UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 10-K

(MARK ONE)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000

[ ] 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 (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) | 10591-6707 (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 [X] No [ ]

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

At February 23, 2001, the aggregate market value of voting stock held by non-affiliates of the Registrant totaled approximately $684,560,000 based on the last sale price as reported by The Nasdaq Stock Market.

Indicate the number of shares outstanding of each of Registrant's classes of common stock as of February 23, 2001:

| CLASS OF COMMON STOCK | NUMBER OF SHARES |
|---|---|
| CLASS A STOCK, $.001 PAR VALUE | 2,575,165 |
| COMMON STOCK, $.001 PAR VALUE | 34,259,851 |

DOCUMENTS INCORPORATED BY REFERENCE:

The Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its Annual Meeting of Shareholders to be held on June 8, 2001, is incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 26 to 28 of this filing.

PART I

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 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 "Factors That May Affect Future Operating Results" 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.

ITEM 1. BUSINESS

GENERAL

Regeneron Pharmaceuticals, Inc., which may be referred to as "we", "us", or "our", is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic drugs for the treatment of serious medical conditions. Our product pipeline includes product candidates for the treatment of obesity, rheumatoid arthritis and other inflammatory conditions, cancer and related disorders, allergies, asthma, and other diseases and disorders. Since inception we have not generated sales or any profits from the commercialization of any of our product candidates.

Our core business strategy is to combine our strong foundation in science and technology with state-of-the-art 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. Our ability to develop product candidates results from the application of our technology platforms. Our technology platforms, in contrast to basic genomics approaches which attempt to identify every gene in a cell or genome, are designed to discover specific genes of therapeutic interest for a particular disease or cell type. We will continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

A key aspect of our strategy is to retain significant ownership and commercialization rights to our pipeline. Below is a summary of our leading clinical programs, as well as several product candidates that are expected to enter clinical trials over the next two years. We retain sole ownership and marketing rights for each of these programs and currently are developing them independent of any corporate partners.

- AXOKINE(R): Acts on the brain region regulating food intake and energy expenditure and is being developed for the treatment of obesity. In November 2000, we announced the preliminary results of a twelve-week Phase II dose-ranging trial of AXOKINE in 170 severely obese patients. In the trial, AXOKINE was generally well tolerated and patients treated with AXOKINE showed medically meaningful and statistically significant weight loss compared to those receiving placebo. Subject to discussions with the FDA, we intend to initiate Phase III testing of AXOKINE in severely obese patients in mid-2001.

- PEGYLATED AXOKINE: Chemically modified version of AXOKINE that is being developed as a more potent, longer-acting form of the protein. Pegylated AXOKINE currently is in late-stage preclinical development and we anticipate initiating a Phase I clinical trial in mid-2001.

- INTERLEUKIN-1 CYTOKINE TRAP (IL-1 TRAP): Protein-based antagonist for the interleukin-1 (called IL-1) cytokine. IL-1 is thought to play a major role in rheumatoid arthritis and other inflammatory diseases. In December 2000, we initiated a Phase I study to assess the safety and tolerability of the IL-1 Trap in patients with rheumatoid arthritis. We expect the study to be completed in the second half of 2001.

- INTERLEUKIN-4/INTERLEUKIN-13 CYTOKINE TRAP (IL-4/IL-13 TRAP): Protein-based antagonist for the interleukin-4 and interleukin-13 (called IL-4 and IL-13) cytokines which are thought to play a major role in diseases such as asthma, allergic disorders, and other inflammatory diseases. We expect to initiate a Phase I clinical trial of a dual IL-4/IL-13 Trap for asthma/allergy-related conditions in late 2001.

- VEGF TRAP: Protein-based antagonist to Vascular Endothelial Growth Factor (called VEGF, also known as Vascular Permeability Factor or VPF), which is required for the growth of blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leak. The VEGF Trap is expected to enter Phase I clinical trials in mid-2001.

- ANGIOPOIETINS: A new family of growth factors that act specifically on the endothelium cells that line blood vessels and may be useful for growing blood vessels in diseased hearts and other tissues with decreased blood flow and for repairing blood vessel leaks that cause swelling and edema in many different diseases such as stroke, diabetic retinopathy, and inflammatory diseases. Selected Angiopoietins, including engineered forms of these growth factors, are in preclinical development.

In addition to the above programs which we are conducting solely on our own, we have formed collaborations to advance other research and development efforts. We are conducting research with The Procter & Gamble Company in muscle diseases and other fields. We are also collaborating with Medarex, Inc. to discover, develop, and commercialize certain human antibodies as therapeutics. In partnership with Amgen Inc., we are conducting clinical trials with Neurotrophin-3, or NT-3, for the treatment of constipating conditions. In all of these research collaborations, we retain 50% of the commercialization rights.

OUR INDEPENDENT PROGRAMS

The following table lists the programs and product candidates for which we retain sole ownership and marketing rights.

| PROGRAM AND PRODUCT CANDIDATE | TARGETED INDICATION | STAGE |
|---|---|---|
| AXOKINE(R) | Obesity | Clinical |
| PEGYLATED AXOKINE | Obesity | Preclinical |
| IL-1 TRAP | Rheumatoid arthritis | Clinical |
| IL-4/13 TRAP | Asthma and allergic disorders | Preclinical |
| TRAPS FOR IL-2, IL-3, IL-4, IL-5, IL-6, IL-15, GAMMA-INTERFERON, TGF-BETA AND OTHERS | Multiple diseases | Research |
| VEGF TRAP | Cancer and related conditions | Preclinical |
| ANGIOPOIETIN-1 | Vascular leak and edema | Preclinical |
| EPHRINS, ANGIOPOIETIN-2 | Cancer and ischemia | Research |
| REGENERON ORPHAN RECEPTORS (RORS) | Osteoarthritis and other cartilage diseases | Research |

AXOKINE. AXOKINE is our patented second generation ciliary neurotrophic factor, called CNTF. We are developing AXOKINE for the treatment of obesity.

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 II 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. Current treatment of obesity consists of diet, exercise, and other lifestyle changes, and a limited number of drugs. There are two approved drugs currently indicated for the treatment of obesity -- sibutramine (Meridia(R), a registered trademark of Knoll Pharmaceutical Company) and orlistat (Xenical(R), a registered trademark of Hoffmann-La Roche, Inc.). According to their approved product labels, over a twelve month treatment period, these drugs, at their approved starting doses, have produced weight loss of between approximately five and nine pounds as compared to patients taking placebo.

In November 2000, we announced the preliminary results of a Phase II clinical trial, which tested the safety and efficacy of AXOKINE in severely obese patients. This Phase II trial was a randomized, double-blind, placebo-controlled, out-patient study conducted at seven sites in the United States. Following an initial two week "run-in period," all subjects received twelve weeks of daily treatment, administered under the skin by patient self-injection. A total of 170 patients were divided into five patient groups. The first four patient groups comprised the pre-specified population for the primary analyses and received placebo, a daily dose of 0.3 micrograms (mcg) of AXOKINE per kilogram (kg), a daily dose of 1.0 mcg/kg, or a daily dose of 2.0 mcg/kg, in each case, over the twelve week treatment period. A fifth group received a daily dose of 1.0 mcg/kg for eight weeks, followed by a blinded withdrawal period in which they received placebo for four weeks. The pre-specified end points of the study were change in weight for the patients who completed the full twelve weeks of treatment ("Completer Analysis"), and change in weight for all patients, whether or not they completed the full twelve weeks of treatment ("Last Observed Value Analysis"). All AXOKINE-treated groups showed medically meaningful and statistically significant weight loss compared to placebo. Summarized below are the results of the four groups comprising the primary analyses.

COMPLETER ANALYSIS

| | MEAN WEIGHT CHANGE FROM BASELINE (POUNDS) | P VALUE (RELATIVE TO PLACEBO) |
|---|---|---|
| Placebo (n=19) | +1.3 | -- |
| 0.3 mcg/kg (n=23) | -3.4 | p = 0.01 |
| 1.0 mcg/kg (n=26) | -8.9 | p < 0.0001 |
| 2.0 mcg/kg (n=19) | -7.5 | p < 0.0001 |

LAST OBSERVED VALUE ANALYSIS

| | MEAN WEIGHT CHANGE FROM BASELINE (POUNDS) | P VALUE (RELATIVE TO PLACEBO) |
|---|---|---|
| Placebo (n=31) | +0.6 | -- |
| 0.3 mcg/kg (n=31) | -2.4 | p = 0.04 |
| 1.0 mcg/kg (n=37) | -7.5 | p < 0.0001 |
| 2.0 mcg/kg (n=33) | -5.8 | p < 0.0001 |

As used in the table above, "n" refers to the number of patients in each patient group. The reference to "p" value (relative to placebo) means the probability of being wrong when asserting that a true difference exists between the results for the patient group in question and the placebo group. For example, a p-value of less than 0.0001 indicates that there is a less than one in ten thousand chance that the mean weight loss observed in the group treated with drug and the mean weight loss observed in the group treated with placebo are the same.

The trial established the optimal dose of AXOKINE to be 1.0 mcg/kg daily. Patients who received the optimal dose of AXOKINE over the twelve week treatment period averaged 10 pounds more weight loss than patients on placebo. Moreover, 46% of these patients in the optimal dose group lost at least 10 pounds, compared to just 5% of the patients who received placebo. Nausea was shown not to be a factor that determined average weight loss in this Phase II study.

The 38 patients in the fifth group who received 1.0 mcg/kg of AXOKINE daily for eight weeks followed by the four week blinded withdrawal period lost weight during the treatment period and did not regain weight while taking placebo during the withdrawal period.

On February 28, 2001 we announced that based on a preliminary analysis of interim data, patients who received AXOKINE therapy during the Phase II study maintained their average weight loss during the three months following their last AXOKINE treatment, relative to patients who received placebo. Moreover, patients in the fifth group who were treated with AXOKINE for only eight weeks continued to maintain their average weight loss for an additional four months following their last treatment. This preliminary analysis is based on a total of 87 patients, comprised of patients from all five groups, who completed the full twelve weeks of treatment in the study and the twelve week follow-up.

No serious adverse events associated with the drug were reported during the trial and the drug was generally well tolerated, as reflected by the following ratio of patients in each treatment group completing the

full twelve weeks of treatment according to the protocol: placebo, 61%; 0.3 mcg/kg, 74%; 1.0 mcg/kg, 70%, and 2.0 mcg/kg, 58%. The most common side effect was dose-dependent injection site reactions (skin redness), which occurred in all patient groups, including placebo, and were generally mild. Other side effects associated with the drug included cough and vomiting, which were notable only in the 2.0 mcg/kg dose group, and nausea, which occurred most frequently in the 2.0 mcg/kg dose group. There was no increase compared to placebo in the incidence of herpes simplex infections in patients taking AXOKINE. Neutralizing antibodies, based on a laboratory test, were not dose-related and occurred in less than 10% of all patients receiving AXOKINE.

Subject to discussions with the FDA, we intend to initiate Phase III testing of AXOKINE in severely obese patients in mid-2001. This Phase III program likely will involve the enrollment of several thousand severely obese patients with a primary double-blind treatment period of approximately one year and an additional one year follow-up treatment period.

In March 2000, we established a research and development collaboration with Emisphere Technologies, Inc. to utilize Emisphere's oral drug delivery technology for AXOKINE. In preliminary preclinical pharmacokinetic studies, the Emisphere technology was able to achieve measurable blood levels of AXOKINE.

PEGYLATED AXOKINE. We are developing a pegylated version of AXOKINE (pegAXOKINE) as a more potent, longer-acting form of the protein. PegAXOKINE may allow for less frequent and/or lower dosing in patients. PegAXOKINE currently is in late-stage preclinical development and we anticipate initiating a Phase I clinical trial in mid-2001. Shearwater Corporation has contracted with us to develop and supply the pegylated reagent for this product candidate.

CYTOKINE TRAPS. Our research on the CNTF class of neurotrophic factors led to the discovery that CNTF, although it is a neurotrophic factor, belongs to the "superfamily" of signaling molecules referred to as 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 drugs already approved or in clinical development. The cytokine superfamily includes factors such as erythropoietin, thrombopoietin, granulocyte-colony stimulating factor, and the interleukins (or ILs).

In the early 1990's, our scientists made a breakthrough in understanding how receptors work for an entire class of interleukins in the human body. Based on this finding, we developed a family of antagonists referred to as "Cytokine Traps." This family includes Cytokine Traps for IL-1, IL-4, and IL-6 and a single Trap that blocks both IL-4 and IL-13. Because these Traps mimic the body's natural receptors, they are effective at catching and holding the cytokines. With the cytokines trapped, the immune system responds as if the perceived threat is under control.

In preclinical studies, these Cytokine Traps are more potent than other antagonists, potentially allowing lower levels of the drug to be used. Moreover, because these Cytokine 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 IL-1, IL-4, IL-6, and IL-13 seem to contribute to a variety of disease states, these Cytokine Traps have the potential to be important therapeutic agents.

IL-1 Trap. In December 2000, we initiated a Phase I study of the IL-1 Trap to assess its safety and tolerability in patients with rheumatoid arthritis. The placebo-controlled, double-blind, dose-escalation study is being conducted at several centers in the United States and includes a single dose phase and a multiple dose phase. We expect the study to be completed in the second half of 2001. The IL-1 Trap is also being evaluated for potential uses in treating other inflammatory diseases.

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 time, the cartilage erodes, resulting in structural damage to the joint. 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.

Rheumatoid arthritis involves an excess of certain cytokines, including IL-1 and tumor necrosis factor (TNF). Drugs that block TNF have already been approved for the treatment of rheumatoid arthritis, while animal studies indicate that IL-1 is also an attractive target for drug development in this disease. In animal models, our IL-1 Trap is a potent blocker of IL-1 activity, has a long half-life in the blood, penetrates into the inflamed joint, and blocks cartilage erosion.

While both TNF and IL-1 can induce arthritis, IL-1 more potently induces cartilage destruction in animal models. In addition, the arthritis caused by TNF in some animals can be prevented by blocking the action of IL-1, indicating that the arthritogenic action of TNF may be mediated, in part, through IL-1. Even stronger evidence for the role of IL-1 in rheumatoid arthritis is that mice that are deficient in the interleukin-1 receptor antagonist (IL-1-ra), a naturally occurring blocker of IL-1 action, develop spontaneously occurring arthritis. The validation of IL-1 blockade as a target for drugs to treat rheumatoid arthritis also appears to have been demonstrated by the positive results reported by another company with administration of IL-1ra in clinical trials in patients with rheumatoid arthritis.

IL-4/IL-13 Trap. Antagonists for IL-4 and IL-13 may be therapeutically useful in a number of allergy and asthma-related conditions, including as adjuncts 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/IL-13 Trap, which is a single molecule that can block both interleukin-4 and interleukin-13. We expect to initiate a clinical trial of a dual IL-4/IL-13 Trap to assess its safety and tolerability for the treatment of asthma/allergy-related conditions late in 2001.

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 an alarming 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, there are too many interleukins present, causing the immune system to overact. Our IL-4/IL-13 Trap may offer unique advantages over other products and product candidates for asthma and allergy-related conditions because of its ability to block both of the cytokines thought to be at the root of these disorders.

Other Cytokine Traps. We have a late stage research program underway for an IL-6 Cytokine 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. We also have patents covering additional Cytokine Traps for IL-2, IL-3, IL-5, IL-15, gamma-interferon, transforming growth factor beta, and others, which are being pursued at the research level. Our research regarding protein-based cytokine antagonists currently includes molecular and cellular research to improve or modify Cytokine 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 Cytokine Traps.

VEGF TRAP AND ANGIOPOIETINS. 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.

Depending on the clinical situation, 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 heart, aid in healing of 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 (VEGF) was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor specifically expressed on blood vessel cells. Our scientists discovered a second family of angiogenic growth factors, termed the Angiopoietins, and we have received patents for 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.

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

Currently, we have a highly potent VEGF antagonist, termed the VEGF Trap, in preclinical development as an anti-angiogenic agent for cancer. We expect to begin a clinical trial of the VEGF Trap as a potential treatment for harmful angiogenesis or vascular leak in settings of cancer and/or other conditions in mid-2001. In addition, we are evaluating Angiopoietin-1 and engineered designer versions of Angiopoietins in preclinical studies to determine their utility for repairing blood vessel leak and for growing blood vessels in ischemia.

We and others have identified a family of growth factors termed the Ephrins and their receptors termed the Ephs. Members of this family have specific roles in angiogenesis and hemopoiesis, which are being pursued in preclinical studies.

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). Furthermore, our scientists have demonstrated that this growth factor receptor system is required for normal cartilage development in mice. In addition, together with collaborators, our scientists have proven 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.

OUR COLLABORATIVE PROGRAMS

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 prescribe for patients with muscle atrophy or other muscle conditions which afflict millions of patients globally. Thus, a factor that might have 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 mechanisms involved in muscle atrophy and hypertrophy. This work is being conducted in collaboration with scientists at Procter & Gamble as part of our collaboration.

NT-3. Amgen-Regeneron Partners' clinical development of NT-3 is currently focused on the treatment of constipating conditions. In 1998, we, on behalf of Amgen-Regeneron Partners, completed a small clinical study that included healthy volunteers and patients suffering from severe idiopathic constipation. We also conducted additional small studies in patients who suffer from constipation associated with conditions such as spinal cord injury and the use of narcotic analgesics. In 2000, we initiated double-blind, placebo-controlled Phase II studies of NT-3 in patients with functional constipation and in spinal cord injury patients with bowel dysfunction. These studies currently are underway and we expect them to be completed in mid-2001. Amgen-Regeneron Partners is developing NT-3 in the United States under a license from Takeda Chemical Industries, Ltd.

OTHER EARLY STAGE PROGRAMS: FIBROSIS AND G-PROTEIN COUPLED RECEPTORS. Fibrotic diseases, such as cirrhosis, result from the excess production of fibrous extracellular matrix by certain cell types that are

inappropriately activated in these diseases. 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. We have further shown that these receptors bind and are activated by the fibrous matrix they produce. Thus, these receptors are important new targets 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.

We also have a research program focused on the discovery and characterization of G-Protein Coupled Receptors, which have historically been among the most useful targets for pharmaceuticals. We use a genomics approach to discover new 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.

OUR 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.

TARGETED GENOMICS(TM): 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.

HIGH THROUGHPUT FUNCTIONOMICS(TM): A major challenge facing the biopharmaceutical industry in the post-genomic era involves 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 mice in which the gene is removed (referred to as "knockout mice"), or is over-produced (referred to as "transgenic mice"), or in which a color-producing gene is substituted for the gene of interest (referred to as "reporter knockin mice") to identify which cells in the body are expressing the gene. Until recently, technical hurdles involved in the generation of mouse models restricted the ability to produce multiple models quickly and efficiently. We have developed proprietary technology that we believe will allow for the rapid and efficient production of genetically modified mice on a high throughput scale enabling rapid assignment of function to gene sequences.

DESIGNER PROTEIN THERAPEUTICS(TM): 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. Examples include the generation of AXOKINE and the development of Cytokine Traps and the VEGF Trap. This technology platform has already produced more than 10 patented proteins, including the IL-1 Trap currently in Phase I clinical testing, and several others in preclinical development.

COLLABORATIVE RELATIONSHIPS

In addition to our independent programs, we currently conduct programs in collaboration with academic and corporate partners. We have entered into research collaboration and licensing agreements with various corporate partners, including Procter & Gamble, Medarex, Amgen, and Sumitomo Pharmaceuticals.

PROCTER & GAMBLE. In May 1997, we entered into a long-term collaboration agreement with Procter & Gamble to discover, develop, and commercialize pharmaceutical products. Procter & Gamble agreed over the first five years of the 1997 collaboration to purchase up to $60.0 million of our equity, of which $42.9 million was purchased in June 1997 and $17.1 million was purchased 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 over the first five years of the 1997 collaboration to provide funding in support of our research efforts related to the collaboration, of which we had received $44.9 million through December 31, 2000. In September 1997, we and Procter & Gamble amended the 1997 collaboration agreement to include AXOKINE and related molecules. Procter & Gamble paid us research progress payments of $5.0 million in 1997 and $5.0 million in 1998 upon the achievement of defined milestones related to AXOKINE. During the third quarter of 1999, Procter & Gamble returned the product rights to AXOKINE to us and ended related research support for our AXOKINE program. However, 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. In addition, in August 2000, we and Procter & Gamble agreed through a binding memorandum of understanding to enter into a new collaboration agreement, replacing the companies' 1997 collaboration agreement. The new agreement extends Procter & Gamble's obligation to fund our research under the new collaboration 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, 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. Neither party may independently perform research on targets subject to research or development activities under the collaboration. In addition, during the research term and for five years thereafter, neither party may develop or commercialize a product that competes with a product developed as part of the collaboration.

Pursuant to the August 2000 binding memorandum of understanding, we and Procter & Gamble have divided rights to the programs from the 1997 collaboration agreement that are no longer part of the companies' collaboration. Procter & Gamble has 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 Regeneron's Orphan Receptors (RORs). Any drugs 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 will be $2.5 million per quarter (before adjustments for future inflation) through December 2005.

The new collaboration agreement will expire 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 these termination rights, the 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 will generally 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.

MEDAREX. In March 2000, we entered into a collaboration under a binding memorandum of understanding with Medarex to discover, develop, and commercialize human antibodies as therapeutics. We will contribute our expertise in discovering and characterizing proteins as drug targets, and Medarex will contribute its HuMAb-Mouse(TM) technology to create fully human antibody products for those targets. Together we have selected more than twenty initial targets, including growth factors, cytokines, and receptors, and plan to add additional targets in the future. We and Medarex intend to prioritize targets based upon a variety of criteria, including target validation, reagent availability, market opportunity, competitive factors, intellectual property position, and the expected feasibility of obtaining antibodies that have the desired properties. The HuMAb-Mouse is a transgenic mouse whose genes for creating mouse antibodies have been inactivated and replaced by human antibody genes. This makes it possible to rapidly create and develop fully human antibodies as drug candidates.

Under the agreement, Medarex and we will share equally all development, manufacturing, and clinical costs of jointly developed products and all net profits and losses. Each of us has the right to opt out of the joint development of an antigen target and receive instead milestones and royalty payments on net sales as may be negotiated by the parties. The agreement terminates upon the later of three years or the date on which neither party is exploiting any jointly developed products. During the term of the agreement, neither party may independently develop any antibody-based products against any of the targets included within the collaboration. In addition, we and Medarex have agreed not to purchase more than twenty percent of each other's stock.

EMISPHERE. In March 2000, we signed an agreement with Emisphere to establish a research and development collaboration to utilize Emisphere's oral drug delivery technology for AXOKINE. In preliminary preclinical pharmacokinetic studies, the Emisphere technology was able to achieve measurable blood levels of AXOKINE. Under the terms of the agreement, we will support research at Emisphere and make payments, including license and milestone payments, based on the satisfaction of pre-determined criteria during the development of orally delivered AXOKINE. The parties have established a steering committee to determine these milestones, which trigger either payment obligations or termination rights for us. The first of these milestones is based on the status of the program as of March 31, 2001. The steering committee shall meet on at least a quarterly basis to review the results of the program. In addition, the agreement is also subject to termination if either party breaches its material obligations thereunder. During the term of the agreement, we will receive exclusive worldwide commercialization rights to oral products that result from the collaboration and pay Emisphere a royalty on sales of any such products.

SHEARWATER. In December 2000, we entered into a license and supply agreement with Shearwater Corporation under which Shearwater will develop and supply a pegylated reagent that could be used to formulate a modified form of AXOKINE. In preclinical studies, a pegylated AXOKINE was substantially longer lasting than unmodified AXOKINE. This may allow less frequent and/or lower dosing in patients. Under the terms of the agreement, Shearwater will develop and supply the reagent and we will manufacture and have exclusive rights to pegylated AXOKINE. Shearwater is entitled to receive milestone payments based on the development of the modified AXOKINE and will be the exclusive supplier of the reagent. We will pay Shearwater a royalty not to exceed 2.5% on sales of any pegylated AXOKINE. The agreement remains in force until the later of ten years from the grant of the first marketing approval for a pegylated AXOKINE or the last to expire patent covering Shearwater's pegylated reagent. In addition, each party shall have the right to terminate the agreement upon bankruptcy of the other party or the other party's breach of a material obligation under the agreement. We have additional termination rights if market or other conditions, including regulatory restrictions, seriously inhibit the ability to develop or market pegylated AXOKINE.

AMGEN. In August 1990, we entered into a collaboration agreement with Amgen to develop and attempt to commercialize two proprietary products, BDNF and NT-3, in the United States. Pursuant to the agreement with Amgen, we formed a partnership with Amgen (Amgen-Regeneron Partners) to complete the development and commercialization of these product candidates. We are required to fund 50% of the development costs of Amgen-Regeneron Partners to maintain 50% of the commercialization rights. Assuming equal capital

contributions to Amgen-Regeneron Partners, we and Amgen share any profits or losses of Amgen-Regeneron Partners equally. Under our agreement with Amgen we are attempting to develop with Amgen and, if such effort is successful, commercialize, market and distribute NT-3 in the United States through Amgen-Regeneron Partners.

Our agreement with Amgen will continue for the longer of the life of the patents covering NT-3 or BDNF or fifteen years from the date on which either product candidate is approved for commercial marketing in any country. The agreement is also subject to termination if either party enters into bankruptcy or breaches its material obligations thereunder. During the term of the agreement, there are restrictions on the ability of either party to independently conduct research or development of NT-3 or BDNF without the other party. Our aggregate capital contribution to Amgen-Regeneron Partners from the partnership's inception in June 1993 through December 31, 2000 was $56.2 million. We expect that our capital contributions for 2001 will total at least $2.2 million. These contributions could increase or decrease, depending upon, among other things, the nature and cost of ongoing and additional NT-3 studies that Amgen-Regeneron Partners may conduct, the outcomes of those studies, and costs associated with the discontinuation of the BDNF studies.

The development and commercialization of NT-3 outside of the United States, Japan, China, and certain other Pacific Rim countries, if any, will be conducted solely by Amgen through a license from us and from Takeda Chemical Industries, Ltd. In return, we will receive royalty payments based on Amgen's net sales of any products in the licensed territory. In the licensed territory, Amgen is solely responsible for funding clinical development and related costs of the licensed products, as well as costs of their commercial exploitation, and has sole discretion with respect to all such development, manufacturing, and marketing of the products and sole responsibility for filing applications for regulatory approvals.

Amgen-Regeneron Partners was conducting clinical trials of BDNF for the treatment of amyotrophic lateral sclerosis (or ALS). Following notification that BDNF did not provide any therapeutic advantage to ALS patients in the clinical trials, we and Amgen discontinued the development of BDNF for ALS in January 2001.

During October 2000, we and Amgen entered into an agreement whereby we acquired Amgen's patents and patent applications relating to CNTF and related molecules for $1.0 million. As part of this agreement, we granted back to Amgen exclusive, royalty free rights under these patents and patent applications solely for human ophthalmic uses. In addition, we agreed not to sue Amgen under our patents and patent applications relating to CNTF and related molecules solely for human ophthalmic uses.

SUMITOMO. In March 1989, Sumitomo Chemical Company, Ltd. entered into a Technology Development Agreement with us and paid us $5.6 million. In addition, Sumitomo Chemical purchased $4.4 million of our equity. In connection with this agreement, we granted Sumitomo Chemical a limited right of first negotiation, over a fifteen year period, to license up to three of our product candidates to commercialize in Japan on financial and commercial terms as we may offer. If Sumitomo Chemical decides it does not wish to enter into a license agreement with us on the terms we propose, we are free to license the product candidate to any other third party in Japan on terms and conditions no more favorable to a third party licensee than those offered to Sumitomo Chemical. We are obligated periodically to inform and, if requested, to meet with Sumitomo Chemical management about our progress in research and development. This agreement shall expire on the earlier of March 20, 2004 or the date that Sumitomo Chemical licenses three product candidates from us, provided that the parties may extend the agreement for an additional five-year term.

BDNF is licensed to Sumitomo Pharmaceuticals Company, Ltd. (a subsidiary of Sumitomo Chemical) for development in Japan. Under our agreement, we supply Sumitomo Pharmaceuticals with BDNF for clinical and preclinical testing and receive payments for manufacturing costs and research progress payments based on the development of BDNF. In addition, we will receive a royalty based on any potential BDNF sales in Japan. The agreement expires at the later of fifteen years from the date of the first commercial sale of BDNF in Japan and the last to expire patent covering BDNF in Japan. In addition, Sumitomo Pharmaceuticals has the unilateral right to terminate the agreement at any time. In light of the recent Amgen-Regeneron Partners' clinical trial results for BDNF, it is likely that Sumitomo Pharmaceuticals will exercise its discretionary right to terminate the license with us for BDNF and, other than amounts currently outstanding

and any wind-down costs, we would not expect to receive further payments from Sumitomo Pharmaceuticals for research progress payments, contract research and development, or contract manufacturing. We recognized revenue from Sumitomo Pharmaceuticals of $7.6 million in 2000, $0.1 million in 1999, and $8.8 million in 1998.

MANUFACTURING

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

In 1993, we purchased our 100,000 square foot Rensselaer, New York manufacturing facility, which is being used to manufacture drugs for our own preclinical and clinical studies. We also use the facility to manufacture a product for Merck under a long-term contract.

Currently, we dedicate approximately 200 people to our manufacturing operations at these facilities.

In 1995, we entered into a long-term manufacturing agreement with Merck & Co., Inc. (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 will manufacture intermediate for Merck for six years, with certain minimum order quantities each year. The Merck Agreement is expected to extend to 2005 and may be terminated at any time by Merck upon payment of a termination fee. Merck agreed to reimburse 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 also agreed to pay an annual facility fee of $1.0 million, subject to annual adjustment for inflation, reimburse us for certain manufacturing costs, pay us a variable fee based on the quantity of intermediate supplied to Merck, and make certain additional payments. We recognized contract manufacturing revenue related to the Merck Agreement of $12.5 million in 2000, $10.0 million in 1999, and $9.1 million in 1998. We cannot assure you that we will be able to manufacture the Merck intermediate successfully for six years, or that Merck will not terminate the Merck Agreement. Either of these events could have a severe negative impact on our financial condition, results of operations, and cash flow.

Among the conditions for regulatory marketing approval of a drug 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 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. 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.

AXOKINE: There is substantial competition in the discovery and development of treatments for obesity. In addition, there are well-established and cost-effective prescription and over-the-counter treatments for this condition. For example, Hoffmann-La Roche and Knoll Pharmaceuticals already market well-established drugs for the treatment of obesity and Amgen and a number of other pharmaceutical companies are developing leptin and related molecules. Clinical trials of leptin are under way. Some of these drugs may offer competitive advantages over AXOKINE. For example, AXOKINE currently is available only in injectible form, while the currently available marketed drugs for the treatment of obesity are delivered in oral dosage forms, which generally are favored by patients over injectible drugs. 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.

CYTOKINE TRAPS: Similarly, marketed products for the treatment of rheumatoid arthritis and asthma are available as either oral or inhaled drugs, 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 drugs recently became available for these disease states. Examples include the TNF-antagonists Enbrel(R) (a registered trademark of Immunex Corporation) and Remicade(R) (a registered trademark of Centocor, Inc.) for rheumatoid arthritis and the leukotriene-modifier Singulair(R) (a registered trademark of Merck & Co., Inc.), as well as various inexpensive corticosteroid drugs for asthma.

VEGF TRAP: Many companies are developing drugs 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, cost, or form of delivery. Additionally, many of these developmental drugs may be at a more advanced stage of development than our product candidate.

NT-3: The treatment of constipating conditions is highly competitive, with a number of companies providing over-the-counter remedies and other competitors attempting to discover and develop improved over-the-counter or prescription treatments. These products may offer competitive advantages over our NT-3 product candidate in efficacy, side-effect profile, cost, or form of delivery.

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, Inc., 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 are considered important to the development of our business. We have been granted 55 U.S. patents and we have more than 100 pending applications. We are the exclusive or 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, Angiopoietins, and NT-3, 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 September 2000, Immunex Corporation filed a request with the European Patent Office seeking the declaration of an Opposition regarding our European patent relating to Cytokine Traps. This is a legal challenge to the validity and scope of our patent. Although we plan to defend the patent diligently, the scope of the patent may be adversely affected following the outcome of the Opposition.

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 cannot assure you that we will file any such applications or, if filed, that the patents will 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 our products or processes or pay licensing fees or cease certain activities to take into account patent right of third parties, causing additional unexpected costs and delays which may have a material adverse effect on us.

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 premarket 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 reasonably predicted.

Clinical trials are conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety, and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA. The phases of clinical studies may overlap. 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. We cannot assure you that the results of preclinical studies or early stage clinical trials will 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 products. 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 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, and 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, 2000, we had 491 full-time employees, 85 of whom 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.

ITEM 2. PROPERTIES

We conduct our research, development, manufacturing, and administrative activities at our own facilities. We currently lease approximately 145,600 square feet, and sublease approximately 9,100 square feet, of office, laboratory, and manufacturing space in Tarrytown, New York. The current monthly base rental charge is $261,565 plus additional rental charges for utilities, increases in taxes, and operating expenses, as defined. The lease and sublease expire on June 30, 2003 and December 31, 2002, respectively, and we have renewal options to extend the agreements for an additional five-year period. We own the Rensselaer facility, consisting of two buildings totaling approximately 104,000 square feet of research, manufacturing, office, and warehouse space.

As our activities expand, additional space may be required. In the future, we may locate, 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 September 2000, Immunex filed a request with the European Patent Office seeking the declaration of an Opposition regarding the scope of our European patent relating to Cytokine Traps. This is a legal challenge to the validity and scope of our patent. Although we plan to defend the patent diligently, the scope of the patent may be adversely affected following the outcome of the Opposition. In addition to this patent challenge, we have from time to time been subject to legal claims arising in connection with our business. While the ultimate results of the patent challenge and legal claims cannot be predicted with certainty, at December 31, 2000, there were no asserted claims against us which, in the opinion of management, if adversely decided, would have a material adverse effect on our financial position or results of operations.

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 28, 2001. 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. ..... | 48 | President, Chief Executive Officer, and Founder |
| George D. Yancopoulos, M.D., Ph.D. ..... | 41 | Executive Vice President and Chief Scientific Officer, and President, Regeneron Research Laboratories |
| Murray A. Goldberg..... | 56 | Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary |
| Randall G. Rupp, Ph.D. ..... | 53 | Senior Vice President, Manufacturing and Process Sciences |
| Neil Stahl, Ph.D. ..... | 44 | Senior Vice President, Preclinical Development and Biomolecular Science |

Information with regard to our directors is incorporated by reference to the Regeneron Pharmaceuticals, Inc. Proxy Statement to be filed in connection with solicitation of proxies for our Annual Meeting of Shareholders to be held on June 8, 2001.

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 bid quotations for the Common Stock as reported by The Nasdaq Stock Market. The bid prices reflect inter-dealer quotations without retail mark-ups, mark-downs, or commissions and do not necessarily represent actual transactions.

| | HIGH | LOW |
|---|---|---|
| 1999 | | |
| First Quarter | $10.125 | $ 6.375 |
| Second Quarter | 8.250 | 5.375 |
| Third Quarter | 9.938 | 6.875 |
| Fourth Quarter | 13.000 | 6.500 |
| 2000 | | |
| First Quarter | $57.375 | $10.953 |
| Second Quarter | 32.625 | 15.125 |
| Third Quarter | 36.250 | 24.625 |
| Fourth Quarter | 41.688 | 19.625 |

As of February 23, 2001, there were 608 shareholders of record of our Common Stock and 65 shareholders of record of our Class A Stock. The closing bid price for the Common Stock on that date was $32.00.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future. In addition, under the terms of our financing from the New York State Urban Development Corporation for the purchase and renovation of our Rensselaer facility, we are not permitted to declare or pay cash dividends to our shareholders.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2000, 1999, and 1998 and at December 31, 2000 and 1999 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, 1997 and 1996 and at December 31, 1998, 1997, and 1996 are derived from our audited financial statements not included in this report.

| | YEAR ENDED DECEMBER 31, | | | | |
|---|---|---|---|---|---|
| | 2000 | 1999 | 1998 | 1997 | 1996 |
| | (IN THOUSANDS, EXCEPT PER SHARE DATA) | | | | |
| STATEMENT OF OPERATIONS DATA | | | | | |
| Revenues | | | | | |
| Contract research and development | $ 36,478 | $ 24,539 | $19,714 | $ 17,400 | $ 17,303 |
| Research progress payments | 6,200 | | 9,500 | 5,000 | |
| Contract manufacturing | 16,598 | 9,960 | 9,113 | 4,458 | 2,451 |
| | 59,276 | 34,499 | 38,327 | 26,858 | 19,754 |
| Expenses | | | | | |
| Research and development | 56,256 | 44,940 | 37,047 | 27,770 | 28,269 |
| General and administrative | 8,309 | 6,355 | 5,838 | 5,765 | 5,880 |
| Depreciation and amortization | 4,421 | 3,426 | 3,019 | 4,389 | 6,084 |
| Contract manufacturing | 15,566 | 3,612 | 5,002 | 2,617 | 1,115 |
| | 84,552 | 58,333 | 50,906 | 40,541 | 41,348 |
| Loss from operations | (25,276) | (23,834) | (12,579) | (13,683) | (21,594) |
| Other income (expense) | | | | | |
| Investment income | 8,480 | 5,207 | 6,866 | 6,242 | 4,360 |
| Loss in Amgen-Regeneron Partners | (4,575) | (4,159) | (2,484) | (3,403) | (14,250) |
| Interest expense | (281) | (284) | (428) | (735) | (940) |
| | 3,624 | 764 | 3,954 | 2,104 | (10,830) |
| Net loss before cumulative effect of a change in accounting principle | (21,652) | (23,070) | (8,625) | (11,579) | (32,424) |
| Cumulative effect of adopting Staff Accounting Bulletin 101 ("SAB 101") | (1,563) | | | | |
| Net loss | $(23,215) | $(23,070) | $(8,625) | $(11,579) | $(32,424) |
| Net loss per share, basic and diluted: | | | | | |
| Net loss before cumulative effect of a change in accounting principle | $ (0.62) | $ (0.74) | $ (0.28) | $ (0.40) | $ (1.33) |
| Cumulative effect of adopting SAB 101 | (0.04) | | | | |
| Net loss per share | $ (0.66) | $ (0.74) | $ (0.28) | $ (0.40) | $ (1.33) |

| | AT DECEMBER 31, | | | | |
|---|---|---|---|---|---|
| | 2000 | 1999 | 1998 | 1997 | 1996 |
| | (IN THOUSANDS) | | | | |
| BALANCE SHEET DATA | | | | | |
| Cash, cash equivalents, and marketable securities | $154,370 | $93,599 | $113,530 | $128,041 | $97,028 |
| Total assets | 208,274 | 136,999 | 156,915 | 168,380 | 137,582 |
| Capital lease obligations and note payable, long-term portion | 2,069 | 2,731 | 3,066 | 3,752 | 5,148 |
| Stockholders' equity | 182,130 | 109,532 | 131,227 | 138,897 | 106,931 |

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

GENERAL

We are a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic drugs for the treatment of serious medical conditions. Our product pipeline includes product candidates for the treatment of obesity, rheumatoid arthritis and other inflammatory conditions, cancer and related disorders, allergies, asthma, and other diseases and disorders. Since inception we have not generated sales or any profits from the commercialization of any of our product candidates.

Below is a summary of our leading clinical programs, as well as several product candidates that are expected to enter clinical trials over the next two years. We retain sole ownership and marketing rights for each of these programs and currently are developing them independent of any corporate partners.

- AXOKINE(R): Acts on the brain region regulating food intake and energy expenditure and is being developed for the treatment of obesity. In November 2000, we announced the preliminary results of a twelve-week Phase II dose-ranging trial of AXOKINE in 170 severely obese patients. In the trial, AXOKINE was generally well tolerated and patients treated with AXOKINE showed medically meaningful and statistically significant weight loss compared to those receiving placebo. Subject to discussions with the FDA, we intend to initiate Phase III testing of AXOKINE in severely obese patients in mid-2001.

- PEGYLATED AXOKINE: Chemically modified version of AXOKINE that is being developed as a more potent, longer-acting form of the protein. Pegylated AXOKINE currently is in late-stage preclinical development and we anticipate initiating a Phase I clinical trial in mid-2001.

- INTERLEUKIN-1 CYTOKINE TRAP (IL-1 TRAP): Protein-based antagonist for the interleukin-1 (called IL-1) cytokine. IL-1 is thought to play a major role in rheumatoid arthritis and other inflammatory diseases. In December 2000, we initiated a Phase I study to assess the safety and tolerability of the IL-1 Trap in patients with rheumatoid arthritis. We expect the study to be completed in the second half of 2001.

- INTERLEUKIN-4/INTERLEUKIN-13 CYTOKINE TRAP (IL-4/IL-13 TRAP): Protein-based antagonist for the interleukin-4 and interleukin-13 (called IL-4 and IL-13) cytokines which are thought to play a major role in diseases such as asthma, allergic disorders, and other inflammatory diseases. We expect to initiate a Phase I clinical trial of a dual IL-4/IL-13 Trap for asthma/allergy-related conditions in late 2001.

- VEGF TRAP: Protein-based antagonist to Vascular Endothelial Growth Factor (called VEGF, also known as Vascular Permeability Factor or VPF), which is required for the growth of blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leak. The VEGF Trap is expected to enter Phase I clinical trials in mid-2001.

- ANGIOPOIETINS: A new family of growth factors that act specifically on the endothelium cells that line blood vessels and may be useful for growing blood vessels in diseased hearts and other tissues with decreased blood flow and for repairing blood vessel leaks that cause swelling and edema in many different diseases such as stroke, diabetic retinopathy, and inflammatory diseases. Selected Angiopoietins, including engineered forms of these growth factors are in preclinical development.

In addition to the above programs which we are conducting solely on our own, we have formed collaborations to advance other research and development efforts. We are conducting research with Procter & Gamble in muscle diseases and other fields. We are also collaborating with Medarex to discover, develop, and commercialize certain human antibodies as therapeutics. In partnership with Amgen, we are conducting clinical trials with NT-3 for the treatment of constipating conditions. In all of these research collaborations, we retain 50% of the commercialization rights.

We have not received revenue from the commercialization 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 our research and development efforts and obtaining regulatory approval from the FDA or 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 noncompetitive or obsolete.

From inception on January 8, 1988 through December 31, 2000, we had a cumulative loss of $223.5 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. Our activities may expand over time and may require additional resources and our operating losses may 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 timing of certain expenses and on the progress of our research and development efforts.

RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2000 AND 1999. Our total revenue increased to $59.3 million in 2000 from $34.5 million in 1999. Contract research and development revenue increased to $36.5 million in 2000 from $24.5 million in 1999. Contract research and development revenue from Procter & Gamble increased to $28.3 million in 2000 from $20.8 million in 1999 as increased revenue under the companies' collaboration agreement more than offset the termination of Procter & Gamble payments related to AXOKINE research in the third quarter of 1999 after Procter & Gamble returned the product rights to AXOKINE to us. Revenue from Amgen-Regeneron Partners increased to $6.2 million in 2000 from $3.6 million in 1999 due to increased clinical trial activity on BDNF and NT-3. In 2000, research progress payments consisted of two non-recurring payments totaling $3.5 million from Procter & Gamble related to its long-term collaboration agreement with us and a payment of $3.0 million (reduced by $0.3 million of Japanese withholding tax) from Sumitomo Pharmaceuticals related to the development of BDNF in Japan. Contract manufacturing revenue increased to $16.6 million in 2000, compared to $10.0 million in 1999. Contract manufacturing revenue related to a long-term agreement with Merck to manufacture a vaccine intermediate at the Company's Rensselaer, New York facility increased to $12.5 million in 2000 from $10.0 million in 1999. In 1999, Merck revenue was primarily compensation for services rendered related to preparing for commercial production, which began in the fourth quarter of 1999. In 2000, Merck revenue primarily consisted of payments related to commercial production. In addition, contract manufacturing revenue in 2000 included $4.1 million related to the manufacture of clinical supplies of BDNF for Sumitomo Pharmaceuticals in connection with a research and development agreement.

Our total operating expenses increased to $84.6 million in 2000 from $58.3 million in 1999. Research and development expenses increased to $56.3 million in 2000 from $44.9 million in 1999, primarily as a result of higher staffing and increased activity in our preclinical and clinical research programs. Research and development expenses were 67% of total operating expenses in 2000, compared to 77% in 1999. General and administrative expenses increased to $8.3 million in 2000 from $6.4 million in 1999 due to higher administrative staffing and related occupancy costs, and an increase in patent expenses related primarily to our acquiring the patent rights to CNTF from Amgen. Depreciation and amortization expense increased to $4.4 million in 2000 from $3.4 million in 1999, as a result of improvements to, and purchases of equipment for, the Company's facilities in Tarrytown, New York and Rensselaer, New York. Contract manufacturing expenses increased to $15.6 million in 2000 from $3.6 million in 1999 due primarily to costs associated with initiating commercial production at our Rensselaer facility of both a vaccine intermediate for Merck and clinical supplies of BDNF for Sumitomo Pharmaceuticals.

Our other income, net, increased to $3.6 million in 2000 from $0.8 million in 1999. Investment income in 2000 increased to $8.5 million from $5.2 million in 1999 due to interest earned on the proceeds of our public offering in April 2000 and our sale of Common Stock to Procter & Gamble in August 2000. The loss in Amgen-Regeneron Partners increased to $4.6 million in 2000 from $4.2 million in 1999 as a result of the partnership's increased clinical trial activity on BDNF and NT-3. Interest expense was $0.3 million in both 2000 and 1999.

During the fourth quarter of 2000, we changed our method of accounting for revenue recognition to conform with the guidance provided by Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, (SAB 101), effective as of January 1, 2000. The cumulative effect of adopting SAB 101 as of January 1, 2000 was to increase our net loss by $1.6 million, or $0.04 per share, with a corresponding increase to deferred revenue which will be recognized in future periods. The SAB 101 adjustment relates to a portion of a 1989 payment received from Sumitomo Chemical in consideration for a fifteen year limited right of first negotiation to license up to three of our product candidates in Japan. In 2000, we recognized contract research and development revenue of $0.4 million that was included in the cumulative effect adjustment as of January 1, 2000.

Our net loss in 2000 was $23.2 million, or $0.66 per share (basic and diluted), compared to a net loss of $23.1 million, or $0.74 per share (basic and diluted), in 1999.

YEARS ENDED DECEMBER 31, 1999 AND 1998. Our total revenue decreased to $34.5 million in 1999 from $38.3 million in 1998, as higher contract research and development revenue and higher contract manufacturing revenue were more than offset by non-recurring research progress payments. Contract research and development revenue increased to $24.5 million in 1999 from $19.7 million in 1998, as revenue from Procter & Gamble increased to $20.8 million in 1999 from $13.5 million in 1998. Effective in the third quarter of 1999, research support under our collaboration agreement with Procter & Gamble increased from $1.1 million per quarter to $7.0 million per quarter. However, Procter & Gamble payments related to AXOKINE research declined in 1999 as AXOKINE progressed into clinical trials and because Procter & Gamble stopped funding AXOKINE research in the third quarter of 1999 after it returned the product rights to AXOKINE to us. We also earned nominal revenue in 1999 from Sumitomo Pharmaceuticals, compared to $4.3 million in 1998, as research payments under our research and development agreement with Sumitomo Pharmaceuticals ended in 1998 and because we did not supply any BDNF to Sumitomo Pharmaceuticals in 1999 for preclinical and clinical use. In addition, in 1998 we received non-recurring research progress payments totaling $9.5 million, consisting of $5.0 million from Sumitomo Pharmaceuticals related to the development of BDNF in Japan (reduced by $0.5 million of Japanese withholding tax) and $5.0 million from Procter & Gamble in connection with the AXOKINE collaboration. Contract manufacturing revenue related to the long-term agreement with Merck increased to $10.0 million in 1999, compared to $9.1 million in 1998, as a result of increased activity in preparation for manufacturing Merck's vaccine intermediate.

Our total operating expenses increased to $58.3 million in 1999 from $50.9 million in 1998. Research and development expenses increased to $44.9 million in 1999 from $37.0 million in 1998, primarily as a result of higher staffing and increased activity in our preclinical and clinical research programs. Research and development expenses were 77% of total operating expenses in 1999, compared to 73% in 1998. General and administrative expenses increased to $6.4 million in 1999 from $5.8 million in 1998 due primarily to an increase in patent expenses related to U.S. and foreign patent filings and higher administrative staffing. Depreciation and amortization expense increased to $3.4 million in 1999 from $3.0 million in 1998, resulting primarily from improvements made to our leased research facilities and offices in Tarrytown, New York. Contract manufacturing expenses, which relate directly to our manufacturing agreement with Merck, decreased to $3.6 million in 1999 from $5.0 million in 1998. During the fourth quarter of 1999, the United States Food and Drug Administration approved Regeneron as a contract manufacturer for the Merck intermediate, and we commenced commercial production and began capitalizing manufacturing costs into inventory. This resulted in a decrease in contract manufacturing expenses, as we discontinued the expensing of pre-commercial production costs and began capitalizing inventory costs.

Our other income, net, decreased to $0.8 million in 1999 from $4.0 million in 1998. Investment income in 1999 decreased to $5.2 million from $6.9 million in 1998 due mainly to lower levels of interest-bearing investments as we funded our operations. The loss in Amgen-Regeneron Partners increased to $4.2 million in 1999 from $2.5 million in 1998 as a result of the partnership's increased clinical trial activity on BDNF and NT-3. Interest expense was $0.3 million in 1999 and $0.4 million in 1998.

Our net loss in 1999 was $23.1 million, or $0.74 per share (basic and diluted), compared to a net loss of $8.6 million, or $0.28 per share (basic and diluted), in 1998.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception in 1988, we have financed our operations primarily through private placements and public offerings of our equity securities, revenue earned under our agreements with Amgen, Sumitomo Chemical, Sumitomo Pharmaceuticals, Merck, and Procter & Gamble, and investment income.

In May 1997, we entered into a long-term collaboration agreement with Procter and Gamble. Procter & Gamble agreed over the first five years of the 1997 collaboration to purchase up to $60.0 million in Regeneron equity, of which $42.9 million was purchased in June 1997 and $17.1 million was purchased in August 2000, and provide funding in support of our research efforts related to the collaboration, of which we have received $44.9 million through December 31, 2000. In August 2000, Procter & Gamble made two non-recurring research progress payments to us totaling $3.5 million. In addition, in August 2000, we and Procter & Gamble agreed through a binding memorandum of understanding to enter into a new long-term collaboration agreement, replacing the companies' 1997 agreement. The new agreement will extend Procter & Gamble's obligation to fund Regeneron's research through December 2005, with no further research obligations by either party thereafter, and focus the companies' collaborative research on therapeutic areas that are of particular interest to Procter & Gamble. Under the original 1997 collaboration agreement, research support from Procter & Gamble would have been $6.8 million per quarter, before adjustments for future inflation, for the period from July 2000 through June 2002. Under the new agreement, beginning in the first quarter of 2001, research support from Procter & Gamble will be $2.5 million per quarter, before adjustments for future inflation, through December 2005.

Our activities relating to BDNF and NT-3, as agreed upon by Amgen and us, are being compensated by Amgen-Regeneron Partners for services rendered, and we recognize these amounts as revenue. In January 2001, Amgen-Regeneron Partners discontinued all development of BDNF for the potential treatment of ALS. We and Amgen fund Amgen-Regeneron Partners through capital contributions, and must make equal payments in order to maintain equal ownership and equal sharing of any profits or losses from the partnership. Our aggregate capital contribution to Amgen-Regeneron Partners from the partnership's inception in June 1993 through December 31, 2000 was $56.2 million. We expect that our capital contributions for 2001 will total at least $2.2 million. These contributions could increase or decrease, depending upon, among other things, the nature and cost of ongoing and additional NT-3 studies that Amgen-Regeneron Partners may conduct, the outcomes of those studies, and costs associated with the discontinuation of the BDNF studies.

In connection with our agreement to collaborate with Sumitomo Pharmaceuticals in the research and development of BDNF in Japan, Sumitomo Pharmaceuticals paid us $25.0 million through December 1997. We also received research progress payments from Sumitomo Pharmaceuticals of $5.0 million (reduced by $0.5 million of Japanese withholding tax) in August 1998 and $3.0 million (reduced by $0.3 million Japanese withholding tax) in April 2000. In addition, Sumitomo Pharmaceuticals has paid us $27.9 million through December 31, 2000 in connection with supplying BDNF for preclinical and clinical use and is obligated to pay us another $3.9 million for materials shipped at the end of 2000. In light of the recent BDNF clinical trial results, it is likely that Sumitomo Pharmaceuticals will exercise its discretionary right to terminate the license with us for BDNF and, other than amounts outstanding at December 31, 2000 and any wind-down costs, we would not expect to receive further payments from Sumitomo Pharmaceuticals for research progress payments, contract research and development, or contract manufacturing.

We invested $6.5 million in 2000, $5.9 million in 1999, and $3.3 million in 1998 in property, plant, and equipment. In addition, we leased $1.1 million of equipment in 1999. In connection with the purchase and renovation of our Rensselaer facility, we obtained financing of $2.0 million from the New York State Urban Development Corporation in 1994, of which $1.5 million is outstanding. Under the terms of this UDC financing, we are not permitted to declare or pay dividends on our equity securities.

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. In September 2000, Immunex filed a request with the European Patent Office seeking the declaration of an Opposition regarding our European patent relating to Cytokine Traps.

This is a legal challenge to the validity and scope of our patent and we may incur substantial expenses in defending the patent.

As of December 31, 2000, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. We may seek additional funding through, among other things, future collaboration agreements and public or private financing. We cannot assure you that additional financing will be available to us or, if available, that it will be available on acceptable terms. In April 2000, we completed a public offering of 2.6 million shares of Common Stock at a price of $29.75 per share and received proceeds, after commissions and expenses, of $72.9 million. In August 2000, we sold 573,630 shares of Common Stock to Procter & Gamble at a price of $29.75 per share and received total proceeds of $17.1 million. The sale of stock to Procter & Gamble was made pursuant to a 1997 securities purchase agreement. In January 2001, we filed a registration statement with the Securities and Exchange Commission (SEC) for a proposed offering of 4.0 million shares of our Common Stock, with an additional 600,000 shares available to cover an over-allotment option. We cannot assure you that our proposed offering will be declared effective or, if declared effective, how many shares of our Common Stock will be sold, what the stock's selling price per share will be, or what our net proceeds will be from the offering.

At December 31, 2000, we had $154.4 million in cash, cash equivalents, and marketable securities. We expect to incur substantial funding requirements for, among other things, research and development activities (including preclinical and clinical testing), expansion and validation of manufacturing facilities, and the acquisition of equipment. We currently anticipate that for 2001 and 2002, approximately 50-70% of our expenditures will be directed toward the preclinical and clinical development of product candidates, including AXOKINE, pegylated AXOKINE, IL-1 Trap, IL-4/IL-13 Trap, VEGF Trap, NT-3, and the Angiopoietins; approximately 10-30% of our expenditures will cover our basic research activities; approximately 5-15% of our expenditures will be directed toward the continued development of our novel technology platforms, including potential efforts to commercialize these technologies; and the remainder of our expenditures will be for general corporate purposes, including capital expenditures and working capital. The amount we need to fund operations and the allocation of our resources 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 arrangements (including those with Procter & Gamble, Medarex, Emisphere, and Amgen). We believe that our existing capital resources will enable us to meet operating needs through the third quarter of 2002. 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 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.

## FUTURE IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS

There are a number of recently issued accounting standards, including Statement of Financial Accounting Standards No. 133, Accounting for Derivative Financial Instruments and for Hedging Activities, which we will be required to adopt in future periods. Our management believes that the future adoption of these accounting standards will not have a material impact on our financial statements.

## FACTORS THAT MAY AFFECT FUTURE OPERATING RESULTS

We caution stockholders and potential investors that the following important factors, among others, in some cases have affected, and in the future could affect, our actual results and could cause our actual results to differ materially from those expressed in any forward-looking statements made by, or on behalf of, us. The statements under this caption are intended to serve as cautionary statements within the meaning of the Private Securities Litigation Reform Act of 1995. The following information is not intended to limit in any way the

characterization of other statements or information under other captions as cautionary statements for such purpose:

- Delay, difficulty, or failure of our research and development programs to produce product candidates that are scientifically or commercially appropriate for further development by us or others.

- Cancellation or termination of material collaborative or licensing agreements (including in particular, but not limited to, those with Procter & Gamble and Amgen) and the resulting loss of research or other funding could have a material adverse effect on us and our operations. A change of control of one or more of our material collaborators or licensees could also have a material adverse effect on us.

- Delay, difficulty, or failure of a clinical trial of any of our product candidates. A clinical trial can fail or be delayed as a result of many causes, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining patients, 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.

- In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our drug 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 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 successfully completed. Patients who have been treated with AXOKINE and NT-3 have developed antibodies, though we have no information that indicates that these antibodies are neutralizing antibodies.

- Delay, difficulty, or failure in obtaining regulatory approval (including approval of our facilities for production) for our products, including delays or difficulties in development because of insufficient proof of safety or efficacy.

- Increased and irregular costs of development, manufacture, regulatory approval, sales, and marketing associated with the introduction of products in the late stage of development.

- Competitive or market factors that may cause use of our products to be limited or otherwise fail to achieve broad acceptance.

- The ability to obtain, maintain, and prosecute intellectual property rights and the cost of acquiring in-process technology and other intellectual property rights, either by license, collaboration, or purchase of another entity.

- Difficulties or high costs of obtaining adequate financing to fund the cost of developing product candidates.

- Amount and rate of growth of our general and administrative expenses, and the impact of unusual charges resulting from our ongoing evaluation of our business strategies and organizational structure.

- Failure of corporate partners to develop or commercialize successfully our products or to retain and expand the markets served by the commercial collaborations; conflicts of interest, priorities, and commercial strategies which may arise between our corporate partners and us.

- Delays or difficulties in developing and acquiring production technology and technical and managerial personnel to manufacture novel biotechnology product in commercial quantities at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

- Difficulties in obtaining key raw materials and supplies for the manufacture of our product candidates.

- The costs and other effects of legal and administrative cases and proceedings (whether civil, such as product- or employment-related, or environmental, or criminal), settlements, and investigations; developments or assertions by or against us relating to intellectual property rights and licenses; the issuance and use of patents and proprietary technology by us and our competitors, including the possible negative effect on our ability to develop, manufacture, and sell our products in circumstances where we are unable to obtain licenses to patents which may be required for our products.

- Underutilization of our existing or new manufacturing facilities or of any facility expansions, resulting in inefficiencies and higher costs; start-up costs, inefficiencies, delays, and increased depreciation costs in connection with the start of production in new plants and expansions.

- Health care reform, including reductions or changes in reimbursement available for prescription medications or other reforms.

- Difficulties in attracting and retaining key personnel.

As our scientific efforts lead to potentially promising new directions, both outside of recombinant protein therapies and into conditions or diseases outside of our current areas of experience and expertise, we will require additional internal expertise or external collaborations in areas in which we currently do not have substantial resources and personnel.

To date, we have received revenues from (1) our licensees and collaborators for research and development efforts, (2) Merck and Sumitomo Pharmaceuticals for contract manufacturing, and (3) investment income. We may not continue to receive these revenues from our licensees, collaborators, or contract manufacturing customers. In the absence of revenues from the commercialization of our product candidates or other sources, our losses will continue as we conduct our research and development activities. Our activities may expand over time and may require additional resources, and our operating losses may 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 timing of certain expenses and on the progress of our research and development efforts. We do not know if we will ever have an approved product or achieve significant revenues or profitable operations. We do not expect to receive any revenue from the commercialization of our product candidates for several years and we intend to continue to invest significantly in our research and development activities. Even if we do successfully develop products that can be marketed and sold commercially, we will need to generate significant revenue from products to achieve and maintain profitability.

Most drug research and development programs never lead to the development of commercially successful products. Only a small minority of all research and development programs ultimately result in commercially successful drugs. We are attempting to develop drugs for human therapeutic uses, and our research and development activities may not be successful and none of our potential product candidates may ever complete clinical trials. Even if clinical trials demonstrate safety and efficacy of our product candidates 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 ability to successfully develop, manufacture, and market our product candidates. 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.

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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements required by this item are included herein as exhibits and listed under Item 14.(A)1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

## PART III

### ITEM 10. DIRECTORS AND OFFICERS OF THE REGISTRANT

Information with respect to directors and executive officers is incorporated by reference to the material captioned "Election of Directors," "Executive Officers of the Registrant," and "Compliance with Section 16(b) of the Securities Exchange Act of 1934" in the Regeneron Pharmaceuticals, Inc. Proxy Statement to be filed in connection with solicitation of proxies for our Annual Meeting of Shareholders to be held on June 8, 2001.

### ITEM 11. EXECUTIVE COMPENSATION

The information called for by this item is incorporated by reference to the material captioned "Executive Compensation" and "Election of Directors" in the Regeneron Pharmaceuticals, Inc. Proxy Statement to be filed in connection with solicitation of proxies for our Annual Meeting of Shareholders to be held on June 8, 2001.

### 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 "Security Ownership of Management" and "Security Ownership of Certain Beneficial Owners" in the Regeneron Pharmaceuticals, Inc. Proxy Statement to be filed in connection with solicitation of proxies for our Annual Meeting of Shareholders to be held on June 8, 2001.

### 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 the Regeneron Pharmaceuticals, Inc. Proxy Statement to be filed in connection with solicitation of proxies for our Annual Meeting of Shareholders to be held on June 8, 2001.

## PART IV

### ITEM 14. 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(f) | By-Laws of the Company, currently in effect (amended as of January 22, 1995). |
| 10.1(b) | Certificate of Amendment of the Restated Certificate of Incorporation of Regeneron Pharmaceuticals, Inc., as of October 18, 1996. |
| 10.2(c)* | Technology Development Agreement dated as of March 20, 1989, between the Company and Sumitomo Chemical Company, Limited. |

| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 10.3(c)* | Neurotrophic Factor Agreement (License Agreement) dated as of May 10, 1988, between the Company and Max Planck Institute fur Psychiatric. |
| 10.4(c)* | Collaboration Agreement dated August 31, 1990, between the Company and Amgen Inc. |
| 10.5(c) | 1990 Amended and Restated Long-Term Incentive Plan. |
| 10.6(d)* | License Agreement dated as of October 7, 1992, between the Company and The Regents of the University of California. |
| 10.7(e)* | 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(h) | Warrant Agreement dated as of June 27, 1996, between the Company and Medtronic, Inc. |
| 10.12(h) | Registration Rights Agreement dated as of June 27, 1996, between the Company and Medtronic, Inc. |
| 10.13(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. |
| 10.14(j) | Stock Purchase Agreement dated as of December 11, 1996, between the Company and Procter & Gamble Pharmaceuticals, Inc. |
| 10.15(j) | Registration Rights Agreement dated as of December 11, 1996, between the Company and Procter & Gamble Pharmaceuticals, Inc. |
| 10.16(k) | Securities Purchase Agreement dated as of May 13, 1997, between the Company and The Procter & Gamble Company. |
| 10.17(k) | Warrant Agreement dated as of May 13, 1997, between the Company and The Procter & Gamble Company. |
| 10.18(k) | Registration Rights Agreement dated as of May 13, 1997, between the Company and The Procter & Gamble Company. |
| 10.19(k)* | Multi-Project Collaboration Agreement dated as of May 13, 1997, between the Company and The Procter & Gamble Company. |
| 10.20(l)* | First Amendment to the Multi-Project Collaboration Agreement dated May 13, 1997, between the Company and The Procter & Gamble Company, dated as of September 29, 1997. |
| 10.21(m) | Employment Agreement, dated as of February 12, 1998 between the Company and Leonard S. Schleifer, M.D., Ph.D. |
| 23.1 | Consent of PricewaterhouseCoopers LLP, Independent Accountants. |
| 23.2 | Consent of Ernst & Young LLP, Independent Auditors. |
| 24 | Power of Attorney. Included in the signature page of this Registration Statement. |

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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-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 1996, filed November 5, 1996.

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

(d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 1992, filed March 30, 1993.

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

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

(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 Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 1997, filed November 10, 1997.

(m) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 1997, filed March 26, 1998.

* 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

On March 29, 2000, we filed a report on Form 8-K regarding the fact that we issued a press release entitled "Regeneron Initiates Phase II Obesity Clinical Trial", a copy of which was included as an exhibit to that filing.

On April 4, 2000, we filed a report on Form 8-K covering the filing of the underwriting agreement related to our sale of 2.6 million shares of Common Stock with total proceeds to us after commissions but before expenses of $73.5 million.

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

Dated: New York, New York
March 2, 2001

KNOW ALL PERSONS BY THESE PRESENTS, that I the undersigned, a director of Regeneron Pharmaceuticals, Inc., a New York corporation, do hereby constitute and appoint Leonard S. Schleifer, Murray A. Goldberg and Stuart Kolinski, and each of them severally to be my true and lawful attorneys-in-fact and agents each acting alone with full power of substitution and revocation, to sign my name to the Regeneron Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2000 and any and all amendments to such Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, and I hereby grant unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done, as full as to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following person on behalf of the registrant in the capacities indicated on March 2, 2001.

| SIGNATURE | TITLE |
|---|---|
| /s/ LEONARD S. SCHLEIFER<br>Leonard S. Schleifer, M.D., Ph.D. | President, Chief Executive Officer, and Director (Principal Executive Officer) |
| /s/ MURRAY A. GOLDBERG<br>Murray A. Goldberg | Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer) |
| /s/ DOUGLAS S. MCCORKLE<br>Douglas S. McCorkle | Controller and Assistant Treasurer (Principal Accounting Officer) |
| /s/ P. ROY VAGELOS<br>P. Roy Vagelos, M.D. | Chairman of the Board |
| *<br>Charles A. Baker | Director |
| Michael S. Brown, M.D. | Director |

| SIGNATURE | TITLE |
| --- | --- |
| * | Director |
| Alfred G. Gilman, M.D., Ph.D. | |
| * | Director |
| Joseph L. Goldstein, M.D. | |
| | Director |
| Fred A. Middleton | |
| * | Director |
| Eric M. Shooter, Ph.D. | |
| | Director |
| George L. Sing | |

*By: /s/ STUART A. KOLINSKI
Stuart A. Kolinski, Esq.
(Attorney-in-Fact)

REGENERON PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

## REPORT OF INDEPENDENT ACCOUNTANTS

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, 2000 and 1999, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, in conformity with generally accepted accounting principles 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, as of December 31, 2000 and 1999 and for each of the three years in the period ended December 31, 2000. The Company's investment in the Partnership is accounted for in accordance with the equity method of accounting. At December 31, 2000, its investment constitutes less than one percent of the Company's assets. At December 31, 1999, its obligation to the Partnership constituted less than two percent of the Company's liabilities. For the years ended December 31, 2000, 1999 and 1998, the Company recorded its pro rata share of the Partnership's net loss of approximately $4.6 million, $4.2 million, and $2.5 million, respectively. 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 generally accepted auditing standards in the United States of America which 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, 2000, the Company changed its method of accounting for revenue recognition, effective January 1, 2000.

PricewaterhouseCoopers LLP

New York, New York
February 7, 2001

REGENERON PHARMACEUTICALS, INC.

BALANCE SHEETS
DECEMBER 31, 2000 AND 1999

| | 2000 | 1999 |
|---|---|---|
| | (IN THOUSANDS, EXCEPT SHARE DATA) | |
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | $ 30,978 | $ 23,697 |
| Marketable securities | 86,634 | 42,463 |
| Receivable due from The Procter & Gamble Company | 6,907 | |
| Receivable due from Merck & Co., Inc. | 1,447 | |
| Receivable due from Amgen-Regeneron Partners | 1,604 | 473 |
| Receivable due from Sumitomo Pharmaceuticals Company, Ltd. | 3,877 | 151 |
| Prepaid expenses and other current assets | 780 | 1,708 |
| Inventory | 1,915 | 4,552 |
| Total current assets | 134,142 | 73,044 |
| Marketable securities | 36,758 | 27,439 |
| Investment in Amgen-Regeneron Partners | 267 | |
| Property, plant, and equipment, at cost, net of accumulated depreciation and amortization | 36,934 | 36,298 |
| Other assets | 173 | 218 |
| Total assets | $ 208,274 | $ 136,999 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable and accrued expenses | $ 9,446 | $ 6,551 |
| Deferred revenue, current portion | 3,728 | 4,686 |
| Due to Merck & Co., Inc. | | 334 |
| Due to Amgen-Regeneron Partners | | 300 |
| Capital lease obligations, current portion | 545 | 1,380 |
| Note payable, current portion | 67 | 68 |
| Total current liabilities | 13,786 | 13,319 |
| Deferred revenue | 9,995 | 11,130 |
| Capital lease obligations | 603 | 1,204 |
| Note payable | 1,466 | 1,527 |
| Other liabilities | 294 | 287 |
| 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; 2,612,845 shares issued and outstanding in 2000 3,605,133 shares issued and outstanding in 1999 | 3 | 4 |
| Common Stock, $.001 par value; 60,000,000 shares authorized; 34,197,104 shares issued and outstanding in 2000 27,817,636 shares issued and outstanding in 1999 | 34 | 28 |
| Additional paid-in capital | 406,391 | 310,296 |
| Unearned compensation | (1,314) | |
| Accumulated deficit | (223,518) | (200,303) |
| Accumulated other comprehensive income (loss) | 534 | (493) |
| Total stockholders' equity | 182,130 | 109,532 |
| Total liabilities and stockholders' equity | $ 208,274 | $ 136,999 |

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

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2000, 1999, AND 1998

| | 2000 | 1999 | 1998 |
|---|---|---|---|
| | (IN THOUSANDS, EXCEPT PER SHARE DATA) | | |
| Revenues | | | |
| Contract research and development | $ 36,478 | $ 24,539 | $ 19,714 |
| Research progress payments | 6,200 | | 9,500 |
| Contract manufacturing | 16,598 | 9,960 | 9,113 |
| | 59,276 | 34,499 | 38,327 |
| Expenses | | | |
| Research and development | 56,256 | 44,940 | 37,047 |
| General and administrative | 8,309 | 6,355 | 5,838 |
| Depreciation and amortization | 4,421 | 3,426 | 3,019 |
| Contract manufacturing | 15,566 | 3,612 | 5,002 |
| | 84,552 | 58,333 | 50,906 |
| Loss from operations | (25,276) | (23,834) | (12,579) |
| Other income, net | | | |
| Investment income | 8,480 | 5,207 | 6,866 |
| Loss in Amgen-Regeneron Partners | (4,575) | (4,159) | (2,484) |
| Interest expense | (281) | (284) | (428) |
| | 3,624 | 764 | 3,954 |
| Net loss before cumulative effect of a change in accounting principle | (21,652) | (23,070) | (8,625) |
| Cumulative effect of adopting Staff Accounting Bulletin 101 ("SAB 101") | (1,563) | | |
| Net loss | $(23,215) | $(23,070) | $ (8,625) |
| Net loss per share amounts, basic and diluted: | | | |
| Net loss before cumulative effect of a change in accounting principle | $ (0.62) | $ (0.74) | $ (0.28) |
| Cumulative effect of adopting SAB 101 | (0.04) | | |
| Net loss | $ (0.66) | $ (0.74) | $ (0.28) |
| Pro forma amounts assuming SAB 101 is applied retroactively: | | | |
| Net loss | | $(22,699) | $ (8,254) |
| Net loss per share, basic and diluted | | $ (0.73) | $ (0.27) |

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

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2000, 1999, AND 1998

| | CLASS A STOCK | | COMMON STOCK | | ADDITIONAL PAID-IN | UNEARNED | ACCUMULATED |
|---|---|---|---|---|---|---|---|
| | SHARES | AMOUNT | SHARES | AMOUNT | CAPITAL | COMPENSATION | DEFICIT |
| | | | | (IN THOUSANDS) | | | |
| BALANCE, DECEMBER 31, 1997 | 4,118 | $ 4 | 26,805 | $27 | $308,109 | $ (720) | $(168,608) |
| Amortization of unearned compensation | | | | | | 360 | |
| Issuance of Common Stock in connection with exercise of stock options | | | 95 | | 452 | | |
| Conversion of Class A Stock to Common Stock | (487) | | 487 | | | | |
| Net loss, 1998 | | | | | | | (8,625) |
| Change in net unrealized gain on marketable securities | | | | | | | |
| BALANCE, DECEMBER 31, 1998 | 3,631 | 4 | 27,387 | 27 | 308,561 | (360) | (177,233) |
| Amortization of unearned compensation | | | | | | 360 | |
| Issuance of Common Stock in connection with exercise of stock options | | | 367 | 1 | 1,427 | | |
| Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution | | | 38 | | 308 | | |
| Conversion of Class A Stock to Common Stock | (26) | | 26 | | | | |
| Net loss, 1999 | | | | | | | (23,070) |
| Change in net unrealized gain/loss on marketable securities | | | | | | | |
| BALANCE, DECEMBER 31, 1999 | 3,605 | 4 | 27,818 | 28 | 310,296 | | (200,303) |

| | ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS) | TOTAL STOCKHOLDERS' EQUITY | COMPREHENSIVE LOSS |
|---|---|---|---|
| | | (IN THOUSANDS) | |
| BALANCE, DECEMBER 31, 1997 | $ 85 | $138,897 | |
| Amortization of unearned compensation | | 360 | |
| Issuance of Common Stock in connection with exercise of stock options | | 452 | |
| Conversion of Class A Stock to Common Stock | | | |
| Net loss, 1998 | | (8,625) | $ (8,625) |
| Change in net unrealized gain on marketable securities | 143 | 143 | 143 |
| BALANCE, DECEMBER 31, 1998 | 228 | 131,227 | $ (8,482) |
| | | | ======== |
| Amortization of unearned compensation | | 360 | |
| Issuance of Common Stock in connection with exercise of stock options | | 1,428 | |
| Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution | | 308 | |
| Conversion of Class A Stock to Common Stock | | | |
| Net loss, 1999 | | (23,070) | $(23,070) |
| Change in net unrealized gain/loss on marketable securities | (721) | (721) | (721) |
| BALANCE, DECEMBER 31, 1999 | (493) | 109,532 | $(23,791) |
| | | | ======== |

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY -- (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2000, 1999, AND 1998

| | CLASS A STOCK | | COMMON STOCK | | ADDITIONAL PAID-IN | UNEARNED | ACCUMULATED |
|---|---|---|---|---|---|---|---|
| | SHARES | AMOUNT | SHARES | AMOUNT | CAPITAL | COMPENSATION | DEFICIT |
| | | | | (IN THOUSANDS) | | | |
| Issuance of Common Stock in a public offering at $29.75 per share | | | 2,600 | 3 | 77,347 | | |
| Cost associated with issuance of equity securities | | | | | (4,496) | | |
| Issuance of Common Stock in connection with exercise of stock options | | | 707 | 1 | 4,445 | | |
| Net issuance of Common Stock to Amgen Inc. in connection with a cashless exercise of warrants | | | 478 | | | | |
| Issuance of Common Stock to The Procter & Gamble Company | | | 574 | | 17,065 | | |
| Net issuance of Common Stock to The Procter & Gamble Company in connection with a cashless exercise of warrants | | | 939 | 1 | (1) | | |
| Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution | | | 54 | | 421 | | |
| Conversion of Class A Stock to Common Stock | (992) | (1) | 992 | 1 | | | |
| Issuance of restricted Common Stock under Long-Term Incentive Plan | | | 35 | | 1,314 | (1,314) | |
| Net loss, 2000 | | | | | | | (23,215) |
| Change in net unrealized gain/loss on marketable securities | | | | | | | |
| BALANCE, DECEMBER 31, 2000 | 2,613 | $ 3 | 34,197 | $34 | $406,391 | $(1,314) | $(223,518) |

| | ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS) | TOTAL STOCKHOLDERS' EQUITY | COMPREHENSIVE LOSS |
|---|---|---|---|
| | | (IN THOUSANDS) | |
| Issuance of Common Stock in a public offering at $29.75 per share | | 77,350 | |
| Cost associated with issuance of equity securities | | (4,496) | |
| Issuance of Common Stock in connection with exercise of stock options | | 4,446 | |
| Net issuance of Common Stock to Amgen Inc. in connection with a cashless exercise of warrants | | | |
| Issuance of Common Stock to The Procter & Gamble Company | | 17,065 | |
| Net issuance of Common Stock to The Procter & Gamble Company in connection with a cashless exercise of warrants | | | |
| Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution | | 421 | |
| Conversion of Class A Stock to Common Stock | | | |
| Issuance of restricted Common Stock under Long-Term Incentive Plan | | | |
| Net loss, 2000 | | (23,215) | $(23,215) |
| Change in net unrealized gain/loss on marketable securities | 1,027 | 1,027 | 1,027 |
| BALANCE, DECEMBER 31, 2000 | $ 534 | $182,130 | $(22,188) |

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

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2000, 1999, AND 1998

| | 2000 | 1999 | 1998 |
|---|---|---|---|
| | | (IN THOUSANDS) | |
| Cash flows from operating activities | | | |
| Net loss | $(23,215) | $(23,070) | $(8,625) |
| Adjustments to reconcile net loss to net cash used in operating activities | | | |
| Loss in Amgen-Regeneron Partners | 4,575 | 4,159 | 2,484 |
| Depreciation and amortization | 4,421 | 3,426 | 3,019 |
| Stock issued in consideration for services rendered | | 360 | 360 |
| Cumulative effect of a change in accounting principle | 1,563 | | |
| Changes in assets and liabilities | | | |
| (Increase) decrease in amounts due from The Procter & Gamble Company | (6,907) | 3,169 | (766) |
| (Increase) decrease in amounts due from Merck & Co., Inc | (1,781) | 1,999 | 42 |
| (Increase) decrease in amounts due from Amgen-Regeneron Partners | (1,131) | 236 | (353) |
| (Increase) decrease in amounts due from Sumitomo Pharmaceuticals Co., Ltd | (3,726) | 16 | 1,948 |
| Increase in investment in Amgen-Regeneron Partners | (5,142) | (768) | (5,211) |
| Increase in prepaid expenses and other assets | (309) | (232) | (704) |
| Decrease (increase) in inventory | 4,050 | (4,033) | (196) |
| (Decrease) increase in deferred revenue | (3,656) | 143 | (3,310) |
| Increase in accounts payable, accrued expenses, and other liabilities | 3,348 | 1,085 | 1,094 |
| Total adjustments | (4,695) | 9,560 | (1,593) |
| Net cash used in operating activities | (27,910) | (13,510) | (10,218) |
| Cash flows from investing activities | | | |
| Purchases of marketable securities | (104,898) | (60,067) | (87,973) |
| Sales of marketable securities | 53,717 | 82,892 | 93,479 |
| Capital expenditures | (6,495) | (5,682) | (3,049) |
| Net cash (used in) provided by investing activities | (57,676) | 17,143 | 2,457 |
| Cash flows from financing activities | | | |
| Net proceeds from the issuance of stock | 94,365 | 1,428 | 452 |
| Principal payments on note payable | (62) | (79) | (74) |
| Capital lease payments | (1,436) | (1,042) | (1,781) |
| Net cash provided by (used in) financing activities | 92,867 | 307 | (1,403) |
| Net increase (decrease) in cash and cash equivalents | 7,281 | 3,940 | (9,164) |
| Cash and cash equivalents at beginning of period | 23,697 | 19,757 | 28,921 |
| Cash and cash equivalents at end of period | $ 30,978 | $ 23,697 | $19,757 |
| Supplemental disclosure of cash flow information | | | |
| Cash paid for interest | $ 274 | $ 265 | $ 388 |

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

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2000, 1999, AND 1998
(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 |

### 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

On January 1, 2000, the Company changed its method of accounting for revenue recognition to conform with the guidance provided by Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements ("SAB 101"). Effective January 1, 2000, the Company recognizes revenue from contract research and development and research progress payments as services are performed, provided a contractual arrangement exists, the contract price is fixed or determinable, and the collection of the resulting receivable is probable. In situations where the Company receives payment in advance of the performance of services, such amounts are deferred and recognized as revenue as the related services are performed. Non-refundable fees, including payments for services, up-front licensing fees, technology fees, and research progress payments (collectively, "Non-refundable Fees"), are recognized as revenue based on the percentage of costs incurred to date, estimated costs to complete, and total expected contract revenue. However, revenue recognized is limited to the amount of Non-refundable Fees received. Non-refundable Fees received in consideration for

granting collaborators the right to license product candidates developed by the Company are recognized as revenue on a straight-line basis over the term of the underlying agreements.

Prior to January 1, 2000, the Company recognized revenue as described above, except that certain Non-refundable Fees were recognized as revenue when there were no additional contractual services to be provided or costs to be incurred by the Company in connection with the Non-refundable Fee.

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 will be recognized in future periods, of which $0.4 million was included in contract research and development revenue in 2000. 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 9b). The effect of income taxes on the cumulative effect adjustment was immaterial.

Prior period financial statements have not been restated to apply SAB 101 retroactively; however, the pro forma amounts included in the Statement of Operations show the net loss and per share net loss assuming the Company had retroactively applied SAB 101 to all prior periods.

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.

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.

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 diluted net loss per share for all periods presented excludes the number of shares issuable upon 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 15.

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 not likely.

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, 2000, 1999, and 1998 have been included in the Statements of Stockholders' Equity.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities, and receivables from The Procter & Gamble Company, Amgen-Regeneron Partners, Sumitomo Pharmaceuticals Company, Ltd., 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. In January 2001, Amgen-Regeneron Partners, a partnership equally owned by the Company and Amgen Inc., discontinued all clinical development of one product following notification that the product did not provide a therapeutic advantage to patients in clinical trials (see Note 9a). The Company has incurred net losses and negative cash flows from operations since its inception, and revenues to date have been limited to payments for research from four collaborators and for contract manufacturing from two pharmaceutical companies and investment income (see Notes 9 and 10). 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 which impose various obligations on the Company. If Regeneron fails to comply with these requirements, licensors may have the right to terminate our licenses.

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.

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.

Disclosures required by Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation ("SFAS No. 123"), including pro forma operating results had the Company prepared its financial statements in accordance with the fair value based method of accounting for stock-based compensation, have been included in Note 11.

Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Capital lease obligations of $1.1 million and $0.4 million were incurred when the Company acquired new equipment in 1999 and 1998, respectively.

During January 1995, the Company issued 600,000 restricted shares of Common Stock ("Restricted Shares"), in consideration for $0.3 million and services to be rendered, in connection with an agreement with the Chairman of the Board of Directors. The difference between the fair market value of the Common Stock on the date the agreement was signed and the purchase price of the Restricted Shares was $1.8 million which the Company has recognized as compensation expense on a pro rata basis over five years as the restriction on the Restricted Shares lapsed.

Included in accounts payable and accrued expenses at December 31, 2000, 1999, and 1998 were $0.7 million, $0.7 million, and $0.5 million of capital expenditures, respectively.

Included in accounts payable and accrued expenses at December 31, 1999 and 1998 were $0.4 million and $0.3 million, respectively, of accrued 401(k) Savings Plan contribution expense. During January 2000 and 1999, the Company contributed 54,003 and 37,653 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at December 31, 2000, 1999, and 1998 were $2.5 million, $1.3 million, and $1.6 million of accrued interest income, respectively.

Reclassifications

Certain reclassifications have been made to the financial statements for 1999 and 1998 to conform with the current year's presentation.

Future Impact of Recently Issued Accounting Standards

There are a number of recently issued accounting standards, including Statement of Financial Accounting Standards No. 133, Accounting for Derivative Financial Instruments and for Hedging Activities, which the Company will be required to adopt in future periods. Management believes that the future adoption of these accounting standards will not have a material impact on the Company's financial statements.

3. MARKETABLE SECURITIES

The Company considers its 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.

(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, 2000 and 1999:

| | AMORTIZED COST BASIS | FAIR VALUE | UNREALIZED HOLDING | | |
|---|---|---|---|---|---|
| | | | GAINS | (LOSSES) | NET |
| AT DECEMBER 31, 2000 | | | | | |
| Maturities within one year | | | | | |
| Corporate debt securities | $ 31,155 | $ 31,196 | $ 44 | $ (3) | $ 41 |
| U.S. Government securities | 55,218 | 55,438 | 254 | (34) | 220 |
| | 86,373 | 86,634 | 298 | (37) | 261 |
| Maturities between one and three years | | | | | |
| Corporate debt securities | 6,302 | 6,357 | 55 | | 55 |
| U.S. Government securities | 30,183 | 30,401 | 256 | (38) | 218 |
| | 36,485 | 36,758 | 311 | (38) | 273 |
| | $122,858 | $123,392 | $609 | $ (75) | $ 534 |
| AT DECEMBER 31, 1999 | | | | | |
| Maturities within one year | | | | | |
| Corporate debt securities | $ 28,366 | $ 28,343 | $ 8 | $ (31) | $ (23) |
| U.S. Government securities | 14,184 | 14,120 | | (64) | (64) |
| | 42,550 | 42,463 | 8 | (95) | (87) |
| Maturities between one and three years | | | | | |
| Corporate debt securities | 10,337 | 10,264 | | (73) | (73) |
| U.S. Government securities | 17,508 | 17,175 | | (333) | (333) |
| | 27,845 | 27,439 | | (406) | (406) |
| | $ 70,395 | $ 69,902 | $ 8 | $(501) | $(493) |

Realized gains and losses are included as a component of investment income. For the years ended December 31, 2000, 1999, and 1998, 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.

4. INVENTORIES

Inventory balances at December 31, 2000 consist primarily of raw materials and other direct and indirect costs associated with the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement ("Merck Costs") (see Note 10). At December 31, 1999, inventory balances consist of Merck Costs and raw materials and other direct and indirect costs associated with the production of brain-derived neurotrophic factor ("BDNF") for Sumitomo Pharmaceuticals Company, Ltd. under a research and development agreement (see Note 9b).

(DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)

Inventories as of December 31, 2000 and 1999 consist of the following:

| | 2000 | 1999 |
|---|---|---|
| Raw materials | $ 535(1) | $1,042 |
| Work-in process | 53(2) | 165(3) |
| Finished products | 1,327 | 3,345 |
| | $1,915 | $4,552 |

- ---------------
(1) Net of reserves of $0.3 million.

(2) Net of reserves of $0.8 million.

(3) Net of reserves of $0.7 million.

5. PROPERTY, PLANT, AND EQUIPMENT

Property, plant, and equipment as of December 31, 2000 and 1999 consist of the following:

| | 2000 | 1999 |
|---|---|---|
| Land | $ 475 | $ 475 |
| Building and improvements | 32,182 | 30,562 |
| Leasehold improvements | 11,689 | 10,364 |
| Construction in progress | | 1,119 |
| Laboratory and other equipment | 25,113 | 21,017 |
| Furniture, fixtures, and computer equipment | 3,672 | 3,124 |
| | 73,131 | 66,661 |
| Less, accumulated depreciation and amortization | (36,197) | (30,363) |
| | $ 36,934 | $ 36,298 |

Depreciation and amortization expense on property, plant, and equipment amounted to $5.8 million, $3.7 million, and $3.0 million, for the years ended December 31, 2000, 1999, and 1998, respectively. Included in these amounts were $1.4 million and $0.3 million of depreciation and amortization expense related to contract manufacturing that was capitalized into inventory for the years ended December 31, 2000 and 1999, respectively.

6. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses as of December 31, 2000 and 1999 consist of the following:

| | 2000 | 1999 |
|---|---|---|
| Accounts payable | $2,590 | $2,642 |
| Accrued payroll and related costs | 2,630 | 1,977 |
| Accrued clinical trial expense | 2,308 | 1,005 |
| Accrued expenses, other | 1,918 | 643 |
| Deferred compensation | | 284 |
| | $9,446 | $6,551 |

7. 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 60 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 January 1995, the Company entered into an agreement with the Chairman of the Board. As partial consideration for services to be rendered, the agreement provided for the Company to sell the Chairman 600,000 restricted shares of Common Stock ("Restricted Shares"), in consideration for $0.3 million, and to grant 285,000 stock options. The Restricted Shares were nontransferable with such restriction lapsing ratably over a five-year period. In accordance with generally accepted accounting principles, the Company recognized compensation expense for the difference between the fair market value of the Common Stock on the date the agreement was signed and the purchase price of the Restricted Shares on a pro rata basis over five years as the restriction on the Restricted Shares lapsed. The unearned compensation was fully amortized at December 31, 1999. For the years ended December 31, 1999 and 1998, the Company recognized compensation expense of $0.4 million in each year. The stock options, which were issued under the Company's Amended and Restated 1990 Long-Term Incentive Plan, entitle the holder to purchase an equal number of shares of Common Stock at a per share price of $3.50, the fair market value of the Common Stock on the date of grant. The options vested over a five year period.

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, 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

(DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)

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.

On April 4, 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.

As of December 31, 2000, a former collaborator holds 107,400 warrants to purchase shares of the Company's Common Stock. The warrants have an exercise price of $21.72 per share, are fully exercisable, expire on June 26, 2001, and are subject to anti-dilution provisions and other defined adjustments.

8. COMMITMENTS AND CONTINGENCIES

a. Operating Leases

The Company leases and subleases laboratory and office space under operating lease agreements which expire through June 30, 2003. The leases provide for base rent plus additional rental charges for utilities, increases in taxes and operating expenses, as defined. The Company has renewal options to extend their leases for an additional five years.

The Company leases certain laboratory and office equipment under operating leases which expire at various times through 2003.

At December 31, 2000, the future minimum noncancelable lease commitments under operating leases were as follows:

| DECEMBER 31, | LABORATORY AND OFFICE SPACE | EQUIPMENT | TOTAL |
|---|---|---|---|
| 2001 | $3,172 | $ 89 | $3,261 |
| 2002 | 3,139 | 49 | 3,188 |
| 2003 | 1,456 | 7 | 1,463 |
| | $7,767 | $145 | $7,912 |

Rent expense under operating leases was:

| YEAR ENDING DECEMBER 31, | LABORATORY AND OFFICE SPACE | EQUIPMENT | TOTAL |
|---|---|---|---|
| 2000 | $2,898 | $186 | $3,084 |
| 1999 | 2,826 | 156 | 2,982 |
| 1998 | 2,466 | 194 | 2,660 |

In addition to its rent expense for laboratory and office space, the Company paid additional rental charges for utilities, real estate taxes, and operating expenses of $2.1 million, $1.0 million, and $0.1 million for the years ended December 31, 2000, 1999, and 1998, respectively.

b. Capital Leases

The Company leases equipment under noncancelable capital leases. Lease terms are generally four years after which, for certain leases, the Company may extend the lease for eight additional months at defined monthly payments, or is required to purchase the equipment at amounts defined by the agreements.

(DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)

As of December 31, 2000, minimum rental payments under all capital leases, including payments to acquire leased equipment, were as follows:

| YEAR ENDING DECEMBER 31, | MINIMUM RENTAL PAYMENTS |
|---|---|
| 2001 | $ 643 |
| 2002 | 464 |
| 2003 | 153 |
| | 1,260 |
| Less, amounts representing interest | (112) |
| Present value of net minimum capital lease payments | $1,148 |

Leased equipment and building improvements included in property, plant, and equipment was $2.4 million and $5.3 million at December 31, 2000 and 1999, respectively; related accumulated depreciation was $1.4 million and $3.1 million for the same respective periods.

In connection with one capital lease, the Company entered into a 38-month equipment maintenance agreement which requires equal quarterly payments which commenced during the second quarter of 2000. The total amount due over the term of the agreement is $0.2 million.

c. Note Payable

In 1994, the Company borrowed $2.0 million from the New York State Urban Development Corporation ("NYS UDC"). The terms of the note provide for monthly payments of principal and interest through December 2014. Outstanding borrowings accrue interest at an effective interest rate of approximately 6.4%. The note is collateralized by a first mortgage on the Company's land, building, and improvements in Rensselaer, New York (book value at December 31, 2000 was $26.4 million). The note also has various financial covenants which include a minimum ratio of current assets over current liabilities, as defined, and a minimum level of tangible net worth, as defined, of $35.0 million. In addition, the Company is not permitted to declare or pay dividends to its stockholders. The provisions of the note require the Company to meet certain defined levels of employment; otherwise, the interest rate on outstanding borrowings will increase to 2.0% above the prime rate (as defined) until the defined levels of employment are attained. As of January 1, 1998, 1999, 2000, and 2001, the Company had not met the defined levels of employment; however, for the years ended December 31, 1998, 1999, and 2000, the NYS UDC elected either not to increase the interest rate, or to only increase the rate by a nominal amount, the effects of which were not material to the financial statements. The estimated fair value of the Company's note payable to the NYS UDC at December 31, 2000 was $1.7 million. The fair value was estimated based on the current rate offered to the Company for debt with similar terms.

Principal payments under the note during each of the next five years, and thereafter, are as follows:

| | |
|---|---|
| 2001 | $ 67 |
| 2002 | 67 |
| 2003 | 68 |
| 2004 | 74 |
| 2005 | 81 |
| Thereafter | 1,176 |
| | $1,533 |

d. 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 scientific collaborators, universities, or consultants. The Company also has research collaborations with Medarex, Inc. and Emisphere Technologies, Inc., and a license and supply agreement with Shearwater Corporation. 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 0.5% 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 $0.6 million, $0.6 million, and $0.7 million for the years ended December 31, 2000, 1999, and 1998, respectively.

9. COLLABORATION AGREEMENTS

a. 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") in the United States. 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. Since the Partnership's inception, the Company has contributed capital to the Partnership of $56.2 million. In 2000, 1999, and 1998, the Company recognized its share of the Partnership net loss in the amounts of $4.6 million, $4.2 million, and $2.5 million, respectively, which represents 50% of the total Partnership net loss. As of December 31, 2000, the Company continues to be an equal partner in the Partnership.

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 years ended December 31, 2000, 1999, and 1998 totaled $6.2 million, $3.6 million, and $1.9 million, respectively. In addition, the Amgen Agreement contains a provision whereby the Company will receive defined amounts ("Research Progress Payments") from Amgen if and when each Product reaches certain levels of development.

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 continues to develop NT-3.

(DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)

Selected financial data of the Partnership as of December 31, 2000 and 1999 and for the years ended December 31, 2000, 1999 and 1998, are as follows:

| BALANCE SHEET DATA | 2000 | 1999 |
|---|---|---|
| Cash and cash equivalents | $5,169 | $3,700 |
| Accounts payable and accrued expenses due to partners(1) | 4,635 | 4,300 |
| Partners' capital accounts | | |
| Amgen | 267 | (300) |
| The Company | 267 | (300) |

(1) At December 31, 2000 and 1999, includes $1.6 million and $0.5 million due the Company, respectively.

| STATEMENT OF OPERATIONS DATA | 2000 | 1999 | 1998 |
|---|---|---|---|
| Interest income | $ 347 | $ 366 | $ 316 |
| Total expenses(2) | (9,497) | (8,684) | (5,284) |
| Net loss | $(9,150) | $(8,318) | $(4,968) |

(2) Includes $6.2 million, $3.6 million, and $1.9 million related to services provided by the Company in 2000, 1999, and 1998, respectively.

During 1990, Amgen purchased 767,656 shares of Series D convertible preferred stock for $15.0 million. Such shares converted into 788,766 shares of Class A Stock in April 1991 at the time of the Company's initial public offering. During April 1996, Amgen purchased from the Company 3.0 million shares of Common Stock and 700,000 warrants for $48.0 million. During March 2000, in accordance with the terms of their warrant agreement, as amended, Amgen exercised their 700,000 warrants with an exercise price of $16.00 per share. As consideration for the exercise price, Amgen tendered 221,958 shares of the Company's Common Stock, which had an aggregate fair market value at the time of exercise equal to the aggregate exercise price of the warrants. The shares of Common Stock delivered to the Company by Amgen were retired upon receipt.

During 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.

b. 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. Sumitomo Pharmaceuticals paid the Company $13.0 million in June 1994 and agreed to pay $3.0 million annually on each January 1 from 1995 to 1998 (inclusive) for research payments. In connection with the R&D Agreement, Sumitomo Pharmaceuticals also makes 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 2000, 1999, and 1998, Regeneron recognized contract research and development revenue from Sumitomo Pharmaceuticals of $0.8 million, $0.1 million, and $4.3 million, respectively. In addition, the Company recognized contract manufacturing revenue of $4.1 million in 2000 for supplying BDNF to Sumitomo Pharmaceuticals.

In connection with the R&D Agreement, in March 1998, Sumitomo Pharmaceuticals initiated a Phase I clinical trial of BDNF in Japan and, in August 1998, signed a license agreement with the Company for the development of BDNF in Japan. Pursuant to the license agreement, Sumitomo Pharmaceuticals made research progress payments of $5.0 million (reduced by $0.5 million of Japanese withholding tax) in August 1998 and $3.0 million (reduced by $0.3 million of Japanese withholding tax) in April 2000. The amounts received in 2000 and 1998 are included in research progress payments.

Sumitomo Pharmaceuticals has the discretionary right to terminate the license for BDNF with the Company. If Sumitomo Pharmaceuticals were to exercise this discretionary right, in light of the January 2001 BDNF clinical trial results (see Note 9a), the Company would not receive any further revenue from Sumitomo Pharmaceuticals for research progress payments, contract research and development, or contract manufacturing.

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 1), the Company is recognizing this payment as revenue on a straight-line basis over the term of the TDA.

In addition, Sumitomo Chemical also entered into a stock purchase agreement whereby it purchased, for $4.4 million, 885,062 shares of Class C Preferred Stock. Such shares converted into 909,401 shares of Class A Stock in April 1991 at the time of the Company's initial public offering.

c. Glaxo Wellcome plc

During 1993, the Company entered into a collaborative research agreement with Glaxo Wellcome plc ("Glaxo"). Products that are developed by the joint efforts of Glaxo and the Company will be commercialized by one or more equally owned joint ventures. Glaxo also purchased 500,000 shares of the Company's Common Stock at a price of $20 per share.

d. The Procter & Gamble Company

In May 1997, the Company entered into a ten-year multi-project collaboration agreement with The Procter & Gamble Company ("P&G") to discover, develop, and commercialize pharmaceutical products (the "P&G Agreement"), as well as a securities purchase agreement and other agreements. The P&G Agreement expanded and superseded a collaboration agreement that the Company and Procter & Gamble Pharmaceuticals, Inc. ("P&G Pharmaceuticals") entered into in December 1996 to jointly discover and develop therapeutics for muscle diseases and disorders. P&G agreed over the first five years of the various agreements to provide funding for Regeneron's research efforts related to the collaboration, of which the Company had received $44.9 million as of December 31, 2000, and to purchase up to $60.0 million in Regeneron equity.

In September 1997, the Company and P&G amended the P&G Agreement to include AXOKINE(R) second generation ciliary neurotrophic factor and related molecules. P&G paid the Company research progress payments of $5.0 million in 1997 and $5.0 million in 1998 upon the achievement of defined milestones related to AXOKINE. During the third quarter of 1999, P&G returned to the Company the product rights to AXOKINE and ended related research support for the Company's AXOKINE program. However, Procter & Gamble will be entitled to receive a small royalty on any sales of AXOKINE.

In August 2000, P&G made two research progress payments to Regeneron totaling $3.5 million. In addition, in August 2000, the Company and P&G agreed through a binding memorandum of understanding to enter into a new collaboration agreement, replacing the P&G Agreement. The new agreement extends

P&G's obligation to fund Regeneron research through December 2005, with no further research obligations by either party thereafter, and focuses their collaborative research on therapeutic areas that are of particular interest to P&G. Under the new agreement, P&G's research funding from 2001 through 2005 is expected to total approximately $50 million (before adjustments for future inflation). 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. P&G and the Company have divided rights to programs from the P&G Agreement that are no longer part of the companies' collaboration.

Contract research and development revenue related to the P&G Agreement, including payments from P&G related to AXOKINE, was $28.3 million, $20.8 million, and $13.5 million in 2000, 1999, and 1998, respectively. At December 31, 2000 and 1998, the P&G contract research revenue receivable was $6.9 million and $3.2 million, respectively. There was no P&G receivable balance at December 31, 1999.

In December 1996, P&G Pharmaceuticals paid $10.0 million and in March 1997 received 800,000 shares of the Company's Common Stock. In June 1997, P&G completed the purchase of 4.35 million shares of the Company's Common Stock at $9.87 per share for a total of $42.9 million and received five year warrants to purchase an additional 1.45 million shares of the Company's stock at $9.87 per share. In August 2000, P&G purchased 573,630 shares of the Company's Common Stock at $29.75 per share for a total of $17.1 million. In addition, in August 2000, in accordance with the terms of their warrant agreement, as amended, P&G exercised 1.45 million warrants at $9.87 per share. As consideration for the exercise price, P&G 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 P&G acquired an additional 938,875 shares of the Company's Common Stock. The 511,125 shares of Common Stock delivered to the Company by P&G were retired upon receipt.

10. 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. The Merck Agreement is expected to extend into 2005 and may be terminated at any time by Merck upon the payment by Merck 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 as Intermediate is shipped to Merck.

In 2000, 1999, and 1998, Merck contract manufacturing revenue includes $0.7 million, $7.1 million, and $8.0 million of Internal Costs, respectively, and $2.3 million, $1.9 million, and $1.1 million of Facility Fee and Additional Payments, respectively. In addition, contract manufacturing revenue includes previously deferred Capital Costs of $2.9 million in 2000 and $0.4 million in 1999, Manufacturing Payments of $6.6 million in 2000, and other variable fees of $0.6 million in 1999 related to the manufacture of Intermediate prior to commencement of the Production Period.

11. 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 provides for the issuance of up to 6,000,000 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, (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 or 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 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 Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("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

(DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)

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.

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 1998, 1999, and 2000, 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, 1998, 1999, and 2000 was 1,994,848, 2,366,180, and 2,533,662, respectively, with weighted average exercise prices of $7.49, $8.00, and $8.31, respectively.

| | NUMBER OF SHARES | WEIGHTED-AVERAGE EXERCISE PRICE |
|---|---|---|
| Stock options outstanding at December 31, 1997..... | 3,616,436 | $ 8.00 |
| 1998: | | |
| Stock options granted..... | 1,006,240 | $ 8.61 |
| Stock options canceled..... | (353,888) | $ 9.62 |
| Stock options exercised..... | (95,163) | $ 4.75 |
| Stock options outstanding at December 31, 1998..... | 4,173,625 | $ 8.08 |
| 1999: | | |
| Stock options granted..... | 2,112,345 | $ 8.08 |
| Stock options canceled..... | (96,704) | $10.14 |
| Stock options exercised..... | (367,470) | $ 3.89 |
| Stock options outstanding at December 31, 1999..... | 5,821,796 | $ 8.29 |
| 2000: | | |
| Stock options granted..... | 2,633,850 | $36.55 |
| Stock options canceled..... | (267,531) | $ 9.23 |
| Stock options exercised..... | (757,056) | $ 7.28 |
| Stock options outstanding at December 31, 2000..... | 7,431,059 | $18.37 |

(DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)

The following table summarizes stock option information as of December 31, 2000:

| | 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 $7.41 | 1,794,954 | 5.61 | $ 5.86 | 1,132,335 | $ 5.03 |
| $7.44 to $8.77 | 1,588,847 | 8.23 | $ 8.55 | 385,879 | $ 8.46 |
| $8.78 to $14.75 | 1,360,178 | 5.21 | $11.21 | 951,448 | $11.55 |
| $14.94 to $37.53 | 730,980 | 8.95 | $25.88 | 64,000 | $17.39 |
| $37.78 | 1,613,354 | 9.97 | $37.78 | | |
| $38.97 to $51.56 | 342,746 | 9.18 | $50.53 | | |
| $3.00 to $51.56 | 7,431,059 | 7.54 | $18.37 | 2,533,662 | $ 8.31 |

The following table summarizes the pro forma operating results of the Company 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. Since option grants awarded during 2000, 1999, and 1998 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.

| | 2000 | 1999 | 1998 |
|---|---|---|---|
| Pro forma net loss | $(33,131) | $(27,739) | $(13,114) |
| Pro forma net loss per share, basic and diluted | $ (0.95) | $ (0.89) | $ (0.42) |

For the purpose of the above pro forma calculation, the fair value of each option granted from the Incentive Plans during 2000, 1999, and 1998 was estimated on the date of grant using the Black-Scholes option-pricing model. The weighted-average fair value of the options granted during 2000, 1999, and 1998 was $24.35, $5.27, and $5.84, respectively. The following table summarizes the assumptions used in computing the fair value of option grants.

| | 2000 | 1999 | 1998 |
|---|---|---|---|
| Expected volatility | 75% | 65% | 85% |
| Expected lives | 3.5 years | 3.5 years | 3 years |
| Dividend yield | 0% | 0% | 0% |
| Risk-free interest rate | 5.90%-6.00% | 6.02%-6.26% | 5.30%-5.44% |

During December 2000, 34,785 shares 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 2001. In accordance with generally accepted accounting principles, the Company recorded unearned compensation of $1.3 million within Stockholders' Equity 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 the Restricted Stock award and will be expensed, on a pro rata basis, over the two year period that the restriction on these shares lapses.

For the years ended December 31, 1999 and 1998, the Company recognized compensation expense from stock-based awards of $0.4 million in each year (see Note 7). No stock-based compensation expense was recognized during the year ended December 31, 2000.

(DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)

As of December 31, 2000, there were 3,774,615 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, 2000, there were 44,246 shares available for future grants under the Plan.

12. 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 $0.5 million in 2000, $0.4 million in 1999, and $0.3 million in 1998; such amounts were accrued as liabilities at December 31, 2000, 1999 and 1998, respectively. During the first quarter of 2001, 2000, and 1999, the Company contributed 17,484, 54,003, and 37,653 shares, respectively, of Common Stock to the Savings Plan in satisfaction of these obligations.

13. INCOME TAXES

There is no provision (benefit) for federal or state income taxes, since the Company has incurred operating losses since inception and has established a valuation allowance equal to the total deferred tax asset.

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2000 and 1999 was as follows:

| | 2000 | 1999 |
|---|---|---|
| Deferred tax assets | | |
| Net operating loss carry-forward | $ 86,935 | $ 74,043 |
| Fixed assets | 1,159 | 1,240 |
| Deferred revenue | 5,620 | 4,865 |
| Research and experimental tax credit carry-forward | 14,101 | 10,309 |
| Other | 2,497 | 1,586 |
| Valuation allowance | (110,312) | (92,043) |

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 35% 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, 2000, the Company had available for tax purposes unused net operating loss carry-forwards of $212.3 million which will expire in various years from 2004 to 2020. The Company's research and experimental tax credit carry-forwards expire in various years from 2004 to 2020. Future changes in the ownership of the Company could limit the future utilization of these net operating loss and tax credit carry-forwards, as defined by the Federal and state tax codes.

## 14. LITIGATION

In September 2000, Immunex Corporation filed a request with the European Patent Office seeking the declaration of an Opposition regarding the scope of the Company's European patent relating to Cytokine Traps. This is a legal challenge to the validity and scope of the Company's patent. Although the Company plans to defend the patent diligently, the scope of the patent may be adversely affected following the outcome of the Opposition. In addition to this patent challenge, the Company, from time to time, has been subject to legal claims arising in connection with its business. While the ultimate results of the patent challenge and legal claims cannot be predicted with certainty, at December 31, 2000 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.

## 15. 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 2000, 1999, and 1998, 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 |
|---|---|---|---|
| 2000: | | | |
| Basic and Diluted | $(23,215) | 34,950 | $(0.66) |
| 1999: | | | |
| Basic and Diluted | $(23,070) | 31,308 | $(0.74) |
| 1998: | | | |
| Basic and Diluted | $ (8,625) | 30,992 | $(0.28) |

Options and warrants which have been excluded from the diluted per share amounts because their effect would have been antidilutive include the following:

| | DECEMBER 31, | | |
|---|---|---|---|
| | 2000 | 1999 | 1998 |
| Weighted Average Number, in thousands | 6,819 | 7,146 | 6,429 |
| Weighted Average Exercise Price | $11.95 | $ 9.31 | $ 9.57 |

## 16. SEGMENT INFORMATION

Beginning in 2000, the Company's operations have been principally managed in two business segments: research and development, and contract manufacturing.

(DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)

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 the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements.

CONTRACT MANUFACTURING: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2000, the Company produced Intermediate under the Merck Agreement (see Note 10) and BDNF for Sumitomo Pharmaceuticals under the R&D Agreement (see Note 9b).

Prior to 2000, the Company's operations were all conducted under the research & development business segment.

The table below presents information about reported segments for the year ended December 31, 2000:

| | RESEARCH & DEVELOPMENT | CONTRACT MANUFACTURING | RECONCILING ITEMS | TOTAL |
|---|---|---|---|---|
| Revenues | $ 42,678 | $16,598 | $ 8,480(1) | $ 67,756 |
| Loss in Amgen-Regeneron Partners | 4,575 | | | 4,575 |
| Depreciation and amortization | 4,421 | (2) | | 4,421 |
| Interest expense | 195 | 86 | | 281 |
| Net (loss) income | (32,641) | 946 | 8,480 | (23,215) |
| Capital expenditures | 6,404 | 65 | | 6,469 |
| Total assets | 18,336 | 34,615 | 155,323(3) | 208,274 |

- ---------------
(1) Represents investment income.

(2) Depreciation and amortization related to contract manufacturing was capitalized into inventory.

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

17. UNAUDITED QUARTERLY RESULTS

Effective January 1, 2000, the Company changed its method of accounting for revenue recognition to conform with the guidance provided by SAB 101 (see Note 2). 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 will be recognized in future periods, of which $0.4 million was included in contract research and development revenue in 2000. The Company's unaudited financial results for the quarters ended March 31, June 30, and September 30, 2000 have been restated to apply SAB 101 retroactively, resulting in the recognition of additional revenue of $0.1 million per quarter.

(DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)

Summarized quarterly financial data for the years ended December 31, 2000 and 1999 are displayed in the following tables.

| | FIRST QUARTER ENDED MARCH 31, 2000 (UNAUDITED)} | |
|---|---|---|
| | AS PREVIOUSLY REPORTED | AS RESTATED |
| Revenues | $11,724 | $11,817 |
| Net loss before cumulative effect of change in accounting principle | $(7,318) | $(7,225) |
| Cumulative effect of adopting SAB 101 | | (1,563) |
| Net loss | $(7,318) | $(8,788) |
| Net loss per share, basic and diluted: | | |
| Net loss before cumulative effect of change in accounting principle | $ (0.23) | $ (0.23) |
| Cumulative effect of adopting SAB 101 | | (0.04) |
| Net loss per share | $ (0.23) | $ (0.27) |

| | SECOND QUARTER ENDED JUNE 30, 2000 (UNAUDITED) | | THIRD QUARTER ENDED SEPTEMBER 30, 2000 (UNAUDITED) | | FOURTH QUARTER ENDED DECEMBER 31, 2000 (UNAUDITED) |
|---|---|---|---|---|---|
| | AS PREVIOUSLY REPORTED | AS RESTATED | AS PREVIOUSLY REPORTED | AS RESTATED | |
| Revenues | $16,667 | $16,760 | $17,436 | $17,529 | $21,650 |
| Net loss | (2,947) | (2,854) | (3,211) | (3,118) | (8,455) |
| Net loss per share, basic and diluted | $ (0.08) | $ (0.08) | $ (0.09) | $ (0.09) | $ (0.23) |

| | FIRST QUARTER ENDED MARCH 31, 1999 (UNAUDITED) | SECOND QUARTER ENDED JUNE 30, 1999 (UNAUDITED) | THIRD QUARTER ENDED SEPTEMBER 30, 1999 (UNAUDITED) | FOURTH QUARTER ENDED DECEMBER 31, 1999 (UNAUDITED) |
|---|---|---|---|---|
| Revenues | $ 6,918 | $ 7,170 | $12,536 | $13,082 |
| Net loss | (8,930) | (7,833) | (4,925) | (1,382) |
| Net loss per share, basic and diluted | $ (0.29) | $ (0.25) | $ (0.16) | $ (0.04) |

## REPORT OF INDEPENDENT AUDITORS

The Partners
Amgen-Regeneron Partners

We have audited the accompanying balance sheets of Amgen-Regeneron Partners, a Delaware general partnership, as of December 31, 2000 and 1999, and the related statements of operations, changes in partners' capital (deficit), and cash flows for each of the three years in the period ended December 31, 2000. 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 audits.

We conducted our audits 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 audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Amgen-Regeneron Partners at December 31, 2000 and 1999, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Los Angeles, California
February 2, 2001

AMGEN-REGENERON PARTNERS

BALANCE SHEETS

| | DECEMBER 31 | |
|---|---|---|
| | 2000 | 1999 |
| | (IN THOUSANDS) | |
| ASSETS | | |
| Total current assets -- cash and cash equivalents..... | $5,169 | $3,700 |
| LIABILITIES AND PARTNERS' CAPITAL (DEFICIT) | | |
| Total current liabilities -- accounts payable and accrued expenses due to partners..... | $4,635 | $4,300 |
| Partners' capital (deficit): | | |
| Amgen..... | 267 | (300) |
| Regeneron..... | 267 | (300) |
| Total partners' capital (deficit)..... | 534 | (600) |
| Total liabilities and partners' capital (deficit)..... | $5,169 | $3,700 |

See accompanying notes.

AMGEN-REGENERON PARTNERS

STATEMENTS OF OPERATIONS

| | YEAR ENDED DECEMBER 31 | | |
|---|---|---|---|
| | 2000 | 1999 | 1998 |
| | (IN THOUSANDS) | | |
| Interest income | $ 347 | $ 366 | $ 316 |
| Total income | 347 | 366 | 316 |
| Expenses: | | | |
| Research and development performed by partners | 9,436 | 8,631 | 5,235 |
| General and administrative | 61 | 53 | 49 |
| Total expenses | 9,497 | 8,684 | 5,284 |
| Net loss | $(9,150) | $(8,318) | $(4,968) |

See accompanying notes.

AMGEN-REGENERON PARTNERS

STATEMENTS OF CHANGES IN PARTNERS' CAPITAL (DEFICIT)

| | AMGEN | REGENERON |
|---|---|---|
| | (IN THOUSANDS) | |
| Balance at December 31, 1997 | $ 364 | $ 364 |
| Capital contributions | 5,211 | 5,211 |
| Net loss | (2,484) | (2,484) |
| Balance at December 31, 1998 | 3,091 | 3,091 |
| Capital contributions | 768 | 768 |
| Net loss | (4,159) | (4,159) |
| Balance at December 31, 1999 | (300) | (300) |
| Capital contributions | 5,142 | 5,142 |
| Net loss | (4,575) | (4,575) |
| Balance at December 31, 2000 | $ 267 | $ 267 |

See accompanying notes.

AMGEN-REGENERON PARTNERS

STATEMENTS OF CASH FLOWS

| | YEAR ENDED DECEMBER 31 | | |
|---|---|---|---|
| | 2000 | 1999 | 1998 |
| | (IN THOUSANDS) | | |
| Cash flows from operating activities: | | | |
| Net loss | $(9,150) | $(8,318) | $(4,968) |
| Increase in accounts payable and accrued expenses | 335 | 521 | 1,955 |
| Net cash used in operating activities | (8,815) | (7,797) | (3,013) |
| Cash flows from financing activities -- capital contributions | 10,284 | 1,536 | 10,422 |
| Increase (decrease) in cash and cash equivalents | 1,469 | (6,261) | 7,409 |
| Cash and cash equivalents at beginning of period | 3,700 | 9,961 | 2,552 |
| Cash and cash equivalents at end of period | $ 5,169 | $ 3,700 | $ 9,961 |

See accompanying notes.

AMGEN-REGENERON PARTNERS

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2000

## 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).

In January 1997, Amgen and Regeneron announced that the Phase 3 clinical trial of BDNF did not demonstrate clinical efficacy in the end points measured in patients with amyotrophic lateral sclerosis (ALS), commonly known as Lou Gehrig's Disease. The trial was designed to evaluate the effects of subcutaneous delivery of BDNF for ALS. On behalf of the Partnership, Amgen continued to conduct clinical trials of intrathecal delivery of BDNF for ALS, and Regeneron continued to conduct clinical trials of subcutaneous delivery of BDNF for ALS. In January 2001, Amgen and Regeneron were notified that clinical trials for both intrathecal and subcutaneous delivery of BDNF did not provide a therapeutic advantage to ALS patients. As a result, the Partnership has discontinued clinical development of BDNF for the treatment of ALS and will incur additional expenses during 2001 to wind up the related clinical trials. Regeneron continues to conduct clinical trials with NT-3 for the treatment of chronic constipation on behalf of the Partnership.

Under the Collaboration Agreement, Amgen will 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 will 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).

### 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, 2000 and 1999, 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.

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 has 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.

Pursuant to the terms of the Collaboration Agreement, Amgen and Regeneron 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 years ended December 31, 2000, 1999 and 1998, the Partnership incurred expenses (including accrued expenses) of $3,204,000, $5,044,000 and $3,379,000, respectively, from Amgen and $6,232,000, $3,587,000 and $1,856,000, respectively, 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, 2000, accounts payable and accrued expenses due to partners was composed of $869,000 of accounts payable and $2,162,000 of accrued clinical costs due to Amgen and $234,000 of accounts payable and $1,370,000 of accrued clinical costs due to Regeneron. At December 31, 1999, accounts payable and accrued expenses due to partners was composed of $888,000 of accounts payable and $2,939,000 of accrued clinical costs due to Amgen and $236,000 of accounts payable and $237,000 of accrued clinical costs due to Regeneron.

EXHIBIT INDEX

| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 3.1(a) | Restated Certificate of Incorporation of Regeneron Pharmaceuticals, Inc. as of June 21, 1991. |
| 3.2(f) | By-Laws of the Company, currently in effect (amended as of January 22, 1995). |
| 10.1(b) | Certificate of Amendment of the Restated Certificate of Incorporation of Regeneron Pharmaceuticals, Inc., as of October 18, 1996. |
| 10.2(c)* | Technology Development Agreement dated as of March 20, 1989, between the Company and Sumitomo Chemical Company, Limited. |
| 10.3(c)* | Neurotrophic Factor Agreement (License Agreement) dated as of May 10, 1988, between the Company and Max Planck Institute fur Psychiatric. |
| 10.4(c)* | Collaboration Agreement dated August 31, 1990, between the Company and Amgen Inc. |
| 10.5(c) | 1990 Amended and Restated Long-Term Incentive Plan. |
| 10.6(d)* | License Agreement dated as of October 7, 1992, between the Company and The Regents of the University of California. |
| 10.7(e)* | 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(h) | Warrant Agreement dated as of June 27, 1996, between the Company and Medtronic, Inc. |
| 10.12(h) | Registration Rights Agreement dated as of June 27, 1996, between the Company and Medtronic, Inc. |
| 10.13(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. |
| 10.14(j) | Stock Purchase Agreement dated as of December 11, 1996, between the Company and Procter & Gamble Pharmaceuticals, Inc. |
| 10.15(j) | Registration Rights Agreement dated as of December 11, 1996, between the Company and Procter & Gamble Pharmaceuticals, Inc. |
| 10.16(k) | Securities Purchase Agreement dated as of May 13, 1997, between the Company and The Procter & Gamble Company. |
| 10.17(k) | Warrant Agreement dated as of May 13, 1997, between the Company and The Procter & Gamble Company. |
| 10.18(k) | Registration Rights Agreement dated as of May 13, 1997, between the Company and The Procter & Gamble Company. |
| 10.19(k)* | Multi-Project Collaboration Agreement dated as of May 13, 1997, between the Company and The Procter & Gamble Company. |
| 10.20(l)* | First Amendment to the Multi-Project Collaboration Agreement dated May 13, 1997, between the Company and The Procter & Gamble Company, dated as of September 29, 1997. |
| 10.21(m) | Employment Agreement, dated as of February 12, 1998 between the Company and Leonard S. Schleifer, M.D., Ph.D. |

| EXHIBIT NUMBER | DESCRIPTION |
| --- | --- |
| 23.1 | Consent of PricewaterhouseCoopers LLP, Independent Accountants. |
| 23.2 | Consent of Ernst & Young LLP, Independent Auditors. |
| 24 | Power of Attorney. Included in the signature page of this Registration Statement. |

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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-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 1996, filed November 5, 1996.

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

(d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 1992, filed March 30, 1993.

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

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

(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 Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 1997, filed November 10, 1997.

(m) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 1997, filed March 26, 1998.

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

EXHIBIT 23.1

CONSENT OF INDEPENDENT ACCOUNTANTS

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 and 333-80663) and on Form S-3 (File No. 333-54326) of Regeneron Pharmaceuticals, Inc., of our report, which is based in part on the report of other auditors, dated February 7, 2001, relating to the financial statements which appears in this Annual Report on Form 10-K.

PricewaterhouseCoopers LLP

New York, New York
February 28, 2001

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, and the Registration Statement (Form S-3 No. 333-54326) and related Prospectus of Regeneron Pharmaceuticals, Inc. for the registration of 4,600,000 shares of its common stock of our report dated February 2, 2001, with respect to the financial statements of Amgen-Regeneron Partners included in Regeneron Pharmaceuticals, Inc.'s Annual Report (Form 10-K) for the year ended December 31, 2000, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Los Angeles, California
February 28, 2001