in effect for a specified period of time.

As part of this transaction, we pledged $31.6 million of U.S. government securities which will be sufficient upon receipt of scheduled principal and interest payments to provide for the payment in full of the first six scheduled interest payments on the notes when due.

Capital Expenditures:

Our additions to property, plant, and equipment totaled $16.9 million in 2003, $45.9 million in 2002, and $9.5 million in 2001, including a total over the three years of $50.2 million related to the expansion of our manufacturing facilities in Rensselaer, New York. In 2004, we expect to incur approximately $10 million to $15 million in capital expenditures which primarily consists of equipment for our expanded manufacturing, research, and development activities, a portion of which will be reimbursed by Aventis.

Funding Requirements:

Our total expenses for research and development from inception through December 31, 2003 have been approximately $721 million. We have not historically segregated all the costs associated with each of our

research programs and it is not possible to forecast their success or the amounts that we may spend in the future. We currently have research and development collaboration agreements with Aventis, Novartis, Procter & Gamble, Medarex, Emisphere, Amgen, and Sumitomo Pharmaceuticals. In 2003, 2002, and 2001, total expenses for research programs conducted under our third-party collaboration agreements were approximately $46 million, $10 million, and $12 million, respectively. The remainder of our research and development expenses in those years related to our own internal research programs.

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). We currently anticipate that in 2004 approximately 50-70% of our expenditures will be directed toward the preclinical and clinical development of product candidates, including the VEGF Trap, IL-1 Trap, IL-4/ 13 Trap, and AXOKINE; approximately 10-20% of our expenditures will cover our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures will be for capital expenditures and general corporate purposes, including working capital.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2003 for leases and long-term debt. None of these obligations extend beyond 5 years.

		Payments Due by Period		
	Total	Less than one year	1 to 3 years	4 to 5 years
		(In millions)		
Convertible Senior Subordinated Notes Payable	$200.0	$ —	$ —	$200.0
Loan Payable(1)	13.8	13.8	—	—
Operating Leases(2)	9.1	5.5	3.4	0.2
Other Long-term Liabilities(3)	0.2	—	0.2	—

(1) Includes amounts representing interest.

(2) Excludes future contingent rental costs for utilities, real estate taxes, and operating expenses. In 2003, these costs were $6.0 million.

(3) Includes long-term portion of restricted cash awards granted in December 2003 which vest semi-annually over an approximate two year period.

In January 2004, the Company amended its Tarrytown lease and exercised its option to extend the lease for certain parts of the leased space through December 2009. The amended lease contains renewal options for certain parts of the leased space through December 2014.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of any collaborative research and development collaborations (including those with Aventis, Procter & Gamble, Medarex, and Emisphere). Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least the end of 2005. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of December 31, 2003, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

Revenue Recognition:

We recognize revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and Emerging Issues Task Force 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). During the third quarter of 2003, we elected to change the method we use to recognize revenue under SAB 104 related to non-refundable collaborator payments, including up-front licensing payments, payments for development activities, and research progress (milestone) payments, to the Substantive Milestone Method, adopted retroactively to January 1, 2003. Under this method, we recognize revenue from non-refundable up-front license payments, not tied to achieving a specific performance milestone, ratably over the period over which we are obligated to perform services. The period over which we are obligated to perform services is estimated based on product development plans. These estimates are likely to change based on the results and progress of clinical trials and drug production. Changes in these estimates could result in a significant change to the amount of revenue recognized in future periods. In addition, if a collaborator terminates the agreement in accordance with the terms of the contract, we would recognize the remainder of the up-front payment at the time of the termination. Payments for development activities are recognized as revenue as earned, ratably over the period of effort. Substantive at-risk milestone payments, which are based on achieving a specific performance milestone, are recognized as revenue when the milestone is achieved and the related payment is due, provided there is no future service obligation associated with that milestone. Previously, we had recognized revenue from non-refundable collaborator payments based on the percentage of costs incurred to date, estimated costs to complete, and total expected contract revenue. However, the revenue recognized was limited to the amount of non-refundable payments received. The change in accounting method was made because we believe that it better reflects the substance of our collaborative agreements and is more consistent with current practices in the biotechnology industry.

Recognition of Deferred Revenue Related to Contract Manufacturing Agreement:

We have entered into a contract manufacturing agreement with Merck under which we manufacture a vaccine intermediate at our Rensselaer, New York facility and perform services. We recognize contract manufacturing revenue from this agreement after the product is tested and approved by, and shipped (FOB Shipping Point) to, Merck, and as services are performed. In connection with the agreement, we agreed to modify portions of our Rensselaer facility to manufacture Merck's vaccine intermediate and Merck agreed to reimburse us for the related capital costs. These capital cost payments were deferred and are recognized as revenue as product is shipped to Merck, based upon our estimate of Merck's order quantities each year through the expected end of the agreement. Since we commenced production of the vaccine intermediate in

November 1999, our estimates of Merck's order quantities each year have not been materially different from Merck's actual orders.

Clinical Trial Accrual Estimates:

For each clinical trial that we conduct, certain clinical trial costs, which are included in research and development expenses, are expensed based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services. We believe that this method best aligns the expenses we record with the efforts we expend on a clinical trial. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates.

Depreciation of Property, Plant and Equipment:

Property, plant, and equipment are stated at cost. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	6-30 years
Leasehold improvements	Life of lease
Laboratory and computer equipment	3-5 years
Furniture and fixtures	5 years

In some situations, the life of the asset may be extended or shortened if circumstances arise that would lead us to believe that the estimated life of the asset has changed. The life of leasehold improvements may change based on the extension of lease contracts with our landlords. Changes in the lives of assets will result in an increase or decrease in the amount of depreciation recognized in future periods. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

Future Impact of Recently Issued Accounting Standards

In December 2003, the Staff of the Securities and Exchange Commission issued SAB 104, *Revenue Recognition*, which supercedes SAB 101, *Revenue Recognition in Financial Statements*. SAB 104's primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, superceded as a result of the issuance of EITF 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Additionally, SAB 104 rescinds the SEC's *Revenue Recognition in Financial Statements Frequently Asked Questions and Answers* (the FAQ) issued with SAB 101 that had been codified in SEC Topic 13, *Revenue Recognition*. Selected portions of the FAQ have been incorporated into SAB 104. While the wording of SAB 104 has changed to reflect the issuance of EITF 00-21, the revenue recognition principles of SAB 101 remain largely unchanged by the issuance of SAB 104. Adoption of SAB 104 was required immediately and did not have a material effect on our financial statements.

In December 2003, the FASB issued a revision to Interpretation No. 46, *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51* (FIN 46R), which was issued in January 2003. FIN 46R clarifies the application of ARB No. 51, *Consolidated Financial Statements*, to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support. FIN 46R requires the consolidation of these entities, known as variable interest entities (VIEs), by the primary beneficiary of the entity. The primary beneficiary is the entity, if any, that will absorb a majority of the entity's expected losses, receive a majority of the entity's expected residual returns, or both. Among other changes, the revisions of FIN 46R (i) clarified some requirements of the original FIN 46, which had been issued in January 2003, (ii) eased some implementation problems, and (iii) added new scope exceptions. FIN 46R deferred the

effective date of the Interpretation for public companies to the end of the first reporting period ending after March 15, 2004, except that all public companies must at a minimum apply the provisions of the Interpretation to entities that were previously considered "special-purpose entities" under the FASB literature prior to the issuance of FIN 46R by the end of the first reporting period ending after December 15, 2003. Adoption of FIN 46R did not have a material impact on our financial statements.

In May 2003, the Financial Accounting Standards Board issued Statement No. 150 (SFAS No. 150), *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 specifies that instruments within its scope embody obligations of the issuer and that the issuer must classify them as liabilities. SFAS No. 150 requires issuers to classify as liabilities the following three types of freestanding financial instruments: (i) mandatorily redeemable financial instruments, (i) obligations to repurchase the issuer's equity shares by transferring assets, and (iii) certain obligations to issue a variable number of shares. SFAS No. 150 defines a "freestanding financial instrument" as a financial instrument that (i) is entered into separately and apart from any of the entity's other financial instruments or equity transactions or (ii) is entered into in conjunction with some other transaction and can be legally detached and exercised on a separate basis. For all financial instruments entered into or modified after May 31, 2003, SFAS No. 150 is effective immediately. For all other instruments of public companies, SFAS No. 150 went into effect at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on our financial statements. In November 2003, the Financial Accounting Standards Board deferred the effective date for selected provisions of SFAS No. 150, limited to mandatorily redeemable noncontrolling interests associated with finite-lived subsidiaries. The deferral of those selected provisions is not expected to have a material impact on our financial statements.

In November 2002, the FASB issued Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others, an interpretation of FASB Statements No. 5, 57 and 107 and a rescission of FASB Interpretation No. 34*. FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees issued. FIN 45 also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of FIN 45 are applicable to guarantees issued or modified after December 31, 2002 and did not have a material impact on our financial statements.

Risk Factors

Regeneron operates in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are included under other captions in this report and should be considered by our investors.

Risks Related to our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. Moreover, if we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through December 31, 2003, we had a cumulative loss of $531.5 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. The extent and timing of our future losses and our profitability, if we are ever to become profitable, are highly uncertain.

We will need additional funding in the future, which may not be available to us, and which would then force us to delay, reduce, or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least the end of 2005. However, this is a forward-looking statement based on our current operating plan and we cannot assure you that there will be no change in projected revenue or expenses that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we cannot make assurances that we will be able to raise such additional funds. The sale of equity or convertible debt securities in the future may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict certain business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. We may be unable to raise sufficient funds to complete the development of our product candidates or to continue operations. As a result, we may face delay, reduction, or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition, or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. The debt, unless converted to shares of our common stock, will mature in October 2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payors and on our and our partners' ability to successfully manufacture and commercialize our product candidate. Our product candidates are delivered either by intravenous or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many causes, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate, and the failure of clinical investigators, trial monitors and other

consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may also fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. For example, the pending trials studying the maintenance of weight loss following short-term treatment regimens with AXOKINE may not have enrolled enough patients to detect statistically significant differences between patients treated with AXOKINE and those taking placebo. These trials were designed before we had access to the data from the completed pivotal Phase III AXOKINE trial, which demonstrated that the magnitude of the average difference in weight loss observed between all AXOKINE-treated subjects and those taking placebo was small.

We would need to reevaluate any drug candidate that did not test favorably and either conduct new trials, which would be expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for our desired indications could harm the development of the product candidate, and our business, financial condition, and results of operations may be materially harmed.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These safety concerns may limit our ability to successfully develop the VEGF Trap.

Genentech and Eyetech are developing VEGF inhibiting molecules for certain diseases of the eye that will be delivered by direct administration to the eye. We are studying the VEGF Trap for the potential treatment of certain diseases of the eye through intravitreal injections in the eye or general administration through intravenous infusions or subcutaneous injections. Although we believe that there are potential clinical advantages to general administration over injections directly in the eye (including patient comfort and acceptance), there are unique potential risks to patients associated with systemic blockage of VEGF by intravenous infusions or subcutaneous injections that could limit or end the VEGF Trap development program. These risks, based on the clinical and pre-clinical experience of systemically delivered VEGF inhibitors, include bleeding, hypertension, and proteinuria. In addition, patients given infusions of any protein, including the VEGF Trap, may develop severe hypersensitivity reactions, referred to as infusion reactions. There may be additional complications or side effects that could harm the development of the VEGF Trap for either the treatment of cancer or diseases of the eye.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases,

the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created at a later date — in some cases even after pivotal clinical trials have been completed. Approximately two-thirds of the subjects who received AXOKINE in the completed Phase III study developed neutralizing antibodies. In addition, subjects who received the IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap in different patient populations and larger clinical trials, subjects given the VEGF Trap will develop antibodies to the product candidate.

A previous Phase III study evaluating AXOKINE demonstrated modest average weight loss over a 12-month period. In addition, a completed Phase II study evaluating the IL-1 Trap in patients with rheumatoid arthritis failed to achieve its primary endpoint.

In March 2003, we reported data from the 12-month treatment period of our initial Phase III pivotal trial of AXOKINE. Although the Phase III study met its primary endpoints and many individuals achieved a medically meaningful weight loss, the average weight loss was small and limited by the development of antibodies.

In October 2003, we reported results from the first Phase II trial of our IL-1 Trap. While patients treated with the highest dose, 100 milligrams of the IL-1 Trap, exhibited improvements in the primary endpoint of the trial, the proportion of ACR 20 responses versus placebo, the results did not achieve statistical significance. We plan to conduct a Phase IIb study of the IL-1 Trap in a larger patient population, testing higher doses than were tested in the previous Phase II trial and for a longer period of time. However, there is no assurance that higher doses will lead to better results than were demonstrated in the previous Phase II trial. In addition, safety or tolerability concerns may arise which limit our ability to deliver higher doses of the IL-1 Trap to patients. We plan to study higher doses of the IL-1 Trap through increased subcutaneous injections and intravenous delivery. Either approach may affect the safety and/or tolerability of the IL-1 Trap, which may limit its commercial potential if the product candidate is ever approved for marketing and sale.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the U.S. Food and Drug Administration, or FDA, for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. We are currently involved in a product liability lawsuit brought by a subject who participated in a clinical trial of one of our drug candidates. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

In May 2003, securities class action lawsuits were commenced against Regeneron and certain of its officers and directors in the United States District Court for the Southern District of New York. A consolidated amended class action complaint was filed in October 2003. The complaint, which purports to be brought on behalf of a class consisting of investors in the Company's publicly traded securities between March 28, 2000 and March 30, 2003, alleges that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE, in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. No reserve for damages has been established because we do not believe that a loss is probable. However, if the outcome of the litigation is adverse to us, we could be subject to significant liability, which could exceed our insurance coverage.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Risks Related to our Dependence on Third Parties

On February 27, 2004, Novartis provided notice to us that they would not participate in the continued development and commercialization of the IL-1 Trap under our collaboration agreement. This may harm our ability to develop and commercialize the IL-1 Trap.

We relied heavily on Novartis to provide their expertise, resources, funding, manufacturing capacity, clinical expertise, and commercial infrastructure to support the IL-1 Trap program. Novartis' decision to withdraw from participating in the development and commercialization of the IL-1 Trap may delay or disrupt the IL-1 Trap program. We do not have the resources and skills to replace those of Novartis to help the development and potential commercialization of the IL-1 Trap. In addition, we will have to fund the development and commercialization of the IL-1 Trap without Novartis' long-term commitment, which will require substantially greater expenditures on our part. While the agreement requires Novartis to continue to fund agreed pre-Phase III development expenses for the nine-month period following its termination decision and imposes additional post-termination obligations on the parties, Novartis may not fulfill all payment and other obligations we believe are required of it under the agreement, which may cause us to incur further costs and risk delays and disruptions to the IL-1 Trap program.

If our collaboration with Aventis for the VEGF Trap is terminated, our ability to develop and commercialize the VEGF Trap in the time expected, or at all, and our business operations would be harmed.

We rely heavily on Aventis to assist with the development of the VEGF Trap. If the VEGF Trap program continues, we will rely on Aventis to assist with providing commercial manufacturing capacity, enrolling and monitoring clinical trials, obtaining regulatory approval, particularly outside the United States, and providing sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if Aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap will be significantly adversely affected. Aventis has the right to terminate rights to our product candidates under its collaboration agreement with us at any time. If Aventis were to terminate its collaboration agreement with us, we might not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing,

or distribution capabilities. Termination of the Aventis collaboration agreement would create new and additional risks to the successful development of the VEGF Trap.

Sanofi-Synthelabo has initiated a tender offer in an attempt to acquire Aventis. It is unclear what the impact of this or any other business combination involving Aventis would have on the VEGF Trap collaboration, including the possibility of a termination of the collaboration agreement and a delay in, or disruption to, the VEGF Trap development program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including Aventis and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we would experience additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development and, following approval, in commercial quantities, in compliance with regulatory requirements and at competitive costs. If we or any of our product collaborators or third-party manufacturers, fillers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

While we believe our current manufacturing facility is adequate for the current production of quantities of active pharmaceutical ingredients, or API, for our product candidates for clinical trials, our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce large quantities of drug material needed for commercialization of our products. We rely entirely on third party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of API for our product candidates. This will require substantial additional funds, and we would need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the underutilization of our manufacturing facilities.

We maintain an 8,000 square foot manufacturing facility in Tarrytown, New York and have large-scale manufacturing operations in Rensselaer, New York. Under a long-term manufacturing agreement with Merck, we produce an intermediate for a Merck pediatric vaccine at our facility in Rensselaer, New York. We also use our facilities to produce API for our own clinical and preclinical candidates. If we no longer use our facilities to manufacture the Merck intermediate or clinical candidates are discontinued, we would have to absorb overhead costs and inefficiencies.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future drug products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell our products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need. We may not be able to enter into marketing, or distribution agreements with third-party providers on acceptable terms, if at all. Currently, we are relying on Aventis for sales, marketing, and distribution of the VEGF Trap. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates. We may be unsuccessful in developing our own sales, marketing, and distribution organization.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including VEGF Trap, IL-1 Trap, IL-4/13 Trap and AXOKINE, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates. For example, AXOKINE is currently formulated for delivery in single use vials. We are in the process of developing a formulation that may be used in multiple use vials. If we are unable to develop this multiple use vial formulation, potential future AXOKINE sales and profitability may be limited. Another example is our IL-1 Trap. We are in the process of developing formulations that would allow delivery of higher doses of the IL-1 Trap to test in clinical trials. This includes formulations for subcutaneous and intravenous administration. If we are unable to develop or manufacture such a higher dose formulation that can be produced in a cost-effective manner, potential future IL-1 Trap sales and profitability may be limited.

Even if our product candidates are ever approved, their commercial success is highly uncertain because our competitors may get to the marketplace before we do with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical, and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also be significant if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale. Genentech has an approved VEGF antagonist on the market and many different pharmaceutical and biotechnology companies

are working to develop competing VEGF antagonists, including Novartis and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. The marketing approval for Genentech's VEGF antagonist, Avastin™, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap. The markets for both rheumatoid arthritis and asthma are both very competitive. Several highly successful medicines are available for these diseases. Examples include the TNF-antagonists Enbrel® (a registered trademark of Amgen), Remicade® (a registered trademark of Centocor), and Humira® (a registered trademark of Abbott) for rheumatoid arthritis, and the leukotriene-modifier Singulair® (a registered trademark of Merck), as well as various inexpensive corticosteroid medicines for asthma. The availability of highly effective FDA approved TNF-antagonists makes it more difficult to successfully develop the IL-1 Trap for the treatment of rheumatoid arthritis. It will be difficult to enroll patients with rheumatoid arthritis to participate in clinical trials of the IL-1 Trap, which may delay or impair our ability to successfully develop the drug candidate. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. There is also substantial competition in the discovery and development of treatments for obesity, as well as established, cost-effective, and emerging surgical, prescription, and over-the-counter treatments for the disease that may offer competitive advantages over AXOKINE. AXOKINE is available only in injectible form, while the currently available marketed medicines for the treatment of obesity, and a late-stage product candidate in development by Sanofi-Synthelabo, are delivered in pill form, which is generally favored over injectible medicines. Therefore, even if AXOKINE is approved for sale, the fact that it must be delivered by injection may severely limit its market acceptance among patients and physicians.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payors.

Sales of biopharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the governments or third-party payors, the market for any biopharmaceutical product will be limited. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of products and services. Significant uncertainty exists as to the reimbursement status of any new therapeutic, particularly if there exist lower-cost standards of care. Third-party payors may not reimburse sales of our products, which would harm our business.

Risks Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of Roy Vagelos, M.D., the Chairman of our Board of Directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, and George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights

from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. One way a patent application may be challenged outside the United States is for a party to file an opposition. These opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will defend additional patent applications in the future as third parties oppose them. Also, our patent rights may not provide us with a proprietary position or competitive advantages against competitors. The enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us.

We may be restricted in our development and/or commercialization activities by third party patents.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties could allege to have blocking patents to our Trap products in clinical development, either because of a proprietary position on fusion proteins or a proprietary position covering components of the Trap or the way it is manufactured. We are aware of certain United States and foreign patents relating to particular IL-4 and IL-13 receptors. Our IL-4/13 Trap includes portions of the IL-4 and IL-13 receptors. In addition, we are aware of a broad patent held by Genentech relating to proteins fused to certain immunoglobulin domains. Our Trap product candidates include proteins fused to immunoglobulin domains. With regard to these patents, we have determined that in our judgment that either our products do not infringe the patents, we do not believe the patents are valid, or we have identified and are testing or developing various modifications that we believe should not infringe the patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Risks Related to our Common Stock

Our stock price may be extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;

• arrivals and departures of key personnel; and

• general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our common stock in the market. Broad market fluctuations may also adversely affect the market price of our common stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price.

A number of our shareholders own a substantial amount of our common stock. If our significant shareholders or we sell substantial amounts of our common stock in the public market, the market price of our common stock could fall. Sales by our significant shareholders, including Amgen, Aventis, and Novartis, also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deemed appropriate.

Item 7A. ***Quantitative and Qualitative Disclosure About Market Risk.***

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in an approximately $1.4 million and $0.7 million change in the fair market value of our investment portfolio at December 31, 2003 and 2002, respectively. The increase is due primarily to a higher investment portfolio balance and slightly longer duration as of December 31, 2003 in comparison to 2002.

Item 8. ***Financial Statements and Supplementary Data***

Our financial statements required by this item are included herein as exhibits and listed under Item 15.(A)1.

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

Not applicable.

Item 9A. ***Controls and Procedures***

We conducted an evaluation of the effectiveness of the Company’s disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. The evaluation was conducted under the supervision and with the participation of Leonard S. Schleifer, our President and Chief Executive Officer, and Murray A. Goldberg, our Chief Financial Officer. Based upon this evaluation, each of Dr. Schleifer and Mr. Goldberg concluded that our disclosure controls and procedures are effective in timely alerting them to material information required to be included in our filings under the Securities Exchange Act of 1934. There has been no significant change in our internal controls over financial reporting during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. While we believe that our disclosure controls and procedures have been effective, in light of the foregoing, we intend to continue to examine and refine our disclosure controls and procedures and monitor ongoing developments in this area.

PART III

Item 10. ***Directors and Officers of the Registrant***

The information required by this item will be contained under the captions “Election of Directors,” “Board Committees,” “Executive Officers of the Registrant,” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our definitive proxy statement with respect to our 2004 Annual Meeting of Shareholders to be filed with the SEC, and is hereby incorporated by reference thereto.

We have adopted a code of ethics that applies to our Chief Executive Officer, Chief Financial Officer, and other senior financial officers. The current version of this code of ethics can be found on the Company’s website (*http://www.regn.com)* under the Investor Relations heading. A broader code of business conduct and ethics, which will apply to all our officers, directors and employees, will be submitted shortly to the Board of Directors for approval.

Item 11. ***Executive Compensation***

The information called for by this item is incorporated by reference to the material captioned “Executive Compensation” and “Compensation of Directors” in our definitive proxy statement with respect to our 2004 Annual Meeting of Shareholders to be filed with the SEC.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management***

The information called for by this item is incorporated by reference to the material captioned “Stock Ownership of Executive Officers and Directors” and “Stock Ownership of Certain Beneficial Owners” in our definitive proxy statement with respect to our 2004 Annual Meeting of Shareholders to be filed with the SEC.

Item 13. ***Certain Relationships and Related Transactions***

The information called for by this item is incorporated by reference to the material captioned “Certain Relationships and Related Transactions” in our definitive proxy statement with respect to our 2004 Annual Meeting of Shareholders to be filed with the SEC.

Item 14. ***Principal Accountant Fees and Services***

The information called for by this item is incorporated by reference to the material captioned “Information about Fees Paid to Independent Auditors” in our definitive proxy statement with respect to our 2004 Annual Meeting of Shareholders to be filed with the SEC.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

(A) 1. Financial Statements

The financials statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and therefore have been omitted.

3. Exhibits

Exhibit Number			Description
3.1	(a)	—	Restated Certificate of Incorporation of Regeneron Pharmaceuticals, Inc. as of June 21, 1991.
3.2	(b)	—	By-Laws of the Company, currently in effect (amended as of January 22, 1995).
10.1	(c)	—	Certificate of Amendment of the Restated Certificate of Incorporation of Regeneron Pharmaceuticals, Inc., as of October 18, 1996.
10.2	(d)	—	Certificate of Amendment of the Certificate of Incorporation of Regeneron Pharmaceuticals, Inc., as of December 17, 2001.
10.3	(e)*	—	Technology Development Agreement dated as of March 20, 1989, between the Company and Sumitomo Chemical Company, Limited.
10.4	(e)*	—	Collaboration Agreement dated August 31, 1990, between the Company and Amgen Inc.
10.5	(e)	—	1990 Amended and Restated Long-Term Incentive Plan.
10.6	(d)	—	2000 Long-Term Incentive Plan.
10.6.1	(n)	—	Amendment No. 1 to 2000 Long-Term Incentive Plan, effective as of June 14, 2002.
10.6.2	(n)	—	Amendment No. 2 to 2000 Long-Term Incentive Plan, effective as of December 20, 2002.
10. 7	(f)*	—	Research and Development Agreement dated as of June 2, 1994, between the Company and Sumitomo Pharmaceuticals Company, Ltd.
10.8	(g)*	—	Manufacturing Agreement dated as of September 18, 1995, between the Company and Merck & Co., Inc.
10.9	(h)	—	Warrant Agreement dated as of April 15, 1996, between the Company and Amgen Inc.
10.10	(h)	—	Registration Rights Agreement dated as of April 15, 1996, between the Company and Amgen Inc.
10.11	(i)	—	Rights Agreement, dated as of September 20, 1996, between Regeneron Pharmaceuticals, Inc. and Chase Mellon Shareholder Services LLC, as Rights Agent, including the form of Rights Certificate as Exhibit B thereto.
10.12	(j)	—	Stock Purchase Agreement dated as of December 11, 1996, between the Company and Procter & Gamble Pharmaceuticals, Inc.
10.13	(j)	—	Registration Rights Agreement dated as of December 11, 1996, between the Company and Procter & Gamble Pharmaceuticals, Inc.
10.14	(k)	—	Securities Purchase Agreement dated as of May 13, 1997, between the Company and The Procter & Gamble Company.
10.15	(k)	—	Warrant Agreement dated as of May 13, 1997, between the Company and The Procter & Gamble Company.
10.16	(k)	—	Registration Rights Agreement, dated as of May 13, 1997, between the Company and The Procter & Gamble Company.

Exhibit Number			Description
10.17	(n)	—	Employment Agreement, dated as of December 20, 2002, between the Company and Leonard S. Schleifer, M.D., Ph.D.
10.18	(l)	—	Indenture, dated as of October 17, 2001, between Regeneron Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, as trustee.
10.19	(l)	—	Pledge Agreement, dated as of October 17, 2001, between Regeneron Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, as trustee.
10.20	(l)	—	Registration Rights Agreement, dated as of October 17, 2001, among Regeneron Pharmaceuticals, Inc., Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, and Robertson Stephens, Inc.
10.21	(m)*	—	Focused Collaboration Agreement, dated as of December 31, 2000, by and between the Company and The Procter & Gamble Company.
10.22	(m)*	—	IL-1 License Agreement, dated June 26, 2002, by and among the Company, Immunex Corporation, and Amgen Inc.
10.23	(o)*	—	Collaboration, License and Option Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and the Company.
10.24	(o)*	—	Stock Purchase Agreement, dates as of March 28, 2003, by and between Novartis Pharma AG and the Company.
10.25	(o)	—	Registration Rights Agreement, dates as of March 28, 2003, by and between Novartis Pharma AG and the Company.
10.26	(p)*	—	Collaboration Agreement, dates as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.27	(p)	—	Stock Purchase Agreement, dates as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.28	(p)*	—	Non-Exclusive Patent License Agreement, effective as of August 18, 2003, by and between Merck & Co., Inc. and Regeneron Pharmaceuticals, Inc.
18.1	(p)	—	Independent Accountant’s Preferability Letter Regarding a Change in Accounting Principle.
23.1		—	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
23.2		—	Consent of Ernst & Young LLP, Independent Auditors.
31		—	Certification of CEO and CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32		—	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Description:

(a) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 1991, filed August 13, 1991.

(b) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 1994, filed March 30, 1995.

(c) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 1996, filed November 5, 1996.

(d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2001, filed March 22, 2002.

(e) Incorporated by reference from the Company’s registration statement on Form S-1 (file number 33-39043).

(f) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 1994, filed November 14, 1994.

(g) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 1995, filed November 14, 1995.

(h) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 1996, filed August 14, 1996.

(i) Incorporated by reference from the Form 8-A for Regeneron Pharmaceuticals, Inc. filed October 15, 1996.

(j) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 1996, filed March 26, 1997.

(k) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 1997, filed August 12, 1997.

(l) Incorporated by reference from the Company's registration statement on Form S-3 (file number 333-74464).

(m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2002, filed August 13, 2002.

(n) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2002, filed March 31, 2003.

(o) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended March 31, 2003, filed May 15, 2003.

(p) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2003, filed November 11, 2003.

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* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

(B) Reports on Form 8-K

Form 8-K, filed February 24, 2004: On February 23, 2004, we issued a press release announcing our fourth quarter and full year 2003 financial and operating results.

Form 8-K, filed March 1, 2004: On February 27, 2004, we issued a press release announcing our plans to initiate a Phase IIb study of the IL-1 Trap in the second half of 2004 and that Novartis Pharma AG notified the Company of its intention not to proceed with the joint development of the IL-1 Trap.

SIGNATURE

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

REGENERON PHARMACEUTICALS, INC.

By: /s/ LEONARD S. SCHLEIFER

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Dated: New York, New York
December 14, 2004

Signature	Title
/s/ LEONARD S. SCHLEIFER, Leonard S. Schleifer, M.D., Ph.D.	President, Chief Executive Officer, and Director (Principal Executive Officer)
* Murray A. Goldberg	Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer)
* Douglas S. McCorkle	Controller and Assistant Treasurer (Principal Accounting Officer)
* George D. Yancopoulos, M.D., Ph.D.	Executive Vice President, Chief Scientific Officer, President, Regeneron Research Laboratories, and Director
* P. Roy Vagelos, M.D.	Chairman of the Board
* Charles A. Baker	Director
* Michael S. Brown, M.D.	Director
* Alfred G. Gilman, M.D., Ph.D.	Director
* Joseph L. Goldstein, M.D.	Director
* Arthur F. Ryan	Director
* Eric M. Shooter, Ph.D.	Director
* George L. Sing	Director

By: /s/ LEONARD S. SCHLEIFER, M.D., PH.D.

Leonard S. Schleifer, M.D., Ph.D.
Attorney-In-Fact

REGENERON PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Regeneron Pharmaceuticals, Inc.:

In our opinion, based upon our audits and the report of other auditors, the accompanying balance sheets and the related statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Regeneron Pharmaceuticals, Inc. (the "Company") at December 31, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America. 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 did not audit the financial statements of Amgen-Regeneron Partners (the "Partnership"), an entity which is fifty percent owned by the Company, for the year ended December 31, 2001. The Company's investment in the Partnership is accounted for in accordance with the equity method of accounting. For the year ended December 31, 2001, the Company recorded its pro rata share of the Partnership's net loss of approximately $1.0 million. The Partnership's financial statements were audited by other auditors whose report thereon has been furnished to us, and our opinion expressed herein, insofar as it relates to the amounts included for the Partnership, is based solely on the report of the other auditors. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits and the report of other auditors provide a reasonable basis for the opinion expressed above.

As discussed in Note 2 to the financial statements, during the year ended December 31, 2003, the Company changed its method of accounting for revenue recognition.

PricewaterhouseCoopers LLP

New York, New York

January 30, 2004, except for the last paragraph of Note 11b
as to which the date is February 27, 2004.

REGENERON PHARMACEUTICALS, INC.

BALANCE SHEETS

December 31, 2003 and 2002

	2003	2002
	(In thousands, except share data)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 118,285	$ 80,077
Marketable securities	164,576	173,282
Restricted marketable securities	10,913	10,912
Accounts receivable	15,529	4,017
Prepaid expenses and other current assets	1,898	1,829
Inventory	9,006	6,831
Total current assets	320,207	276,948
Marketable securities	72,792	20,402
Restricted marketable securities		10,573
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	80,723	76,825
Other assets	5,833	6,826
Total assets	$ 479,555	$ 391,574
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 18,933	$ 30,309
Deferred revenue, current portion	40,173	9,659
Loan payable to Novartis Pharma AG	13,817	
Capital lease obligations, current portion		150
Total current liabilities	72,923	40,118
Deferred revenue	68,830	5,475
Notes payable	200,000	200,000
Other long-term liabilities	159	
Total liabilities	341,912	245,593
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding — none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; 2,365,873 shares issued and outstanding in 2003 2,491,181 shares issued and outstanding in 2002	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; 53,165,635 shares issued and outstanding in 2003 41,746,133 shares issued and outstanding in 2002	53	42
Additional paid-in capital	673,118	573,184
Unearned compensation	(4,101)	(3,643)
Accumulated deficit	(531,533)	(424,075)
Accumulated other comprehensive income	104	471
Total stockholders' equity	137,643	145,981
Total liabilities and stockholders' equity	$ 479,555	$ 391,574

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

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2003, 2002, and 2001

	2003	2002	2001
	(In thousands, except per share data)		
Revenues			
Contract research and development	$ 47,366	$ 10,924	$ 12,071
Contract manufacturing	10,131	11,064	9,902
	57,497	21,988	21,973
Expenses			
Research and development	136,024	124,953	92,542
Contract manufacturing	6,676	6,483	6,509
General and administrative	14,785	12,532	9,607
	157,485	143,968	108,658
Loss from operations	(99,988)	(121,980)	(86,685)
Other income (expense)			
Investment income	4,462	9,462	13,162
Interest expense	(11,932)	(11,859)	(2,657)
	(7,470)	(2,397)	10,505
Net loss	$(107,458)	$(124,377)	$ (76,180)
Net loss per share, basic and diluted	$ (2.13)	$ (2.83)	$ (1.81)

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

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY

For the Years Ended December 31, 2003, 2002, and 2001

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income(Loss)	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount						
						(In thousands, except per share data)				
Balance, December 31, 2000	2,613	$ 3	34,197	$ 34	$406,391	$(1,314)	$(223,518)	$ 534	$ 182,130	
Issuance of Common Stock in a public offering at $25.00 per share			6,630	7	165,743				165,750	
Cost associated with issuance of equity securities					(9,096)				(9,096)	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			254		1,868				1,868	
Issuance of Common Stock to Medtronic, Inc. in connection with a cashless exercise of warrants			37							
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			17		477				477	
Conversion of Class A Stock to Common Stock	(50)		50							
Issuance of restricted Common Stock under Long-Term Incentive Plan, net of forfeitures			79		2,207	(2,207)				
Amortization of unearned compensation						732			732	
Issuance of stock options in consideration for consulting services					34				34	
Net loss, 2001							(76,180)		(76,180)	$ (76,180)
Change in net unrealized gain/loss on marketable securities								640	640	640
Balance, December 31, 2001	2,563	3	41,264	41	567,624	(2,789)	(299,698)	1,174	266,355	$ (75,540)
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			251		2,149				2,149	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			22		764				764	
Conversion of Class A Stock to Common Stock	(72)	(1)	72	1						
Issuance of restricted Common Stock under Long-Term Incentive Plan, net of forfeitures			137		2,644	(2,644)				
Amortization of unearned compensation						1,790			1,790	
Issuance of stock options in consideration for consulting services					3				3	
Net loss, 2002							(124,377)		(124,377)	$(124,377)
Change in net unrealized gain/loss on marketable securities								(703)	(703)	(703)
Balance, December 31, 2002	2,491	2	41,746	42	573,184	(3,643)	(424,075)	471	145,981	$(125,080)

(Continued)

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY — (Continued)

For the Years Ended December 31, 2003, 2002, and 2001

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount						
					(In thousands, except per share data)					
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			601		1,941				1,941	
Issuance of Common Stock to Novartis Pharma AG			7,527	8	47,992				48,000	
Issuance of Common Stock to Aventis Pharmaceuticals Inc.			2,800	3	44,997				45,000	
Issuance of Common Stock to Merck & Co. Inc.			109		1,500				1,500	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			43		747				747	
Conversion of Class A Stock to Common Stock	(125)		125							
Issuance of restricted Common Stock under Long-Term Incentive Plan, net of forfeitures			215		2,757	(2,757)				
Amortization of unearned compensation						2,299			2,299	
Net loss, 2003							(107,458)		(107,458)	$(107,458)
Change in net unrealized gain/loss on marketable securities								(367)	(367)	(367)
Balance, December 31, 2003	2,366	$ 2	53,166	$ 53	$673,118	$(4,101)	$(531,533)	$ 104	$ 137,643	$(107,825)

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

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2003, 2002, and 2001

	2003	2002	2001
		(In thousands)	
Cash flows from operating activities			
Net loss	$(107,458)	$(124,377)	$ (76,180)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	12,937	8,454	6,077
Non-cash compensation expense	2,562	1,793	766
Non-cash expense related to a license agreement	1,500		
Changes in assets and liabilities			
(Increase) decrease in accounts receivable	(11,512)	(1,042)	10,860
Decrease (increase) in prepaid expenses and other assets	589	184	(2,108)
Increase in inventory	(1,049)	(1,732)	(941)
Increase (decrease) in deferred revenue	93,869	1,498	(87)
Increase in accounts payable, accrued expenses, and other liabilities	2,429	4,699	4,293
Total adjustments	101,325	13,854	18,860
Net cash used in operating activities	(6,133)	(110,523)	(57,320)
Cash flows from investing activities			
Purchases of marketable securities	(276,447)	(234,463)	(159,731)
Purchases of restricted marketable securities	(11,055)	(5,514)	(31,620)
Sales or maturities of marketable securities	231,261	199,317	124,189
Maturities of restricted marketable securities	22,054	16,514	
Capital expenditures	(29,656)	(34,370)	(8,223)
Net cash used in investing activities	(63,843)	(58,516)	(75,385)
Cash flows from financing activities			
Net proceeds from the issuance of stock	94,678	2,149	158,522
Net proceeds from the issuance of convertible notes			192,703
Principal payments on note payable			(1,533)
Borrowings under loan payable	13,656		
Capital lease payments	(150)	(426)	(572)
Net cash provided by financing activities	108,184	1,723	349,120
Net increase (decrease) in cash and cash equivalents	38,208	(167,316)	216,415
Cash and cash equivalents at beginning of period	80,077	247,393	30,978
Cash and cash equivalents at end of period	$ 118,285	$ 80,077	$ 247,393
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 11,003	$ 11,038	$ 161

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

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS

For the Years Ended December 31, 2003, 2002, and 2001
(Unless otherwise noted, dollars in thousands, except per share data)

1. Organization and Business

Regeneron Pharmaceuticals, Inc. (the "Company" or "Regeneron") was incorporated in January 1988 in the State of New York. The Company is engaged in research and development programs to discover and commercialize therapeutics to treat human disorders and conditions. The Company's facilities are located in New York. The Company's business is subject to certain risks including, but not limited to, uncertainties relating to conducting pharmaceutical research, obtaining regulatory approvals, commercializing products, and obtaining and enforcing patents.

2. Summary of Significant Accounting Policies

Property, Plant, and Equipment

Property, plant, and equipment are stated at cost. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	6-30 years
Leasehold improvements	Life of lease
Laboratory and computer equipment	3-5 years
Furniture and fixtures	5 years

Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset. The Company capitalized interest costs of $0.6 million and $0.2 million in 2003 and 2002, respectively.

The Company periodically assesses the recoverability of property and equipment and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Asset impairment is determined to exist if estimated future undiscounted cash flows are less than the carrying amount in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. As of December 31, 2003, there were no impairments of long-lived assets.

Cash and Cash Equivalents

For purposes of the statement of cash flows and the balance sheet, the Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined based on standards that approximate the first-in, first-out method. Inventories are shown net of applicable reserves.

Revenue Recognition and Change in Accounting Principle

a. Contract Research and Development and Research Progress Payments

The Company recognizes revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* ("SAB 104") and

FASB Emerging Issue Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). SAB 104 superseded Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statement* ("SAB 101"), in December 2003. During the third quarter of 2003, the Company elected to change the method it uses to recognize revenue under SAB 101 related to non-refundable collaborator payments, including up-front licensing payments, payments for development activities, and research progress (milestone) payments, to the Substantive Milestone Method, adopted retroactively to January 1, 2003. There is no cumulative effect of this change in accounting principle on prior periods. Under this method, the Company recognizes revenue from non-refundable up-front license payments, not tied to achieving a specific performance milestone, ratably over the period over which the Company is obligated to perform services. Payments for development activities are recognized as revenue as earned, ratably over the period of effort. Substantive at-risk milestone payments, which are based on achieving a specific performance milestone, are recognized as revenue when the milestone is achieved and the related payment is due, provided there is no future service obligation associated with that milestone. The change in accounting method was made because the Company believes that it better reflects the substance of the Company's collaborative agreements and is more consistent with current practices in the biotechnology industry.

Previously, the Company had recognized revenue from non-refundable collaborator payments based on the percentage of costs incurred to date, estimated costs to complete, and total expected contract revenue. However, the revenue recognized was limited to the amount of non-refundable payments received. This accounting method was adopted on January 1, 2000 upon the release of SAB 101. Prior to January 1, 2000, revenue from certain non-refundable collaborator payments was recognized when there were no additional contractual services to be provided or costs to be incurred by the Company in connection with the non-refundable payment. The cumulative effect of adopting SAB 101 at January 1, 2000 amounted to $1.6 million of additional loss, with a corresponding increase to deferred revenue that is being recognized in subsequent periods, of which $0.4 million was included in contract research and development revenue in each of 2003, 2002, and 2001. The $1.6 million represents a portion of a 1989 payment received from Sumitomo Chemical Co. Ltd. in consideration for a fifteen year limited right of first negotiation to license up to three of the Company's product candidates in Japan (see Note 11d). The effect of income taxes on the cumulative effect adjustment was immaterial.

b. Contract Manufacturing

The Company has entered into contract manufacturing agreements under which it manufactures products and performs services for third parties. Contract manufacturing revenue is recognized as products are shipped and as services are performed (see Notes 11d and 12).

Investment Income

Interest income, which is included in investment income, is recognized as earned.

Accounting for the Impairment of Long-Lived Assets

Long-lived assets, such as fixed assets, are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Estimated undiscounted expected future cash flows are used to determine if an asset is impaired in which case the asset's carrying value would be reduced to fair value. For all periods presented, no impairment losses were recorded.

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Patents

As a result of the Company's research and development efforts, it has obtained, applied, or is applying for a number of patents to protect proprietary technology and inventions. All costs associated with patents are expensed as incurred.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research collaboration and licensing agreements (see Note 10f), the cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, expenses related to the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. All costs associated with research and development are expensed as incurred.

For each clinical trial that the Company conducts, certain clinical trial costs, which are included in research and development expenses, are expensed based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services. During the course of a clinical trial, the Company adjusts its rate of clinical expense recognition if actual results differ from the Company's estimates.

Net Loss Per Share

Net loss per share, basic and diluted, is computed on the basis of the net loss for the period divided by the weighted average number of shares of Common Stock and Class A Stock outstanding during the period. The basic net loss per share excludes restricted stock awards until vested. The diluted net loss per share for all periods presented excludes unvested restricted stock awards and the number of shares issuable upon conversion of outstanding convertible debt and exercise of outstanding stock options and warrants, since such inclusion would be antidilutive. Disclosures required by Statement of Financial Accounting Standards No. 128, *Earnings per Share*, have been included in Note 18.

Income Taxes

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which realization is uncertain. See Note 16.

Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. Comprehensive losses for the years ended December 31, 2003, 2002, and 2001 have been included in the Statements of Stockholders' Equity.

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities, restricted marketable securities, and receivables from Aventis Pharmaceuticals Inc., Novartis Pharma AG, The Procter & Gamble Company, and Merck & Co., Inc. The Company generally invests its excess cash in obligations of the U.S. government and its agencies, bank deposits, investment grade debt securities issued by corporations, governments, and financial institutions, and money market funds that invest in these instruments. The Company has established guidelines that relate to credit quality, diversification, and maturity, and that limit exposure to any one issue of securities.

Risks and Uncertainties

Regeneron has had no sales of its products and there is no assurance that the Company's research and development efforts will be successful, that the Company will ever have commercially approved products, or that the Company will achieve significant sales of any such products. The Company has incurred net losses and negative cash flows from operations since its inception, and revenues to date have principally been limited to payments for research from six collaborators and for contract manufacturing from two pharmaceutical companies and investment income (see Notes 11 and 12). The Company operates in an environment of rapid change in technology and is dependent upon the services of its employees, consultants, collaborators, and certain third-party suppliers of materials. Regeneron, as licensee, licenses certain technologies that are important to the Company's business which impose various obligations on the Company. If Regeneron fails to comply with these requirements, licensors may have the right to terminate the Company's licenses.

Contract research and development revenue in 2003 was primarily earned from Aventis Pharmaceuticals Inc., Novartis Pharma AG, and The Procter & Gamble Company under collaboration agreements (see Notes 11a, 11b and 11e). Under the collaboration agreement with Aventis, agreed upon VEGF Trap development expenses incurred by Regeneron during the term of the agreement will be funded by Aventis. In addition, the Company may receive a $25.0 million payment upon achievement of an early-stage clinical milestone and up to $360.0 million in additional milestone payments upon receipt of specified VEGF Trap marketing approvals. Aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Under the collaboration agreement with Novartis, agreed upon IL-1 Trap development expenses will either be shared with or fully funded by Novartis, depending on the phase of clinical development. The agreement with Novartis contains provisions for termination, including termination by Novartis without cause with at least nine months advance notice. Under the long-term collaboration with Procter & Gamble, Procter & Gamble is obligated to provide payments to fund Regeneron research of $2.5 million per quarter, before adjustments for inflation, through December 2005, with no further research obligations by either party thereafter. Contract manufacturing revenue in 2003 was earned from Merck & Co., Inc. under a long-term manufacturing agreement that extends until November 2005 (see Note 12), but may be terminated at any time by Merck with at least one year's notice without penalty and may be extended by mutual agreement.

The Company has entered into a license and supply agreement with Nektar Therapeutics under which Nektar is the only supplier of a pegylated reagent used to formulate pegylated AXOKINE, one of our product candidates.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Significant estimates include useful lives of property, plant, and equipment and the periods over which certain revenues and

(Unless otherwise noted, dollars in thousands, except per share data)

expenses will be recognized, including contract research and development revenue recognized from non-refundable up-front licensing payments, contract manufacturing revenue recognized from reimbursed deferred capital costs, and expense recognition of certain clinical trial costs which are included in research and development expenses.

Stock-based Employee Compensation

The accompanying financial position and results of operations of the Company have been prepared in accordance with APB Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"). Under APB No. 25, generally, no compensation expense is recognized in the accompanying financial statements in connection with the awarding of stock option grants to employees provided that, as of the grant date, all terms associated with the award are fixed and the quoted market price of the Company's stock, as of the grant date, is equal to or less than the amount an employee must pay to acquire the stock as defined.

The Company has stock-based incentive plans, which are more fully described in Note 14a. The following table illustrates the effect on the Company's net loss and net loss per share had compensation costs for the incentive plans been determined in accordance with the fair value based method of accounting for stock-based compensation as prescribed by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* ("SFAS No. 123"). Since option grants awarded during 2003, 2002, and 2001 vest over several years and additional awards are expected to be issued in the future, the pro forma results shown below are not likely to be representative of the effects on future years of the application of the fair value based method.

	2003	2002	2001
Net loss, as reported	$(107,458)	$(124,377)	$ (76,180)
Add: Stock-based employee compensation expense included in reported net loss	2,562	1,790	732
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(45,042)	(45,676)	(32,890)
Pro forma net loss	$(149,938)	$(168,263)	$(108,338)
Net loss per share, basic and diluted:			
As reported	$ (2.13)	$ (2.83)	$ (1.81)
Pro forma	$ (2.97)	$ (3.83)	$ (2.57)

In 2003, the Company's Chief Executive Officer was granted permission by the Board of Directors to initiate a one-time net cashless exercise of stock options. Upon completion of the net cashless exercise, the Company recognized $0.3 million of compensation expense, which equaled the excess of the fair market value of the shares over the option exercise price on the date that the Board of Directors granted its consent for the transaction.

Other disclosures required by SFAS No. 123 have been included in Note 14a.

Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

In 2003, 2002, and 2001, the Company awarded 219,367, 139,611, and 80,535 shares, respectively, of Restricted Stock under the Regeneron Pharmaceuticals, Inc. Long-Term Incentive Plan (see Note 14a). The Company records unearned compensation in Stockholders' Equity related to these awards based on the fair

market value of shares of the Company's Common Stock on the grant date of the Restricted Stock award, which is expensed, on a pro rata basis, over the approximately two year period that the restrictions on these shares lapse. In 2003, 2002 and 2001, the Company recognized $2.3 million, $1.8 million and $0.7 million, respectively, of compensation expense related to Restricted Stock awards.

Included in accounts payable and accrued expenses at December 31, 2003, 2002, and 2001 were $0.8 million, $13.5 million, and $1.9 million of capital expenditures, respectively.

Included in accounts payable and accrued expenses at December 31, 2002, 2001, and 2000 were $0.7 million, $0.8 million, and $0.5 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2003, 2002, and 2001, the Company contributed 42,543, 21,953, and 17,484 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at December 31, 2003, 2002, and 2001 were $0.9 million, $2.0 million, and $2.0 million of accrued interest income, respectively.

Reclassifications

Certain reclassifications have been made to the financial statements for 2002 and 2001 to conform with the current year's presentation.

Future Impact of Recently Issued Accounting Standards

In December 2003, the Staff of the Securities and Exchange Commission issued SAB 104, *Revenue Recognition*, which supercedes SAB 101, *Revenue Recognition in Financial Statements*. SAB 104's primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, superceded as a result of the issuance of EITF 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Additionally, SAB 104 rescinds the SEC's *Revenue Recognition in Financial Statements Frequently Asked Questions and Answers* (the "FAQ") issued with SAB 101 that had been codified in SEC Topic 13, *Revenue Recognition*. Selected portions of the FAQ have been incorporated into SAB 104. While the wording of SAB 104 has changed to reflect the issuance of EITF 00-21, the revenue recognition principles of SAB 101 remain largely unchanged by the issuance of SAB 104. Adoption of SAB 104 was required immediately and did not have a material effect on the Company's financial statements.

In December 2003, the FASB issued a revision to Interpretation No. 46, *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51* ("FIN 46R"), which was issued in January 2003. FIN 46R clarifies the application of ARB No. 51, *Consolidated Financial Statements* to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support. FIN 46R requires the consolidation of these entities, known as variable interest entities ("VIEs"), by the primary beneficiary of the entity. The primary beneficiary is the entity, if any, that will absorb a majority of the entity's expected losses, receive a majority of the entity's expected residual returns, or both. Among other changes, the revisions of FIN 46R (a) clarified some requirements of the original FIN 46, which had been issued in January 2003, (b) eased some implementation problems, and (c) added new scope exceptions. FIN 46R deferred the effective date of the Interpretation for public companies to the end of the first reporting period ending after March 15, 2004, except that all public companies must at a minimum apply the provisions of the Interpretation to entities that were previously considered "special-purpose entities" under the FASB literature prior to the issuance of FIN 46R by the end of the first reporting period ending after December 15, 2003. Adoption of FIN 46R did not have a material impact on the Company's financial statements.

In May 2003, the Financial Accounting Standards Board issued Statement No. 150 ("SFAS No. 150"), *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS

No. 150 specifies that instruments within its scope embody obligations of the issuer and that the issuer must classify them as liabilities. SFAS No. 150 requires issuers to classify as liabilities the following three types of freestanding financial instruments: (1) mandatorily redeemable financial instruments, (2) obligations to repurchase the issuer's equity shares by transferring assets, and (3) certain obligations to issue a variable number of shares. SFAS No. 150 defines a "freestanding financial instrument" as a financial instrument that (1) is entered into separately and apart from any of the entity's other financial instruments or equity transactions or (2) is entered into in conjunction with some other transaction and can be legally detached and exercised on a separate basis. For all financial instruments entered into or modified after May 31, 2003, SFAS No. 150 is effective immediately. For all other instruments of public companies, SFAS No. 150 went into effect at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on the Company's financial statements. In November 2003, the Financial Accounting Standards Board deferred the effective date for selected provisions of SFAS No. 150, limited to mandatorily redeemable noncontrolling interests associated with finite-lived subsidiaries. The deferral of those selected provisions is not expected to have a material impact on the Company's financial statements.

In November 2002, the FASB issued Interpretation No. 45 ("FIN 45"), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others, an interpretation of FASB Statements No. 5, 57 and 107 and a rescission of FASB Interpretation No. 34.* FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees issued. FIN 45 also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of FIN 45 are applicable to guarantees issued or modified after December 31, 2002 and did not have a material impact on the Company's financial statements.

3. Marketable Securities

The Company considers its unrestricted marketable securities to be "available-for-sale," as defined by Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Gross unrealized holding gains and losses are reported as a net amount in a separate component of stockholders' equity entitled Accumulated Other Comprehensive Income (Loss). The net change in unrealized holding gains and losses is excluded from operations and included in stockholders' equity as a separate component of comprehensive loss.

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

The following tables summarize the amortized cost basis of marketable securities, the aggregate fair value of marketable securities, and gross unrealized holding gains and losses at December 31, 2003 and 2002:

	Amortized Cost Basis	Fair Value	Unrealized Holding		
			Gains	(Losses)	Net
At December 31, 2003					
Maturities within one year					
Corporate debt securities	$ 40,586	$ 40,578	$ 6	$(14)	$ (8)
U.S. government securities	123,893	123,998	107	(2)	105
	164,479	164,576	113	(16)	97
Maturities between one and two years					
Corporate debt securities	28,928	28,931	18	(15)	3
U.S. government securities	40,749	40,803	54		54
Asset-backed securities	3,108	3,058		(50)	(50)
	72,785	72,792	72	(65)	7
	$237,264	$237,368	$185	$(81)	$104
At December 31, 2002					
Maturities within one year					
Corporate debt securities	$ 69,531	$ 69,580	$ 99	$(50)	$ 49
U.S. government securities	98,057	98,410	353		353
Asset-backed securities	3,059	3,067	8		8
Foreign government securities	2,225	2,225			
	172,872	173,282	460	(50)	410
Maturities between one and two years					
Corporate debt securities	6,015	6,007		(8)	(8)
U.S. government securities	2,047	2,131	84		84
Asset-backed securities	12,279	12,264	15	(30)	(15)
	20,341	20,402	99	(38)	61
	$193,213	$193,684	$559	$(88)	$471

Realized gains and losses are included as a component of investment income. For the years ended December 31, 2003, 2002, and 2001, gross realized gains and losses were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the securities, adjusted for the amortization of any discount or premium. The fair value of marketable securities has been estimated based on quoted market prices. Unrealized holding losses at December 31, 2003 have been losses for less than one year.

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

4. Accounts Receivable

Accounts receivable as of December 31, 2003 and 2002 consist of the following:

	2003	2002
Receivable from Aventis Pharmaceuticals Inc. (see Note 11a)	$ 8,917	
Receivable from Novartis Pharma AG (see Note 11b)	3,177	
Receivable from The Procter & Gamble Company (see Note 11e)	2,670	$2,610
Receivable from Merck & Co. Inc. (see Note 12)	765	1,404
Receivable from Amgen-Regeneron Partners (see Note 11c)		3
	$15,529	$4,017

5. Inventories

Inventory balances at December 31, 2003 and 2002 consist of raw materials, work-in process, and finished products associated with the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement (see Note 12).

Inventories as of December 31, 2003 and 2002 consist of the following:

	2003	2002
Raw materials	$ 388	$ 357
Work-in process	—(1)	261(2)
Finished products	8,618	6,213(3)
	$9,006	$6,831

(1) Net of reserves of $0.2 million.

(2) Net of reserves of $30 thousand.

(3) Net of reserves of $1.2 million.

6. Property, Plant, and Equipment

Property, plant, and equipment as of December 31, 2003 and 2002 consist of the following:

	2003	2002
Land	$ 475	$ 475
Building and improvements	56,054	32,547
Leasehold improvements	29,108	14,224
Construction-in-progress	1,443	38,645
Laboratory and other equipment	51,536	36,762
Furniture, fixtures, and computer equipment	5,092	4,540
	143,708	127,193
Less, accumulated depreciation and amortization	(62,985)	(50,368)
	$ 80,723	$ 76,825

Depreciation and amortization expense on property, plant, and equipment amounted to $13.0 million, $8.5 million, and $7.0 million, for the years ended December 31, 2003, 2002, and 2001, respectively. Included

(Unless otherwise noted, dollars in thousands, except per share data)

in these amounts was $1.1 million of depreciation and amortization expense related to contract manufacturing that was capitalized into inventory for each of the three years ended December 31, 2003, 2002, and 2001.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2003 and 2002 consist of the following:

	2003	2002
Accounts payable	$ 3,878	$13,297
Accrued payroll and related costs	5,125	4,162
Accrued clinical trial expense	3,876	4,515
Accrued capital expenditures	211	4,322
Accrued expenses, other	3,551	1,721
Interest payable on convertible notes	2,292	2,292
	$18,933	$30,309

8. Deferred Revenue

Deferred revenue as of December 31, 2003 and 2002 consists of the following:

	2003	2002
Current portion:		
Received from Aventis Pharmaceuticals Inc.	$10,909	
Received from Novartis Pharma AG	22,100	
Received from Merck & Co., Inc.	6,262	$7,788
Other	902	1,871
	$40,173	$9,659
Long-term portion:		
Received from Aventis Pharmaceuticals Inc.	$65,455	
Received from Merck & Co., Inc.	3,375	$5,398
Other		77
	$68,830	$5,475

9. Stockholders' Equity

The Company's Amended Certificate of Incorporation provides for the issuance of up to 40 million shares of Class A Stock, par value $0.001 per share, and 160 million shares of Common Stock, par value $0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that Class A Stockholders are entitled to ten votes per share, while Common Stockholders are entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. The Company's Board of Directors (the "Board") is authorized to issue up to 30 million shares of preferred stock, in series, with rights, privileges, and qualifications of each series determined by the Board.

During 1996, the Company adopted a Shareholder Rights Plan in which Rights were distributed as a dividend at the rate of one Right for each share of Common Stock and Class A Stock (collectively, "Stock")

held by shareholders of record as of the close of business on October 18, 1996. Each Right initially entitles the registered holder to buy a unit ("Unit") consisting of one-one thousandth of a share of Series A Junior Participating Preferred Stock ("A Preferred Stock") at a purchase price of $120 per Unit (the "Purchase Price"). Initially the Rights were attached to all Stock certificates representing shares then outstanding, and no separate Rights certificates were distributed. The Rights will separate from the Stock and a "distribution date" will occur upon the earlier of (i) ten days after a public announcement that a person or group of affiliated or associated persons, excluding certain defined persons, (an "Acquiring Person") has acquired, or has obtained the right to acquire, beneficial ownership of 20% or more of the outstanding shares of Stock or (ii) ten business days following the commencement of a tender offer or exchange offer that would result in a person or group beneficially owning 20% or more of such outstanding shares of Stock. The Rights are not exercisable unless a distribution date occurs and will expire at the close of business on October 18, 2006 unless earlier redeemed by the Company, subject to certain defined restrictions, for $.01 per Right. In the event that an Acquiring Person becomes the beneficial owner of 20% or more of the then outstanding shares of Stock (unless such acquisition is made pursuant to a tender or exchange offer for all outstanding shares of the Company, at a price determined by a majority of the independent directors of the Company who are not representatives, nominees, affiliates, or associates of an Acquiring Person to be fair and otherwise in the best interest of the Company and its shareholders after receiving advice from one or more investment banking firms), each Right will entitle the holder to purchase, at the Right's then current exercise price, common shares (or, in certain circumstances, cash, property or other securities of the Company) having a value twice the Right's Exercise Price. The Right's Exercise Price is the Purchase Price times the number of shares of Common Stock associated with each Right (initially, one). Upon the occurrence of any such events, the Rights held by an Acquiring Person become null and void. In certain circumstances, a Right entitles the holder to receive, upon exercise, shares of common stock of an acquiring company having a value equal to two times the Right's Exercise Price.

As a result of the Shareholder Rights Plan, the Company's Board designated 100,000 shares of preferred stock as A Preferred Stock. The A Preferred Stock has certain preferences, as defined.

In April 2000, the Company completed a public offering of 2.6 million shares of Common Stock at a price of $29.75 per share for net proceeds, after commissions and expenses, of $72.9 million. In March and April 2001, the Company completed a public offering in which it issued 6.63 million shares of Common Stock at a price of $25.00 per share and received proceeds, after commissions and expenses, of $156.7 million.

In March 2001, Medtronic, Inc. exercised 107,400 warrants with an exercise price of $21.72 per share on a "cashless" basis and received 37,306 shares of the Company's Common Stock.

In October 2001, the Company completed a private placement of $200.0 million aggregate principal amount of senior subordinated notes, which are convertible into shares of the Company's Common Stock. See Note 10e.

In March 2003, Novartis Pharma AG purchased $48.0 million of newly issued unregistered shares of the Company's Common Stock. Regeneron issued 2,400,000 shares of Common Stock to Novartis in March 2003 and an additional 5,127,050 shares in May 2003 for a total of 7,527,050 shares based upon the average closing price of the Common Stock for the 20 consecutive trading days ending May 12, 2003. See Note 11b.

In August 2003, Regeneron issued to Merck & Co., Inc., 109,450 newly issued unregistered shares of the Company's Common Stock as consideration for a non-exclusive license agreement granted by Merck to the Company. See Note 10f.

In September 2003, Aventis Pharmaceuticals Inc. purchased 2,799,552 newly issued unregistered shares of the Company's Common Stock for $45.0 million, based upon the average closing price of the Common Stock for the five consecutive trading days ending September 4, 2003. See Note 11a.

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

10. Commitments and Contingencies

a. Operating Leases

The Company leases and subleases laboratory, manufacturing, and office facilities in Tarrytown, New York under operating lease agreements which, as of December 31, 2003, expired through December 2006. In January 2004, the Company extended these leases, which, as amended, expire through December 2009 and contain renewal options for lease extensions on certain facilities through December 2014. The Company also leases manufacturing, office, and warehouse facilities in Rensselaer, New York under an operating lease agreement which expires in July 2007 and contains renewal options to extend the lease for two additional five-year terms and a purchase option. The leases provide for base rent plus additional rental charges for utilities, taxes, and operating expenses, as defined.

The Company leases certain laboratory and office equipment under operating leases which expire at various times through 2007.

At December 31, 2003, the future minimum noncancelable lease commitments under operating leases were as follows:

December 31,	Facilities	Equipment	Total
2004	$5,327	$190	$5,517
2005	1,810	119	1,929
2006	1,495	33	1,528
2007	159	2	161
	$8,791	$344	$9,135

Rent expense under operating leases was:

Year Ending December 31,	Facilities	Equipment	Total
2003	$5,394	$305	$5,699
2002	4,556	257	4,813
2001	3,455	249	3,704

In addition to its rent expense for various facilities, the Company paid additional rental charges for utilities, real estate taxes, and operating expenses of $6.0 million, $3.6 million, and $3.0 million for the years ended December 31, 2003, 2002, and 2001, respectively.

b. Capital Leases

In 2003 and prior years, the Company had leased equipment under noncancelable capital leases. Lease terms were generally four years after which, for certain leases, the Company purchased the equipment at amounts defined by the agreements. As of December 31, 2003, the Company had no remaining capital leases outstanding.

At December 31, 2002, leased equipment and building improvements included in property, plant, and equipment was $1.1 million; related accumulated depreciation was $0.9 million.

c. Note Payable

In 1994, the Company borrowed $2.0 million from the New York State Urban Development Corporation. The terms of the note provided for monthly payments of principal and interest through December 2014. In October 2001, the remaining principal balance on this note of $1.5 million was paid in full.

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

d. Loan Payable

In March 2003, the Company entered into a collaboration agreement with Novartis Pharma AG ("Novartis"). In accordance with that agreement, Regeneron funded its share of 2003 development expenses through a loan from Novartis, which bears interest at a rate per annum equal to the LIBOR rate plus 2.5%, compounded quarterly (3.65% at December 31, 2003). The loan and accrued interest thereon will be forgiven should certain defined pre-clinical and clinical milestones be reached; otherwise, such amounts are payable on July 1, 2004. As of December 31, 2003, the loan due Novartis, including accrued interest, totaled $13.8 million. See Note 11b.

e. Convertible Debt

In October 2001, the Company issued $200.0 million aggregate principal amount of convertible senior subordinated notes ("Notes") in a private placement for proceeds to the Company of $192.7 million, after deducting the initial purchasers' discount and out-of-pocket expenses (collectively, "Deferred Financing Costs"). The Notes bear interest at 5.5% per annum, payable semi-annually, and mature on October 17, 2008. Deferred Financing Costs, which are included in other assets, are amortized as interest expense over the period from the Notes' issuance to stated maturity. The Notes are convertible, at the option of the holder at any time, into shares of the Company's Common Stock at a conversion price of approximately $30.25 per share, subject to adjustment in certain circumstances. Regeneron may redeem the Notes, in whole or in part, at any time before October 17, 2004 if the closing price of the Company's Common Stock has exceeded 150% of the conversion price then in effect for a specified period of time ("Early Redemption"). Upon any such Early Redemption, the Company is required to pay interest that would have been due up through October 17, 2004. Regeneron may also redeem some or all of the Notes at any time on or after October 17, 2004 if the closing price of the Company's Common Stock has exceeded 140% of the conversion price then in effect for a specified period of time. The fair market value of the Notes fluctuates over time. The estimated fair value of the Notes at December 31, 2003 was approximately $190.3 million.

With respect to the Notes, the Company pledged as collateral $31.6 million of U.S. government securities ("Restricted Marketable Securities") with maturities at various dates through October 2004. At December 31, 2003, the balance of the Restricted Marketable Securities had an amortized cost basis of $10.9 million, due to scheduled interest payments made on the Notes in 2002 and 2003. Upon maturity, the proceeds of the Restricted Marketable Securities will be sufficient to pay the scheduled interest payments on the Notes when due in 2004. The Company considers its Restricted Marketable Securities to be "held-to-maturity," as defined by Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. These securities are reported at their amortized cost, which includes the direct costs to acquire the securities, plus the amortization of any discount or premium, and accrued interest earned on the securities.

(Unless otherwise noted, dollars in thousands, except per share data)

The following table summarizes the amortized cost basis and aggregate fair value of Restricted Marketable Securities, and gross unrealized holding gains and losses, at December 31, 2003 and 2002. Fair value has been estimated based on quoted market prices.

	Amortized Cost Basis	Fair Value	Unrealized Holding Gains
At December 31, 2003			
Maturities within one year			
U.S. government securities	$10,913	$10,989	$ 76
At December 31, 2002			
Maturities within one year			
U.S. government securities	$10,912	$10,963	$ 51
Maturities between one and two years			
U.S. government securities	10,573	10,803	230
	$21,485	$21,766	$281

f. Research Collaboration and Licensing Agreements

As part of the Company's research and development efforts, the Company enters into research collaboration and licensing agreements with related and unrelated companies, scientific collaborators, universities, and consultants. The Company also has research collaborations with Medarex, Inc. and Emisphere Technologies, Inc., and a license and supply agreement with Nektar Therapeutics. These agreements contain varying terms and provisions which include fees and milestones to be paid by the Company, services to be provided, and ownership rights to certain proprietary technology developed under the agreements. Some of the agreements contain provisions which require the Company to pay royalties, as defined, at rates that range from 0.25% to 12%, in the event the Company sells or licenses any proprietary products developed under the respective agreements.

Certain agreements, where the Company is required to pay fees, provide for the Company, upon 30 to 90-day written notice, to terminate such agreements. With respect to payments associated with these agreements, the Company incurred expenses of $2.7 million, $1.7 million, and $1.1 million for the years ended December 31, 2003, 2002, and 2001, respectively.

In August 2003, Merck & Co., Inc. ("Merck") granted the Company a non-exclusive license agreement to certain patents and patent applications which may be used in the development and commercialization of AXOKINE®. As consideration, the Company issued to Merck 109,450 newly issued unregistered shares of its Common Stock (the "Merck Shares"), valued at $1.5 million based on the fair market value of shares of the Company's Common Stock on the agreement's effective date. The agreement also requires the Company to make an additional payment to Merck upon receipt of marketing approval for a product covered by the licensed patents. In addition, the Company would be required to pay royalties, at staggered rates in the mid-single digits, based on the net sales of products covered by the licensed patents.

At any time prior to the date that Merck has the right to sell the Merck Shares under the Securities Act of 1933 (the "Sales Date"), Regeneron has the right to buy back the Merck Shares from Merck for a purchase price equal to the greater of (a) $1.5 million and (b) the lesser of (i) the fair market value of the shares and (ii) $1.65 million. Unless Regeneron has previously exercised its right to buy back the Merck Shares, on the Sales Date if the fair market value of the Merck Shares (the "Market Price") is less than

$1.5 million, Regeneron will be required to make a cash payment to Merck equal to the difference between the Market Price and $1.5 million. Conversely, if on the Sales Date the Market Price is greater than $1.65 million, Merck will be required, at its option, to either (i) make a cash payment to Regeneron equal to the difference between the Market Price and $1.65 million (the "Excess Amount") or (ii) return a number of the Merck Shares to Regeneron, calculated by dividing the Excess Amount by the fair market value of a share of the Company's Common Stock on the Sales Date. The fair market value of the shares based on the Company's closing Common Stock price at December 31, 2003, was $1.6 million.

11. Collaboration Agreements

a. Aventis Pharmaceuticals Inc.

In September 2003, the Company entered into a collaboration agreement (the "Aventis Agreement") with Aventis Pharmaceuticals Inc. ("Aventis") to jointly develop and commercialize the Company's Vascular Endothelial Growth Factor ("VEGF") Trap throughout the world with the exception of Japan, where product rights remain with Regeneron. In connection with this agreement, Aventis made a non-refundable up-front payment of $80.0 million and purchased 2,799,552 newly issued unregistered shares of the Company's Common Stock for $45.0 million, based upon the average closing price of the Common Stock for the five consecutive trading days ending September 4, 2003.

Under the Aventis Agreement, Regeneron and Aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap. Aventis has agreed to make a $25.0 million payment to the Company upon achievement of an early-stage clinical milestone. The Company may also receive up to $360.0 million in additional milestone payments upon receipt of specified marketing approvals for up to eight VEGF Trap indications in Europe or the United States.

Under the Aventis Agreement, agreed upon development expenses incurred by both companies during the term of the agreement will be funded by Aventis. If the collaboration becomes profitable, Regeneron will reimburse Aventis for 50 percent of the VEGF Trap development expenses, or $10.8 million as of December 31, 2003, in accordance with a formula based on the amount of development expenses and Regeneron's share of the collaboration profits, or at a faster rate at Regeneron's option. Regeneron has the option to conduct additional pre-Phase III studies at its own expense.

Aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, Regeneron's obligation with respect to reimbursing Aventis, from a portion of the Company's profits, for 50 percent of the VEGF Trap development expenses will also terminate and the Company will retain all rights to the VEGF Trap.

Revenue related to payments from Aventis is being recognized under the Substantive Milestone Method (see Note 2) in accordance with SAB 104. The up-front payment of $80.0 million and reimbursement of Regeneron-incurred development expenses are being recognized as contract research and development revenue. Milestone payments will be recognized as research progress payments. In 2003 the Company recognized $14.3 million of contract research and development revenue in connection with the Aventis Agreement. At December 31, 2003, amounts receivable from Aventis totaled $8.9 million and deferred revenue was $76.4 million.

b. Novartis Pharma AG

In March 2003, the Company entered into a collaboration agreement (the "Novartis Agreement") with Novartis Pharma AG ("Novartis") to jointly develop and commercialize the Company's Interleukin-1 Cytokine Trap ("IL-1 Trap"). In connection with this agreement, Novartis made a non-refundable up-front payment of $27.0 million and purchased $48.0 million of newly issued unregistered shares of the Company's

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)

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Common Stock. Regeneron issued 2,400,000 shares of Common Stock to Novartis in March 2003 and an additional 5,127,050 shares in May 2003 for a total of 7,527,050 shares based upon the average closing price of the Common Stock for the 20 consecutive trading days ending May 12, 2003.

Development expenses incurred during 2003 were shared equally by the Company and Novartis. Regeneron funded its share of 2003 development expenses through a loan (the "2003 Loan") from Novartis, which bears interest at a rate per annum equal to the LIBOR rate plus 2.5%, compounded quarterly (3.65% at December 31, 2003). The 2003 Loan and accrued interest thereon will be forgiven should certain defined pre-clinical and clinical milestones be reached; otherwise, such amounts are payable on July 1, 2004. As of December 31, 2003, the 2003 Loan balance due Novartis, including accrued interest, totaled $13.8 million.

Revenue related to payments from Novartis is being recognized as contract research and development revenue under the Substantive Milestone Method (see Note 2) in accordance with SAB 104. The up-front payment of $27.0 million and reimbursement of Novartis' share of Regeneron-incurred development expenses are being recognized as contract research and development revenue. Forgiveness of the 2003 Loan and accrued interest (if forgiven as described above) will be recognized as a research progress payment. In 2003 the Company recognized $21.4 million of contract research and development revenue in connection with the Novartis Agreement. At December 31, 2003, amounts receivable from Novartis totaled $3.2 million and deferred revenue was $22.1 million.

On February 27, 2004, the Company announced that Novartis had provided notice of its intention not to proceed with the joint development of the IL-1 Trap. Under the terms of the collaboration agreement, Novartis remains obligated to fund agreed upon pre-Phase III IL-1 Trap development expenses during the nine-month notice period before its voluntary termination becomes effective. Novartis and the Company retain rights under the collaboration agreement to elect to collaborate on the development and commercialization of other IL-1 Trap antagonists being developed independently by the other party that are in earlier stages of development than the IL-1 Trap.

c. Amgen Inc.

In August 1990, the Company entered into a collaboration agreement (the "Amgen Agreement") with Amgen Inc. ("Amgen") to develop and attempt to commercialize two proprietary products (BDNF and NT-3, individually the "Product," collectively the "Products"). The Amgen Agreement, among other things, provided for Amgen and the Company to form a partnership ("Amgen-Regeneron Partners" or the "Partnership") to complete the development and to commercialize the Products. Amgen and the Company hold equal ownership interests (subject to adjustment for any future inequities in capital contributions, as defined). The Partnership is the exclusive distributor of Products in the United States, and Amgen has received a license from the Company to market the Products outside the United States and outside Japan and certain Pacific Rim countries. The Company accounts for its investment in the Partnership in accordance with the equity method of accounting. In 2003, 2002, and 2001, the Company recognized its share of the Partnership net loss in the amounts of $63 thousand, $27 thousand, and $1.0 million, respectively, which represents 50% of the total Partnership net loss. In September 2002, the Company and Amgen each made capital withdrawals of $0.5 million from the Partnership. At December 31, 2003, the Company continues to be an equal partner in the Partnership.

In January 2001, Amgen-Regeneron Partners discontinued all clinical development of BDNF for the potential treatment of amyotrophic lateral sclerosis ("ALS") following notification that BDNF did not provide a therapeutic advantage to ALS patients in clinical trials. The Partnership has no ongoing development activities for NT-3 at this time.

Payments the Company receives from the Partnership in connection with services provided to the Partnership, are recognized as contract research and development revenue as earned. Such revenue for the

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years ended December 31, 2003, 2002, and 2001 totaled $2 thousand, $2 thousand and $1.2 million, respectively.

Selected financial data as of and for the years ended December 31, 2003 and 2002 are not significant. Selected financial data of the Partnership for the year ended December 31, 2001 are as follows.

Statement of Operations Data	2001
Interest income	$ 169
Total expenses(1)	(2,172)
Net loss	$(2,003)

(1) Includes $1.2 million related to services provided by the Company in 2001.

In October 2000, Amgen and Regeneron entered into an agreement whereby Regeneron acquired Amgen's patents and patent applications relating to ciliary neurotrophic factor ("CNTF") and related molecules for $1.0 million. As part of this agreement, Regeneron granted back to Amgen exclusive, royalty free rights under these patents and patent applications solely for human ophthalmic uses. In addition, Regeneron entered into a covenant not to sue Amgen under Regeneron's patents and patent applications relating to CNTF and related molecules solely for human ophthalmic uses.

In July 2002, Amgen and Immunex Corporation (now part of Amgen) granted the Company a non-exclusive license to certain patents and patent applications which may be used in the development and commercialization of the IL-1 Trap. The license followed two other licensing arrangements under which Regeneron obtained a non-exclusive license to patents owned by ZymoGenetics, Inc. and Tularik Inc. for use in connection with the IL-1 Trap program. These license agreements would require the Company to pay royalties based on the net sales of the IL-1 Trap if and when it is approved for sale. In total, the royalty rate under these three agreements would be in the mid-single digits.

d. Sumitomo Pharmaceuticals Company, Ltd.

In June 1994, the Company entered into a research and development agreement (the "R&D Agreement") with Sumitomo Pharmaceuticals Company, Ltd. ("Sumitomo Pharmaceuticals") to collaborate in the research and development of BDNF in Japan. In connection with the R&D Agreement, Sumitomo Pharmaceuticals made payments to the Company for its activities in developing and validating manufacturing processes for BDNF, and manufacturing and supplying BDNF and other research materials to Sumitomo Pharmaceuticals. In 2001, Regeneron recognized contract research and development revenue from Sumitomo Pharmaceuticals of $0.1 million. In addition, the Company recognized contract manufacturing revenue of $0.1 million in 2001 as supplies of BDNF were received (FOB Destination Point) by Sumitomo Pharmaceuticals.

During 1989, Sumitomo Chemical Co., Ltd. ("Sumitomo Chemical"), an affiliate of Sumitomo Pharmaceuticals, entered into a Technology Development Agreement ("TDA") with Regeneron and paid the Company $5.6 million. In consideration for this payment, Sumitomo Chemical received a fifteen year limited right of first negotiation to license up to three of the Company's product candidates in Japan. In connection with the Company's implementation of SAB 101 (see Note 2), the Company is recognizing this payment as revenue on a straight-line basis over the term of the TDA.

e. The Procter & Gamble Company

In May 1997, the Company entered into a long-term collaboration agreement with The Procter & Gamble Company ("Procter & Gamble") to discover, develop, and commercialize pharmaceutical products

(the "P&G Agreement") and Procter & Gamble agreed to provide funding for Regeneron's research efforts related to the collaboration. In connection with the collaboration, in June 1997 and August 2000, Procter & Gamble purchased 4.35 million and 573,630 shares of the Company's Common Stock at $9.87 and $29.75 per share for a total of $42.9 million and $17.1 million, respectively. In June 1997, Procter & Gamble also received five year warrants to purchase an additional 1.45 million shares of the Company's stock at $9.87 per share, which were exercised in August 2000. As consideration for the exercise price, Procter & Gamble tendered 511,125 shares of the Company's Common Stock which had an aggregate value at the time of exercise, based upon the average market price of the Company's Common Stock over approximately the prior 30 trading days, equal to the aggregate exercise price of the warrants. The net result of this warrant exercise was that Procter & Gamble acquired an additional 938,875 shares of the Company's Common Stock. The 511,125 shares of Common Stock delivered to the Company by Procter & Gamble were retired upon receipt. These equity purchases were in addition to a purchase by Procter & Gamble Pharmaceuticals, Inc. of 800,000 shares of the Company's Common Stock for $10.0 million that was completed in March 1997.

Effective December 31, 2000, the Company and Procter & Gamble entered into a new collaboration agreement, replacing the P&G Agreement. The new agreement extends Procter & Gamble's obligation to fund Regeneron research through December 2005, with no further research obligations by either party thereafter, and focuses the companies' collaborative research on therapeutic areas that are of particular interest to Procter & Gamble. Under the new agreement, research support from Procter & Gamble is $2.5 million per quarter, before adjustments for inflation, through December 2005. Any drugs that result from the collaboration will continue to be jointly developed and marketed worldwide, with the companies equally sharing development costs and profits. Procter & Gamble and the Company divided rights to programs from the P&G Agreement that are no longer part of the companies' collaboration. Research funding from Procter & Gamble related to the collaboration totaled $80.0 million through December 31, 2003. In addition, in 1997 through 1999, Procter & Gamble also provided research support for the Company's AXOKINE program and, as a result, will be entitled to receive a small royalty on any sales of AXOKINE.

Contract research and development revenue related to the Company's collaboration with Procter & Gamble was $10.6 million, $10.5 million, and $10.4 million in 2003, 2002, and 2001, respectively. At December 31, 2003, 2002, and 2001, the Procter & Gamble contract research revenue receivable was $2.7 million, $2.6 million, and $2.7 million, respectively.

12. Manufacturing Agreement

During 1995, the Company entered into a long-term manufacturing agreement with Merck & Co., Inc., as amended, (the "Merck Agreement") to produce an intermediate (the "Intermediate") for a Merck pediatric vaccine at the Company's Rensselaer, New York facility. The Company agreed to modify portions of its facility for manufacture of the Intermediate and to assist Merck in securing regulatory approval for such manufacture in the Company's facility. The Merck Agreement calls for the Company to manufacture Intermediate for Merck for six years (the "Production Period"), with certain minimum order quantities each year. The Production Period commenced in November of 1999, is expected to extend until November 2005, and may be extended by mutual agreement. Merck may terminate the agreement with at least one year's notice without payment of a termination fee.

Merck agreed to reimburse the Company for the capital costs to modify the facility ("Capital Costs"). Merck also agreed to pay an annual facility fee (the "Facility Fee") of $1.0 million beginning March 1995, subject to annual adjustment for inflation. During the Production Period, Merck agreed to reimburse the Company for certain manufacturing costs, pay the Company a variable fee based on the quantity of Intermediate supplied to Merck, and make additional bi-annual payments ("Additional Payments"), as defined. In addition, Merck agreed to reimburse the Company for the cost of Company activities performed on behalf of Merck prior to the Production Period and for miscellaneous costs during the Production Period

("Internal Costs"). These payments are recognized as contract manufacturing revenue as follows: (i) payments for Internal Costs are recognized as the activities are performed, (ii) the Facility Fee and Additional Payments are recognized over the period to which they relate, (iii) payments for Capital Costs were deferred and are recognized as Intermediate is shipped to Merck, and (iv) payments related to the manufacture of Intermediate during the Production Period ("Manufacturing Payments") are recognized after the Intermediate is tested and approved by, and shipped (FOB Shipping Point) to, Merck.

In 2003, 2002, and 2001, Merck contract manufacturing revenue totaled $10.1 million, $11.1 million, and $9.8 million, respectively. Such amounts include $1.7 million, $1.8 million, and $1.8 million of previously deferred Capital Costs, respectively. In addition, Merck contract manufacturing revenue for 2002 includes a non-recurring $1.0 million payment received in August 2002 related to services the Company provided in prior years.

13. Supply Agreement

In December 2002, the Company entered into an agreement (the "Serono Agreement") with Serono S.A. ("Serono") to use Regeneron's proprietary Velocigene technology platform to provide Serono with knock-out and transgenic mammalian models of gene function ("Materials"). Serono made an advance payment of $1.5 million (the "Retainer") to Regeneron in December 2002, which was accounted for as deferred revenue. Regeneron recognizes revenue and reduces the Retainer as Materials are shipped to and accepted by Serono. The Serono Agreement contains provisions for minimum yearly order quantities and replenishment of the Retainer when the balance declines below a specified threshold. In 2003, the Company recognized $0.7 million of contract research and development revenue in connection with the Serono Agreement.

14. Incentive and Stock Purchase Plans

a. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan") which, as amended, provides for the issuance of up to 11,000,000 shares of Common Stock in respect of awards. In addition, shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Board of Directors, (collectively, "Participants") may receive awards as determined by a committee of independent directors ("Committee"). The awards that may be made under the 2000 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

Stock Option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the Option is granted. Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three to five year period. The Committee also determines the expiration date of each Option; however, no ISO is exercisable more than ten years after the date of grant.

Restricted Stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as defined by the 2000 Incentive Plan, the ownership of the Restricted Stock, which has not vested, will be transferred to the Company, except under defined circumstances with Committee approval, in consideration of amounts, if any,

paid by the Participant to acquire such shares. In addition, if the Company requires a return of the Restricted Shares, it also has the right to require a return of all dividends paid on such shares.

Phantom Stock awards provide the Participant the right to receive, within 30 days of the date on which the share vests, an amount, in cash and/or shares of the Company's Common Stock as determined by the Committee, equal to the sum of the fair market value of a share of Common Stock on the date such share of Phantom Stock vests and the aggregate amount of cash dividends paid with respect to a share of Common Stock during the period from the grant date of the share of Phantom Stock to the date on which the share vests. Stock Bonus awards are bonuses payable in shares of Common Stock which are granted at the discretion of the Committee.

Other Awards are other forms of awards which are valued based on the Company's Common Stock. Subject to the provisions of the 2000 Incentive Plan, the terms and provisions of such Other Awards are determined solely on the authority of the Committee.

During 1990, the Company established the 1990 Incentive Plan which, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Board of Directors, received awards as determined by a committee of independent directors. Under the provisions of the 1990 Incentive Plan, there will be no future awards from the plan. Awards under the 1990 Incentive Plan consisted of Incentive Stock Options and Nonqualified Stock Options which generally vest on a pro rata basis over a three or five year period and have a term of ten years.

The 1990 and 2000 Incentive Plans contain provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined.

The Company may incur charges to operations in connection with awards from these Incentive Plans. In accordance with APB No. 25 and related interpretations, the Company will record compensation expense from employee stock-based awards under certain conditions. Generally, when the terms of the award and the amount the employee must pay to acquire the stock are fixed, compensation expense for options, restricted stock, and stock bonus awards will total the grant date intrinsic value, if any, amortized over the vesting period. For other awards, including phantom stock, compensation expense will be recognized over the life of the award based on the cash remitted to settle the award or the intrinsic value of the award on the date of exercise.

Transactions involving stock option awards during 2003, 2002, and 2001, under the 1990 and 2000 Incentive Plans, are summarized in the table below. Option exercise prices were equal to the fair market value of the Company's Common Stock on the date of grant. The total number of options exercisable at December 31, 2003, 2002, and 2001 was 5,940,268, 4,670,695, and 3,374,169, respectively, with weighted average exercise prices of $19.45, $15.80, and $11.99, respectively.

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)

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	Number of Shares	Weighted-Average Exercise Price
Stock options outstanding at December 31, 2000	7,431,059	$18.37
2001:		
Stock options granted	2,325,947	$28.51
Stock options canceled	(170,712)	$23.74
Stock options exercised	(258,255)	$ 7.67
Stock options outstanding at December 31, 2001	9,328,039	$21.10
2002:		
Stock options granted	2,693,010	$19.97
Stock options canceled	(183,031)	$22.63
Stock options exercised	(274,068)	$ 9.96
Stock options outstanding at December 31, 2002	11,563,950	$21.08
2003:		
Stock options granted	2,609,570	$13.45
Stock options canceled	(265,107)	$22.62
Stock options exercised	(795,114)	$ 7.07
Stock options outstanding at December 31, 2003	13,113,299	$20.38

The following table summarizes stock option information as of December 31, 2003:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 3.00 to $ 6.00	357,640	.98	$ 5.04	357,640	$ 5.04
$ 6.13 to $12.75	2,948,836	4.59	$ 9.00	2,531,747	$ 9.10
$12.80 to $13.00	2,352,705	9.92	$13.00	1,035	$12.98
$13.06 to $19.43	2,406,199	8.83	$19.00	669,476	$19.00
$19.65 to $28.01	2,776,899	7.72	$26.83	1,154,435	$27.41
$28.12 to $51.56	2,271,020	6.90	$38.76	1,225,935	$37.77
$ 3.00 to $51.56	13,113,299	7.29	$20.38	5,940,268	$19.45

The effect on the Company's net loss and net loss per share had compensation costs for the Incentive Plans been determined in accordance with the fair value based method of accounting for stock-based compensation as prescribed by SFAS No. 123 is shown in Note 2. For the purpose of the pro forma calculation, the fair value of each option granted from the Incentive Plans during 2003, 2002, and 2001 was estimated on the date of grant using the Black-Scholes option-pricing model. The weighted-average fair value of the options granted during 2003, 2002, and 2001 was $10.11, $14.10, and $21.22, respectively. The following table summarizes the assumptions used in computing the fair value of option grants.

	2003	2002	2001
Expected volatility	80%	70%	75%
Expected lives	5 years	5 years	5 years
Dividend yield	0%	0%	0%
Risk-free interest rate	3.01%-4.26%	3.98%-4.72%	4.74%-5.23%

During 2003, 2002, and 2001, 219,367, 139,611, and 80,535 shares, respectively, of Restricted Stock were awarded under the 2000 Incentive Plan. These shares are nontransferable with such restriction lapsing with respect to 25% of the shares every six months over a two-year period beginning in January 2004, 2003, and 2002, respectively. In accordance with generally accepted accounting principles, the Company recorded unearned compensation within Stockholders' Equity of $2.9 million, $2.7 million, and $2.3 million in 2003, 2002, and 2001, respectively, related to these awards. This amount was based on the fair market value of shares of the Company's Common Stock on the date of grant and will be expensed, on a pro rata basis, over the two year period that the restriction on these shares lapses. During 2003, 2002 and 2001, 4,431, 2,183 and 1,413 shares, respectively, of Restricted Stock were forfeited due to employee terminations. The Company reduced unearned compensation within Stockholders' Equity by $0.1 million, in each of the three years ended December 31, 2003, 2002 and 2001 related to these forfeited awards.

The Company recognized compensation expense from stock-based awards of $2.3 million $1.8 million, and $0.7 million in 2003, 2002, and 2001, respectively.

As of December 31, 2003, there were 1,653,642 shares available for future grants under the 2000 Incentive Plan.

b. Executive Stock Purchase Plan

In 1989, the Company adopted an Executive Stock Purchase Plan (the "Plan") under which 1,027,500 shares of Class A Stock were reserved for restricted stock awards. The Plan provides for the compensation committee of the Board of Directors to award employees, directors, consultants, and other individuals ("Plan participants") who render service to the Company the right to purchase Class A Stock at a price set by the compensation committee. The Plan provides for the vesting of shares as determined by the compensation committee and, should the Company's relationship with a Plan participant terminate before all shares are vested, unvested shares will be repurchased by the Company at a price per share equal to the original amount paid by the Plan participant. During 1989 and 1990, a total of 983,254 shares were issued, all of which vested as of December 31, 1999. As of December 31, 2003, there were 44,246 shares available for future grants under the Plan.

15. Employee Savings Plan

In 1993, the Company adopted the provisions of the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan (the "Savings Plan"). The terms of the Savings Plan provide for employees who have met defined service requirements to participate in the Savings Plan by electing to contribute to the Savings Plan a percentage of their compensation to be set aside to pay their future retirement benefits, as defined. The Savings Plan, as amended and restated during 1998, provides for the Company to make discretionary contributions ("Contribution"), as defined. The Company recorded Contribution expense of $0.9 million in 2003, $0.8 million in 2002, and $0.8 million in 2001; such amounts were accrued as liabilities at December 31, 2003, 2002, and 2001, respectively. During the first quarter of 2004, 2003, and 2002, the Company contributed 64,333, 42,543, and 21,953 shares, respectively, of Common Stock to the Savings Plan in satisfaction of these obligations.

16. Income Taxes

There is no benefit for federal or state income taxes for the years ended December 31, 2003 and 2002, since the Company has incurred operating losses since inception and established a valuation allowance equal to the total deferred tax asset. During the year ended December 31, 2001, the Company capitalized research and development costs for tax purposes resulting in taxable income of $7.0 million, which was offset by net operating loss carryforwards. The effects of the alternative minimum tax on the 2001 provision were immaterial.

(Unless otherwise noted, dollars in thousands, except per share data)

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2003 and 2002 was as follows:

	2003	2002
Deferred tax assets		
Net operating loss carry-forward	$ 135,357	$ 125,544
Fixed assets	7,177	4,199
Deferred revenue	43,372	6,022
Research and experimental tax credit carry-forward	18,233	16,092
Capitalized research and development costs	33,102	37,646
Other	3,832	3,395
Valuation allowance	(241,073)	(192,898)
	—	—

For all years presented, the Company's effective income tax rate is zero. The difference between the Company's effective income tax rate and the Federal statutory rate of 34% is attributable to state tax benefits and tax credit carry-forwards offset by an increase in the deferred tax valuation allowance.

As of December 31, 2003, the Company had available for tax purposes unused net operating loss carry-forwards of $340.2 million which will expire in various years from 2006 to 2023. The Company's research and experimental tax credit carry-forwards expire in various years from 2004 to 2023. Under the Internal Revenue Code and similar state provisions, substantial changes in the Company's ownership could result in an annual limitation on the amount of net operating loss and tax credit carry-forwards that can be utilized in future years to offset future taxable income. The annual limitation may result in the expiration of net operating losses and tax credit carry-forwards before utilization.

17. Legal Matters

In May 2003, securities class action lawsuits were commenced against Regeneron and certain of the Company's officers and directors in the United States District Court for the Southern District of New York. The complaints, which purport to be brought on behalf of a class consisting of investors in the Company's publicly traded securities between March 28, 2000 and March 30, 2003, allege that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE, in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. The Company's management believes that the lawsuits are without merit. The ultimate outcome of these matters cannot presently be determined. Accordingly, no provision for any liability that may result upon the resolution of these matters has been made in the accompanying financial statements.

The Company, from time to time, has been subject to other legal claims arising in connection with its business. While the ultimate results of the legal claims cannot be predicted with certainty, at December 31, 2003 there were no asserted claims against the Company which, in the opinion of management, if adversely decided would have a material adverse effect on the Company's financial position, results of operations, and cash flows.

18. Net Loss Per Share

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of Common and Class A shares outstanding. In 2003, 2002, and 2001, the Company reported net losses and, therefore, no common stock equivalents were included in the computation of diluted

net loss per share since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Net Loss (Numerator, in thousands)	Shares (Denominator, in thousands)	Per Share Amount
2003:			
Basic and diluted	$(107,458)	50,490	$(2.13)
2002:			
Basic and diluted	$(124,377)	43,918	$(2.83)
2001:			
Basic and diluted	$ (76,180)	42,075	$(1.81)

Shares issuable upon the exercise of options and warrants, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the diluted per share amounts because their effect would have been antidilutive, include the following:

	December 31,		
	2003	2002	2001
Options and Warrants:			
Weighted average number, in thousands	11,299	9,533	7,598
Weighted average exercise price	$ 22.07	$19.43	$22.40
Restricted Stock			
Weighted average number, in thousands	159	88	39
Convertible Debt:			
Weighted average number, in thousands	6,611	6,611	1,377
Conversion price	$ 30.25	$30.25	$30.25

19. Segment Information

The Company’s operations are managed in two business segments: research and development, and contract manufacturing.

Research and development: Includes all activities related to the discovery of potential therapeutics for human medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to (i) the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements and (ii) the supply of specified, ordered research materials using Regeneron-developed proprietary technology (see Note 13).

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2003, 2002, and 2001, the Company produced Intermediate under the Merck Agreement (see Note 12).

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

The table below presents information about reported segments for the years ended December 31, 2003, 2002, and 2001:

	Research & Development	Contract Manufacturing	Reconciling Items	Total
2003:				
Revenues	$ 47,366	$10,131	—	$ 57,497
Depreciation and amortization	11,894	—(1)	$ 1,043	12,937
Interest expense	161	—	11,771	11,932
Net (loss) income	(103,604)	3,455	(7,309)(2)	(107,458)
Capital expenditures	16,944	—	—	16,944
Total assets	92,369	12,889	374,297(3)	479,555
2002:				
Revenues	$ 10,924	$11,064	—	$ 21,988
Depreciation and amortization	7,411	—(1)	$ 1,043	8,454
Interest expense	36	2	11,821	11,859
Net (loss) income	(126,597)	4,579	(2,359)(2)	(124,377)
Capital expenditures	45,878	36	—	45,914
Total assets	75,589	12,479	303,506(3)	391,574
2001:				
Revenues	$ 12,071	$ 9,902	—	$ 21,973
Depreciation and amortization	5,866	—(1)	$ 211	6,077
Interest expense	114	40	2,503	2,657
Net (loss) income	(90,192)	3,353	10,659(2)	(76,180)
Capital expenditures	9,469	29	—	9,498
Total assets	37,948	9,369	448,080(3)	495,397

(1) Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.

(2) Represents investment income net of interest expense related to convertible notes issued in October 2001 (see Note 10e).

(3) Includes cash and cash equivalents, marketable securities, restricted marketable securities, prepaid expenses and other current assets, and other assets.

20. Unaudited Quarterly Results

During the third quarter of 2003, the Company elected to change the method it uses to recognize revenue under SAB 101 related to non-refundable collaborator payments, including up-front licensing payments, payments for development activities, and research progress (milestone) payments, to the Substantive Milestone Method, adopted retroactively to January 1, 2003 (see Note 2). The Company's unaudited financial results for the quarters ended March 31 and June 30, 2003 have been restated in accordance with the new revenue recognition method. There is no impact on the Company's financial results for any period prior to January 1, 2003.

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Summarized quarterly financial data for the years ended December 31, 2003 and 2002 are displayed in the following tables.

	First Quarter Ended March 31, 2003 (Unaudited)		Second Quarter Ended September 30, 2003 (Unaudited)	
	As Previously Reported	As Restated	As Previously Reported	As Restated
Revenues	$ 10,136	$ 9,925	$ 10,532	$ 8,908
Net loss	(30,110)	(30,321)	(28,736)	(30,360)
Net loss per share, basic and diluted	$ (0.68)	$ (0.68)	$ (0.58)	$ (0.61)

	Third Quarter Ended September 30, 2003 (Unaudited)	Fourth Quarter Ended December 31, 2003 (Unaudited)
Revenues	$ 17,392	$ 21,272
Net loss	(27,400)	(19,377)
Net loss per share, basic and diluted	$ (0.52)	$ (0.35)

	First Quarter Ended March 31, 2002 (Unaudited)	Second Quarter Ended June 30, 2002 (Unaudited)	Third Quarter Ended September 30, 2002 (Unaudited)	Fourth Quarter Ended December 31, 2002 (Unaudited)
Revenues	$ 4,941	$ 5,569	$ 6,566	$ 4,912
Net loss	(25,445)	(30,423)	(32,816)	(35,693)
Net loss per share, basic and diluted	$ (0.58)	$ (0.69)	$ (0.75)	$ (0.81)

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Partners

Amgen-Regeneron Partners

We have audited the accompanying balance sheet of Amgen-Regeneron Partners, a Delaware general partnership as of December 31, 2001 and the related statements of operations, changes in partners' capital (deficit), and cash flows for year ended December 31, 2001. These financial statements are the responsibility of the Partnership's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides 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 Amgen-Regeneron Partners at December 31, 2001, and the results of its operations and its cash flows for the year ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Los Angeles, California

February 4, 2002

AMGEN-REGENERON PARTNERS

BALANCE SHEET

December 31, 2001
(In thousands)

ASSETS	
Total current assets — cash and cash equivalents	$2,610
LIABILITIES AND PARTNERS' CAPITAL	
Total current liabilities — accounts payable and accrued expenses due to partners	$ 768
Partners' capital:	
Amgen	921
Regeneron	921
Total partners' capital	1,842
Total liabilities and partners' capital	$2,610

See accompanying notes.

AMGEN-REGENERON PARTNERS

STATEMENT OF OPERATIONS

Year Ended December 31, 2001
(In thousands)

Interest income	$ 169
Total income	169
Expenses:	
Research and development performed by partners	2,094
General and administrative	78
Total expenses	2,172
Net loss	$(2,003)

See accompanying notes.

AMGEN-REGENERON PARTNERS

STATEMENT OF CHANGES IN PARTNERS' CAPITAL (DEFICIT)

Year Ended December 31, 2001

	Amgen	Regeneron
	(In thousands)	
Balance at December 31, 2000	$ 267	$ 267
Capital contributions	1,655	1,656
Net loss	(1,001)	(1,002)
Balance at December 31, 2001	$ 921	$ 921

See accompanying notes.

AMGEN-REGENERON PARTNERS

STATEMENT OF CASH FLOWS

Year Ended December 31, 2001
(In thousands)

Cash flows from operating activities:	
Net loss	$(2,003)
Decrease in accounts payable and accrued expenses	(3,867)
Net cash used in operating activities	(5,870)
Cash flows from financing activities — capital contributions	3,311
Decrease in cash and cash equivalents	(2,559)
Cash and cash equivalents at beginning of year	5,169
Cash and cash equivalents at end of year	$ 2,610

See accompanying notes.

AMGEN-REGENERON PARTNERS

NOTES TO FINANCIAL STATEMENTS

December 31, 2001

1. Summary of Significant Accounting Policies

Business and Organization

Amgen-Regeneron Partners (the Partnership), a general partnership, was formed on June 21, 1991, under the laws of the state of Delaware between Amgen Inc. (Amgen) and Regeneron Pharmaceuticals, Inc. (Regeneron). The Partnership was formed to develop and commercialize in the United States brain-derived neurotrophic factor (BDNF) and Neurotrophin-3 (NT-3, together with BDNF, the Products) for human pharmaceutical use, in conformity with a collaboration agreement (the Collaboration Agreement) (Note 3).

The Partnership has conducted clinical trials of the Products in the past. Following a review of available clinical trial data, the Partnership discontinued the development of BDNF for the treatment of amyotrophic lateral sclerosis (ALS) in January 2001. There are no ongoing development activities for NT-3 at this time.

Cash Equivalents

The Partnership considers only those investments which are highly liquid, readily convertible to cash and which mature within three months of the date of purchase as cash equivalents. At December 31, 2001, cash and cash equivalents consisted of a single interest bearing money market account.

Research and Development

Research and development costs are expensed as incurred. Clinical trial costs, which are a component of research and development costs, are recognized based upon the estimated levels of effort expended on those trials.

Income Taxes

The Partnership’s financial statements do not include a provision (credit) for income taxes. Income taxes, if any, are the liability of the individual partners.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

2. Capital Contributions, Allocation of Profits and Losses and Cash Distributions

Capital contributions are recorded in the capital account of each partner. Capital account contributions are generally made quarterly in advance based upon capital calls made by the Committee pursuant to projected cash requirements of the Partnership. Cash distributions, if any, and profits or losses are allocated to each partner’s capital account in proportion to their respective capital account contributions.

AMGEN-REGENERON PARTNERS

NOTES TO FINANCIAL STATEMENTS — (Continued)

3. Collaboration Agreement

In August 1990, Amgen and Regeneron entered into the Collaboration Agreement to develop and commercialize BDNF and NT-3, compounds for which Regeneron possesses substantial scientific, technical and proprietary information. Each party agreed to perform research and development on the Products under product development programs approved by the Committee. Upon Amgen's notification in writing to Regeneron that the preparation of an Investigational New Drug Application for each Product was to commence, the licenses granted by the partners to the Partnership for the underlying technologies, discussed below, became effective on a Product-by-Product basis. Also, upon such notification, further research and development of the Products under the licenses became the obligation of the Partnership. These licenses grant the Partnership an exclusive royalty-free right to develop, make, have made, use, sell and distribute each Product for human pharmaceutical use in the United States. The Partnership has, in turn, granted to Amgen and Regeneron exclusive royalty-free sublicenses for the underlying technologies to the extent necessary to fulfill their obligations under the Collaboration Agreement. These sublicenses became effective at the same time the related licenses granted the Partnership became effective.

Under the Collaboration Agreement, Amgen would be primarily responsible for the manufacture and commercialization of the Products in the United States if successfully developed by the Partnership. Amgen's costs in connection with such activities would be reimbursed at agreed-to rates. Unless terminated earlier, the Partnership will continue in effect, with respect to each Product, until the later of the expiration of the last United States patent of each Product, or 15 years from the date on which each Product was approved for sale in the United States.

A Joint Management Committee (the Committee) is responsible for the overall management of the business and affairs of the Partnership as well as activities performed under the Collaboration Agreement. Each partner has appointed three representatives to the Committee. One additional representative may be appointed by a partner if the balance of their capital account becomes more than twice the amount of the balance of the other partner's capital account (Note 2).

Pursuant to the terms of the Collaboration Agreement, and subject to the approval by both parties, Amgen and Regeneron can conduct certain research and development activities on behalf of the Partnership, including contracting with third parties to conduct clinical trials. Amgen also provides on behalf of the Partnership certain quantities of materials, primarily for clinical testing. Amgen and Regeneron are paid for such services and materials at amounts approved by the Committee. During the year ended December 31, 2001, the Partnership incurred expenses (including accrued expenses) of $866,000 from Amgen and $1,228,000 from Regeneron for such services and materials. These amounts are included in research and development expense in the accompanying statements of operations. In addition, certain other costs associated with the development of the Products have been incurred by the partners but not charged to the Partnership or reflected in the accompanying financial statements as the related development activities are not billable to the Partnership under the terms of the Collaboration Agreement. At December 31, 2001, accounts payable and accrued expenses due to partners was composed of $143,000 of accounts payable and $378,000 of accrued clinical costs due to Amgen and $170,000 of accounts payable and $77,000 of accrued clinical costs due to Regeneron.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 33-50480, 33-85330, 33-97176, 333-33891, 333-80663, 333-61132, 333-97375, and 333-119257) and on Form S-3 (File No. 333-74464) of Regeneron Pharmaceuticals, Inc., of our report dated January 30, 2004, except for the last paragraph of Note 11b, as to which the date is February 27, 2004, relating to the financial statements which appear in this Annual Report on Form 10-K/A Amendment No. 2.

PricewaterhouseCoopers LLP

New York, New York

December 13, 2004

Exhibit 23.2

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 33-50480) pertaining to the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan, the Registration Statements (Form S-8 No. 33-85330, Form S-8 No. 33-97176, Form S-8 No. 333-33891, and Form S-8 No. 333-80663) pertaining to the Regeneron Pharmaceuticals, Inc. Amended and Restated 1990 Long-Term Incentive Plan, the Registration Statements (Form S-8 No. 333-61132, Form S-8 No. 333-97375 and Form S-8 No. 333-119257) pertaining to the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan, and the Registration Statement (Form S-3 No. 333-74464) pertaining to the registration of common stock issuable upon the conversion of Regeneron Pharmaceuticals, Inc.'s Senior Subordinated Notes due 2008, of our report dated February 4, 2002, with respect to the 2001 financial statements of Amgen-Regeneron Partners included in Regeneron Pharmaceuticals, Inc.'s Annual Report (Form 10-K/A Amendment No. 2) for the year ended December 31, 2003, filed with the Securities and Exchange Commission.

/s/ ERNST & YOUNG LLP

Los Angeles, California

December 13, 2004

Exhibit 31

**Certification of CEO and CFO Pursuant to Rule 13a-14(a)
under the Securities Exchange Act of 1934, as Adopted Pursuant
to Section 302 of the Sarbanes-Oxley Act of 2002**

CERTIFICATIONS

I, Leonard S. Schleifer, certify that:

1. I have reviewed this annual report on Form 10-K, as amended by Amendment No. 2 filed on December 14, 2004, of Regeneron Pharmaceuticals, 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 annual 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 to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this annual report is being prepared;

(b) [Intentionally omitted per SEC's transition rules in SEC's Release Nos. 33-8238 and 34-47986];

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

(d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter 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 officers 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 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.

By: /s/ LEONARD S. SCHLEIFER

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Date: December 14, 2004

I, Murray A. Goldberg, certify that:

1. I have reviewed this annual report on Form 10-K, as amended by Amendment No. 2 filed on December 14, 2004, of Regeneron Pharmaceuticals, 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 annual 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 to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this annual report is being prepared;

(b) [Intentionally omitted per SEC's transition rules in SEC Release Nos. 33-8238 and 34-47986];

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

(d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter 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 officers 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 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.

By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Senior Vice President, Finance & Administration, Treasurer, and Assistant Secretary

Date: December 14, 2004

Exhibit 32

Certification of CEO and CFO Pursuant to

18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with Amendment No. 2 to the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ending December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, 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.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
December 14, 2004

/s/ Murray A. Goldberg

Murray A. Goldberg
Chief Financial Officer
December 14, 2004

This certification accompanies the Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of § 18 of the Securities Exchange Act of 1934, as amended.