

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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2008

OR

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

Commission file number 0-19034

**REGENERON PHARMACEUTICALS, INC.**

*(Exact name of registrant as specified in its charter)*

New York

*(State or other jurisdiction of  
incorporation or organization)*

13-3444607

*(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:**

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock - par value \$.001 per share	Nasdaq Global Select Market

**Securities registered pursuant to section 12(g) of the Act: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$1,081,564,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2008, the last trading day of the registrant's most recently completed second fiscal quarter.

The number of shares outstanding of each of the registrant's classes of common stock as of February 13, 2009:

<u>Class of Common Stock</u>	<u>Number of Shares</u>
Class A Stock, \$.001 par value	2,246,698
Common Stock, \$.001 par value	77,730,064

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2009 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 58 to 61 of this filing.

## PART I

### ITEM 1. BUSINESS

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

#### General

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST<sup>®</sup> (rilonacept) Injection for Subcutaneous Use, which is now available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We also have six clinical development programs, including three late-stage clinical programs. Our late stage programs are aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group, VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC, and ARCALYST which is being developed for the treatment of gout. Our earlier stage clinical programs are REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis, REGN421, an antibody to Delta-like ligand-4 (Dl14), which is being developed in oncology, and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All three of these antibodies are being developed in collaboration with sanofi-aventis.

We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Our antibody program is being conducted primarily in collaboration with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*<sup>™</sup> technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (*VelocImmune*<sup>®</sup>) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Our first three antibody product candidates currently in clinical trials were developed using *VelocImmune*. Over the course of the next several years, we plan to advance an average of two to three new antibody product candidates into clinical development each year. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

#### Commercial Product:

##### **ARCALYST<sup>®</sup> (rilonacept) – Cryopyrin-Associated Periodic Syndromes (CAPS)**

In February 2008, we received marketing approval from the U.S. Food and Drug Administration (FDA) for ARCALYST<sup>®</sup> (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We shipped \$10.7 million of ARCALYST to our distributors in 2008. ARCALYST is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST is the only therapy approved in the United States for patients with CAPS, a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. CAPS is caused by a range of mutations in the gene NLRP3 (formerly known as *CIAS1*) which encodes a protein named cryopyrin. In addition to FCAS and MWS, CAPS includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). ARCALYST has not been studied for the treatment of NOMID.

In March 2008, ARCALYST became available for prescription in the United States and we transitioned the patients who participated in the CAPS pivotal study from clinical study drug to commercial supplies. In 2009, we expect to ship \$20-24 million of ARCALYST to our U.S. distributors. In July 2008, we submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for ARCALYST for the treatment of CAPS in the European Union.

#### Clinical Programs:

## 1. Aflibercept (VEGF Trap) – Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are enrolling patients in four Phase 3 trials that combine aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial is evaluating aflibercept as a 2<sup>nd</sup> line treatment for metastatic colorectal cancer (the VELOUR study) in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial is evaluating aflibercept as a 1<sup>st</sup> line treatment for metastatic pancreatic cancer in combination with gemcitabine (the VANILLA study). A third trial is evaluating aflibercept as a 1<sup>st</sup> line treatment for metastatic androgen independent prostate cancer in combination with docetaxel/prednisone (the VENICE study). The fourth trial is evaluating aflibercept as a 2<sup>nd</sup> line treatment for metastatic non-small cell lung cancer in combination with docetaxel (the VITAL study). All four trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. As of February 2009, each of the four Phase 3 trials was over one-third enrolled, and initial data from the Phase 3 program is expected in 2010. In addition, a Phase 2 study of aflibercept in 1<sup>st</sup>-line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin (the AFFIRM study) began recruiting patients in January 2009.

Aflibercept is also being studied in a Phase 2 single-agent study in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA). This trial is now fully enrolled and we expect to have initial data from this trial by mid-2009. The FDA has granted Fast Track designation to aflibercept for the treatment of SMA.

In addition, multiple exploratory studies are being conducted in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) evaluating aflibercept as a single agent or in combination with chemotherapy regimens in a variety of cancer indications.

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## Aflibercept Collaboration with the sanofi-aventis Group

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

## 2. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of age-related macular degeneration (wet AMD). We and Bayer HealthCare also initiated a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME) in late 2008. Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), are comparing VEGF Trap-Eye and ranibizumab (Lucentis<sup>®</sup>, a registered trademark of Genentech, Inc.), an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating dosing intervals of four and eight weeks for VEGF Trap-Eye compared with ranibizumab dosed according to its U.S. label every four weeks over the first year. As needed dosing (PRN) with both agents will be evaluated in the second year of the studies. We and Bayer Healthcare expect to complete enrollment of the VIEW 1 and VIEW 2 trials in 2009 and initial data are expected in late 2010.

In August 2008, we and Bayer HealthCare AG announced the preliminary results of a Phase 2 study in wet AMD which demonstrated that patients treated with VEGF Trap-Eye achieved durable improvements in visual acuity and retinal thickness for up to one year. In September 2008, the complete results of this study, including additional data on reductions in the size of the active choroidal neovascularization membrane (CNV), the active lesion that is the underlying cause of vision loss in patients with wet AMD, were reported at the 2008 annual meeting of the Retina Society.

In this double-masked Phase 2 trial, patients were initially treated with either fixed monthly or quarterly dosing for 12 weeks and then continued to receive treatment for another 40 weeks on a PRN dosing schedule. Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 milligrams (mg) for 12 weeks followed by PRN dosing achieved mean improvements in visual acuity versus baseline of 9.0 letters ( $p < 0.0001$  versus baseline) and 5.4 letters ( $p < 0.085$  versus baseline), respectively, at the end of one year. The proportion of patients with vision of 20/40 or better (part of the legal minimum requirement for an unrestricted driver's license in the U.S.) increased from 23% at baseline to 45% at week 52 in patients initially treated with 2.0 mg monthly and from 16% at baseline to 47% at week 52 in patients initially treated with 0.5 mg monthly. Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 mg also achieved mean decreases in retinal thickness versus baseline of 143 microns ( $p < 0.0001$  versus baseline) and 125 microns ( $p < 0.0001$  versus baseline) at week 52, respectively.

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During the week 12 to week 52 PRN dosing period, patients initially dosed on a 2.0 mg monthly schedule received, on average, only 1.6 additional injections and those initially dosed on a 0.5 mg monthly schedule received, on average, 2.5 additional injections.

While PRN dosing following a fixed quarterly dosing regimen (with dosing at baseline and week 12) also yielded improvements in visual acuity and retinal thickness versus baseline at week 52, the results generally were not as robust as those obtained with initial fixed monthly dosing.

In this Phase 2 study, treatment with VEGF Trap-Eye was also associated with a reduction in the size of the CNV lesion. Patients initially receiving either a 2.0 mg or 0.5 mg monthly fixed dose of VEGF Trap-Eye for 12 weeks followed by PRN dosing experienced statistically significant 3.41 mm<sup>2</sup> and 1.42 mm<sup>2</sup> reductions in mean CNV size at 48 weeks (the final one-year analysis endpoint from the independent reading center) versus baseline, respectively. Patients in the 2.0 mg monthly cohort also achieved a statistically significant 1.75 mm<sup>2</sup> reduction in total lesion size. A reduction in total lesion size was not seen in the cohort initially dosed with 0.5 mg monthly.

In this Phase 2 study, VEGF Trap-Eye was generally well tolerated and there were no reported drug-related serious adverse events. There was one reported case of culture-negative endophthalmitis/uveitis in the study eye, which was deemed not to be drug-related. The most commonly reported adverse events were those typically associated with intravitreal injections.

The recently initiated Phase 2 DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye regimens versus laser treatment. The study will be enrolling approximately 200 patients in the U.S., Canada, European Union, and Australia. The patients in the study will be treated for 52 weeks followed by six additional months of safety evaluation. The primary efficacy endpoint is the change in best corrected visual acuity (BCVA) from baseline to week 24.

### **Collaboration with Bayer HealthCare**

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and other diseases and disorders. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare. In 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of VEGF Trap-Eye in wet AMD, and can earn up to \$90 million in additional development and regulatory milestones related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

### **3. ARCALYST® (rilonacept) – Inflammatory Diseases**

We are evaluating ARCALYST in certain diseases and disorders, in addition to CAPS, where IL-1 may play an important role. In September 2008, we announced the results of a Phase 2 study which evaluated the efficacy and safety of ARCALYST versus placebo in the prevention of gout flares induced by the initiation of urate-lowering drug therapy that is used to control gout. In this 83-patient, double-blind, placebo-controlled study, the mean number of flares per patient over the first 12 weeks of urate-lowering therapy was 0.79 with placebo and 0.15 with ARCALYST (p=0.0011), an 81% reduction. This was the primary endpoint of the study. All secondary endpoints also were met with statistical significance. In the first 12 weeks of treatment, 45.2% of patients treated with placebo experienced a gout flare and, of those, 47.4% had more than one flare. Among patients treated with ARCALYST, only 14.6% experienced a gout flare (p=0.0037 versus placebo) and none had more than one flare. Injection-site reaction was the most commonly reported adverse event with ARCALYST and no serious drug-related adverse events were reported.

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Gout is characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The uric acid can form crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the uric acid crystals and prevent reformation. During the first months of allopurinol therapy, while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We are in the process of initiating a Phase 3 clinical development program with ARCALYST® (rilonacept) for the treatment of gout. Two Phase 3 clinical trials will evaluate ARCALYST versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. We plan to initiate a Phase 3 clinical trial of ARCALYST for acute gout that will evaluate treatment with ARCALYST alone versus ARCALYST in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The Phase 3 clinical development program will also include a separate safety study.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody which is in clinical development. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody, and to receive 45% of net profits on sales of the antibody product, in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe. Under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to ARCALYST.

### **4. Monoclonal Antibodies**

We and sanofi-aventis are collaborating on the discovery, development, and commercialization of fully human monoclonal antibodies generated using our *VelocImmune*<sup>®</sup> technology. The first therapeutic antibodies to enter clinical development under the collaboration are REGN88, an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis, and REGN475, an antibody to Nerve Growth Factor (NGF) that is being developed for the treatment of pain. In addition, a Phase I trial is in the process of being initiated for REGN421, an antibody to Delta-like ligand-4 (Dll4) that is being evaluated in oncology in patients with advanced malignancies. Over the course of the next several years, we and sanofi-aventis plan to advance an average of two to three new antibodies into clinical development each year.

### **Research and Development Technologies:**

One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different “families” of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called “receptors,” which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of secreted proteins can have clinical benefit.

Regeneron scientists have developed two different technologies to design protein therapeutics to block the action of specific secreted proteins. The first technology, termed the “Trap” technology, was used to generate our first approved product, ARCALYST, as well as aflibercept, and VEGF Trap-Eye which are in Phase 3 clinical trials. These novel “Traps” are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the “Fc region”, resulting in high affinity product candidates. *VelociSuite*<sup>™</sup> is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies.

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### ***VelociSuite*<sup>™</sup>**

*VelociSuite* consists of *VelocImmune*<sup>®</sup>, *VelociGene*<sup>®</sup>, *VelociMouse*<sup>®</sup>, and *VelociMab*<sup>™</sup>. The *VelocImmune* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune* was generated by exploiting our *VelociGene* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or “humanized,” with corresponding human immune gene loci. *VelocImmune* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune* and our entire *VelociSuite* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knockout models, a color or fluorescent marker is substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body, during normal body functioning, as well as in disease processes. For the optimization of pre-clinical development and toxicology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

The *VelociMouse* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, Regeneron’s *VelociMice* are suitable for direct phenotyping or other studies. We have also developed our *VelociMab* platform for the rapid generation of expression cell lines for our Traps and our *VelocImmune* human monoclonal antibodies.

### **Antibody Collaboration with sanofi-aventis**

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$75 million of research from the collaboration’s inception through December 31, 2008 and will fund up to \$100 million per year in 2009 through 2012. Sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

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In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene*<sup>®</sup> platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of \$21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

## **License Agreement with AstraZeneca**

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made two \$20.0 million annual, non-refundable payments to us, one in February 2007 and the other in February 2008. AstraZeneca is required to make up to four additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first two additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune* technology.

## **License Agreement with Astellas**

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made two \$20.0 million annual, non-refundable payments to us, one in April 2007 and the other in June 2008. Astellas is required to make up to four additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first two additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

## **Academic *VelocImmune*<sup>®</sup> Investigators Program**

In September 2008, we entered into an agreement that will provide researchers at Columbia University Medical Center with access to our *VelocImmune* technology platform. Under the agreement, scientists at Columbia will use *VelocImmune* mice to generate antibodies against their research targets and will conduct research to discover potential human therapeutics based on the antibodies. We have an exclusive option to license the antibodies for development and commercialization as therapeutic or diagnostic products and will pay Columbia a low single-digit royalty on ensuing product sales.

## **National Institutes of Health Grant**

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We are using our *VelociGene* technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our *VelociGene* technology in the Knockout Mouse Project. We are generating a collection of targeting vectors and targeted mouse ES cells which can be used to produce knockout mice. These materials are available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, as amended in September 2008, we are entitled to receive a minimum of \$24.5 million over the five-year period beginning September 2006, including \$1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which are being supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

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## **Research Programs:**

### ***Oncology and Angiogenesis***

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. 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. In 1994, we discovered a second family of angiogenic growth factors, termed Angiopoietins, and we have received patents covering members of this family. Angiopoietins include naturally occurring positive and negative regulators of angiogenesis, as described in numerous scientific manuscripts published by our scientists and their collaborators. Angiopoietins are being evaluated in preclinical research by us and our academic collaborators. Our preclinical studies have revealed that VEGF and Angiopoietins normally function in a coordinated and collaborative manner during blood vessel growth. Manipulation of both VEGF and Angiopoietins seems to be of value in blocking vessel growth. We have research programs focusing on several targets in the areas of oncology and angiogenesis.

Tumors depend on the growth of new blood vessels (a process called "angiogenesis") to support their continued growth. Therapies that block tumor angiogenesis, specifically those that block VEGF, the key initiator of tumor angiogenesis, recently have been validated in human cancer patients. However, anti-VEGF approaches do not work in all patients, and many tumors can become resistant to such therapies.

In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. We are in the process of initiating Phase 1 clinical development of a fully human monoclonal antibody to Dll4 that was discovered using our *VelocImmune*<sup>®</sup> technology.

### ***Metabolic and Related Diseases***

Food intake and metabolism are regulated by complex interactions between diverse neural and hormonal signals that serve to maintain an optimal balance between energy intake, storage, and utilization. The hypothalamus, a small area at the base of the brain, is critically involved in integrating peripheral signals which reflect nutritional status and neural outputs which regulate appetite, food seeking behaviors, and energy expenditure. Metabolic disorders, such as type 2 diabetes, reflect a dysregulation in the systems which ordinarily tightly couple energy intake to energy expenditure. Our preclinical research program in this area encompasses the study of peripheral (hormonal) regulators of food intake and metabolism in health and disease. We have identified several targets in these therapeutic areas and are evaluating potential antibodies to evaluate in preclinical studies.

### ***Muscle Diseases and Disorders***

Muscle atrophy occurs in many neuromuscular diseases and also when muscle is unused, as often occurs during prolonged hospital stays and during convalescence. Currently, physicians have few options to treat subjects with muscle atrophy or other muscle conditions which afflict millions of people globally. Thus, a treatment that has beneficial effects on skeletal muscle could have significant clinical benefit. Our muscle research program is currently focused on conducting in vivo and in vitro experiments with the objective of demonstrating and further understanding the molecular pathways involved in muscle atrophy and hypertrophy, and discovering therapeutic candidates that can modulate these pathways. We have several molecules in late stage research and are evaluating them for possible further development.

### **Other Therapeutic Areas**

We also have research programs focusing on ophthalmology, inflammatory and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

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### **Manufacturing**

Our manufacturing facilities are located in Rensselaer, New York and consist of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space. At December 31, 2008, we employed 246 people at our Rensselaer facilities. There were no impairment losses associated with long-lived assets at these facilities as of December 31, 2008.

Among the conditions for regulatory marketing approval of a medicine is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the good manufacturing practice (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 areas of production and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, are also subject to inspections by or under the authority of the FDA and by other national, federal, state, and local agencies. If our manufacturing facilities fail to comply with FDA and other regulatory requirements, we will be required to suspend manufacturing. This would likely have a material adverse effect on our financial condition, results of operations, and cash flow.

### **Competition**

We face substantial competition from pharmaceutical, biotechnology, and chemical companies (see "Risk Factors – *Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.*"). Our competitors include Genentech, Novartis, Pfizer Inc., Bayer HealthCare, Onyx Pharmaceuticals, Inc., Abbott Laboratories, sanofi-aventis, Merck & Co., Amgen Inc., Roche, and others. Many of our competitors have substantially greater research, preclinical, and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also be significant if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even when 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.

*ARCALYST® (riloncept).* There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Company, Novartis, and Xoma Ltd. are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis has filed applications in the U.S. and Europe seeking regulatory approval of its IL-1 antibody in CAPS. Novartis is also developing its IL-1 antibody in gout and other inflammatory diseases. These drug candidates could offer competitive advantages over ARCALYST. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize ARCALYST.

*Aflibercept and VEGF Trap-Eye.* Many companies are developing therapeutic molecules designed to block the actions of VEGF specifically and angiogenesis in general. A variety of approaches have been employed, including antibodies to VEGF, antibodies to the VEGF receptor, small molecule antagonists to the VEGF receptor tyrosine kinase, and other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to our VEGF Trap in efficacy, side-effect profile, or method of delivery. Additionally, some of these molecules are either already approved for marketing or are at a more advanced stage of development than our product candidate.

In particular, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and a number of pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Pfizer, and Imclone Systems Incorporated (now a wholly-owned subsidiary of Eli Lilly). Many of these molecules are further along in development than aflibercept and may offer competitive advantages over our molecule. Pfizer and Onyx Pharmaceuticals (together with its partner Bayer) are selling and marketing oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors.

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The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of wet AMD, DME, and other eye indications. Lucentis was approved by the FDA in June 2006 for the treatment of wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF, VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a significant competitive challenge in this indication. The National Eye Institute initiated a Phase 3 trial to compare Lucentis to Avastin in the treatment of wet AMD. Avastin (Genentech) is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other areas.

*REGN88.* We are developing REGN88 for the treatment of rheumatoid arthritis as part of our global, strategic collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex Corporation), Remicade® (Centocor, Inc.), and Humira® (Abbott), and other marketed therapies makes it difficult to successfully develop and commercialize

REGN88. REGN88 is a human monoclonal antibody targeting the interleukin-6 receptor. Roche is developing Actemra™ (tocilizumab) an antibody against the interleukin-6 (IL-6) receptor. Roche's antibody is approved for marketing and sale in Europe and is the subject of a filed Biologics License Application with the FDA for the treatment of rheumatoid arthritis. Roche's IL-6 receptor antibody, other clinical candidates in development, and the drugs on the market to treat rheumatoid arthritis could offer competitive advantages over REGN88. This could delay or impair our ability to successfully develop and commercialize REGN88.

*REGN421.* We are also developing REGN421 for the treatment of various cancers as part of our antibody collaboration with sanofi-aventis. Many companies are developing therapeutic molecules designed to block angiogenesis. A variety of different approaches have been employed, including developing a number of antagonists to VEGF and Dll4 and other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to REGN421 in efficacy, side-effect profile, or method of delivery. Additionally, some of these molecules are either already approved for marketing or are at a more advanced stage of development than our product candidate. In particular, OncoMed Pharmaceuticals, Inc. has a Dll4 antibody in Phase 1 clinical development.

*REGN475.* We are also developing REGN475 for the treatment of pain as part of our antibody collaboration with sanofi-aventis. The availability of effective FDA approved non-steroidal anti-inflammatory drugs (NSAIDs) including NSAIDs available over-the-counter without a prescription, and other marketed therapies, may make it difficult to successfully develop and commercialize REGN475. REGN475 is a human monoclonal antibody targeting Nerve Growth Factor (NGF). Pfizer is also developing an antibody against NGF that is in Phase 3 clinical trials for the treatment of pain due to osteoarthritis. Pfizer's NGF antibody, other clinical candidates in development, and other drugs on the market, including over-the-counter medications, to treat pain could offer competitive advantages over REGN475, which could delay or impair our ability to successfully develop and commercialize REGN475.

*Other Areas.* Many pharmaceutical and biotechnology companies are attempting to discover new therapeutics for indications in which we invest substantial time and resources. 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 that are the focus of other research or development programs we are now conducting. These competitors include Amgen and Genentech, as well as many others. Many firms and entities are engaged in research and development in the areas of cytokines, interleukins, angiogenesis, and muscle conditions. Some of these competitors are currently conducting advanced preclinical and clinical research programs in these areas. These and other competitors may have established substantial intellectual property and other competitive advantages.

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

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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 or other consideration for use of their technology. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties or other consideration for use of the technology they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from these 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 (see "Risk Factors – *We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.*"). Our policy is to file patent applications to protect technology, inventions, and improvements that we consider important to our business and operations. We are the nonexclusive licensee of a number of additional U.S. patents and patent applications. We also rely upon trade secrets, know-how, and continuing technological innovation in an effort to develop and maintain our competitive position. We or our licensors or collaborators have filed patent applications on various products and processes relating to our product candidates 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.

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, when appropriate, to file product and process patent applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

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

### **Government Regulation**

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of ARCALYST® (rilonacept) and our product candidates (see "Risk Factors – *If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.*"). All of our product candidates will require regulatory approval before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval requirements by the FDA and foreign authorities. Many aspects of the structure and substance of the FDA and foreign pharmaceutical regulatory practices have been reformed during recent years, and continued reform is under consideration in a number of jurisdictions. The ultimate outcome and impact of such reforms and potential reforms cannot be predicted.

The activities required before a product candidate may be marketed in the United States begin with preclinical tests. Preclinical tests include laboratory evaluations and animal studies to assess the potential safety and efficacy of the product candidate and its formulations. The results of these studies must be



submitted to the FDA as part of an Investigational New Drug Application, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase 1, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase 2, clinical trials are conducted with subjects afflicted with a specific disease or disorder to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. In Phase 3, large-scale clinical trials are

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conducted with patients afflicted with the specific disease or disorder in order to provide enough data to understand the efficacy and safety profile of the product candidate, as required by the FDA. The results of the preclinical and clinical testing of a biologic product candidate are then submitted to the FDA in the form of a Biologics License Application, or BLA, for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to a BLA, the FDA may grant marketing approval, request additional information, or deny the application.

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

Approval of a product candidate by comparable regulatory authorities in foreign countries is generally required prior to commencement of marketing of the product in those countries. The approval procedure varies among countries and may involve additional testing, and the time required to obtain such approval may differ from that required for FDA approval.

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

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

## **Business Segments**

We manage our business as one segment which includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions and the development and commercialization of these discoveries. This segment also includes revenues and expenses related to (i) research and development activities conducted under our collaboration agreements with third parties and our grant from the NIH, (ii) ARCALYST<sup>®</sup> (rilonacept) product sales for the treatment of CAPS, and (iii) the supply of specified, ordered research materials using Regeneron-developed proprietary technology. Prior to 2007, our operations were managed in two business segments: research and development, and contract manufacturing. In 2006, the contract manufacturing segment included all revenues and expenses related to the commercial production of a product under a contract with Merck, which expired in October 2006. For financial information about these segments, see Note 21, "Segment Information", beginning on page F-33 in our Financial Statements.

## **Employees**

As of December 31, 2008, we had 919 full-time employees, of whom 185 held a Ph.D. and/or M.D., or PharmD degree. We believe that we have been successful in attracting skilled and experienced personnel in a highly competitive environment; however, competition for these personnel is intense. None of our personnel are covered by collective bargaining agreements and our management considers its relations with our employees to be good.

## **Available Information**

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

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## **ITEM 1A. RISK FACTORS**

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

### **Risks Related to Our Financial Results and Need for Additional Financing**

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

From inception on January 8, 1988 through December 31, 2008, we had a cumulative loss of \$875.9 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

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

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

***The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.***

As of December 31, 2008, cash, cash equivalents, restricted cash, and marketable securities totaled \$527.5 million and represented 79% of our total assets. We have invested available cash balances primarily in money market funds and U.S. Treasury, U.S. government agency, corporate, and asset-backed securities. We consider assets classified as marketable securities to be “available-for-sale,” as defined by Statement of Financial Accounting Standards No. (SFAS) 115, *Accounting for Certain Investments in Debt and Equity Securities*. Marketable securities totaled \$278.0 million at December 31, 2008, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders’ equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that is charged against income. For example, during the year ended December 31, 2008, we recorded charges for other-than-temporary impairments totaling \$2.5 million related to two marketable securities in our investment portfolio. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security’s sale or maturity, and such amounts may be material.

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## **Risks Related to ARCALYST® (riloncept) and the Development of Our Product Candidates**

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

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners’ ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are studying aflibercept, VEGF Trap-Eye, ARCALYST, and our antibody candidates in a wide variety of indications. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are being, or are planned to be, studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

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

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

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

***Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.***

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous

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cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST in only a small number of patients with CAPS. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret<sup>®</sup> (Amgen, Inc.), Enbrel<sup>®</sup> (Immunex Corporation), and Remicade<sup>®</sup> (Centocor, Inc.), ARCALYST affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST may interfere with the body's ability to fight infections. Treatment with Kineret (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST in new disease settings. These side effects may also result in a reduction, or even the elimination, of sales of ARCALYST in approved indications.

***ARCALYST<sup>®</sup> (rilonacept) and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.***

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of rilonacept were detected in patients with CAPS after treatment with ARCALYST. Nineteen of 55 subjects (35%) who received ARCALYST for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

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

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

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## **Risks Related to Intellectual Property**

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

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

***We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.***

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition

of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*<sup>®</sup> technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST<sup>®</sup> (rilonacept), aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

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

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

## **Regulatory and Litigation Risks**

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

We cannot sell or market products without regulatory approval. Although we obtained regulatory approval for ARCALYST for the treatment of CAPS in the United States, we may be unable to obtain regulatory approval of ARCALYST in any other country or in any other indication. Regulatory agencies outside the United States may require additional information or data with respect to any future submission for ARCALYST for the treatment of CAPS.

If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

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

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST for the treatment of CAPS or any of our product candidates in those countries.

***If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.***

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use

ARCALYST that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

***If we market and sell ARCALYST® (rilonacept) in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.***

In addition to FDA and related regulatory requirements, we are subject to health care “fraud and abuse” laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly

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and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

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

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

***Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.***

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated rules and listing standards covering a variety of subjects. Compliance with these rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors’ and officers’ liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

***In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.***

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company’s internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial

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reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2008, which report is included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2008. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

***Changes in laws and regulations affecting the healthcare industry could adversely affect our business.***

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies; and
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business.

The enactment in the United States of the Medicare Prescription Drug Improvement and Modernization Act of 2003 and possible legislation which could ease the entry of competing follow-on biologics into the marketplace are examples of changes and possible changes in laws that could adversely affect our business.

#### **Risks Related to Our Reliance on Third Parties**

***If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.***

We rely heavily on the funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to \$400 million between 2009 and 2012 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, and REGN475, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

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***If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.***

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

***If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.***

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

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

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

We rely on third party service providers to support the distribution of ARCALYST and many other related activities in connection with the commercialization of ARCALYST for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST for the treatment of CAPS will not be successful.

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## **Risks Related to the Manufacture of Our Product Candidates**

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

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

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

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

***If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.***

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

***Third-party supply failures or a business interruption at our manufacturing facility in Rensselaer, New York could adversely affect our ability to supply our products.***

We manufacture all of our bulk drug materials for ARCALYST and our product candidates at our manufacturing facility in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, or other problems at the facility.

Certain raw materials necessary for manufacturing and formulation of ARCALYST and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

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## **Risks Related to Commercialization of Products**

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

We are marketing and selling ARCALYST for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We have no sales, marketing, commercial, or

distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

***There may be too few patients with CAPS to profitably commercialize ARCALYST® (rilonacept) in this indication.***

Our only approved product is ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. As a result, there may be too few patients with CAPS to profitably commercialize ARCALYST in this indication.

***Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.***

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

Genentech has an approved VEGF antagonist, Avastin® (beracizumab), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, Inc., and Pfizer. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

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The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, ranibizumab (Lucentis®), for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF, VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformatted version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute is conducting a Phase 3 trial comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech) and the potential off-label use of Avastin (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (ImmuneX), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST. This is one of the reasons we discontinued the development of ARCALYST in adult rheumatoid arthritis. In addition, even if ARCALYST is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma, and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis has filed applications in the U.S. and Europe seeking regulatory approval of its IL-1 antibody in CAPS. Novartis is also developing its IL-1 antibody in gout and other inflammatory diseases. Novartis has stated that its IL-1 antibody demonstrated long-lasting clinical remission in patients with CAPS and that its clinical candidate could develop into a major therapeutic advance in the treatment of CAPS. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. The successful development of these competing molecules could impair our ability to successfully commercialize ARCALYST.

We have plans to develop ARCALYST for the treatment of certain gout indications. Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of these gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST in these diseases.

***The successful commercialization of ARCALYST® (rilonacept) and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.***

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we have announced plans to initiate a Phase 3 program studying the use of ARCALYST for the treatment of certain gout indications. Patients suffering from these gout indications are



currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

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We market and sell ARCALYST<sup>®</sup> (rilonacept) in the United States for the treatment of a group of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST. Physicians may not prescribe ARCALYST, and CAPS patients may not be able to afford ARCALYST, if third party payers do not agree to reimburse the cost of ARCALYST therapy and this would adversely affect our ability to commercialize ARCALYST profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since ARCALYST and our product candidates in clinical development, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

#### **Risk Related to Employees**

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

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

***Our move to new facilities in mid-2009 could lead to disruptions in our business operations.***

We plan to move most of our laboratories and headquarters to new facilities in mid-2009. There is a risk that this physical move could lead to damage to equipment or other business assets or the loss of important data, or that we could encounter problems with our new facilities, which could disrupt or delay our business operations.

#### **Risks Related to Our Common Stock**

***Our stock price is extremely volatile.***

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

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- progress, delays, or adverse results in clinical trials;
  - announcement of technological innovations or product candidates by us or competitors;
  - fluctuations in our operating results;
  - third party claims that our products or technologies infringe their party patents;
  - public concern as to the safety or effectiveness of ARCALYST<sup>®</sup> (rilonacept) or any of our product candidates;

- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

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

***Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.***

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of December 31, 2008, our five largest shareholders plus Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, beneficially owned 55.9% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2008. As of December 31, 2008, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 19.1% the shares of Common Stock then outstanding. Under our investor agreement with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2012 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

***Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.***

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, 2008, holders of Class A Stock held 22.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, plus any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in us taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of December 31, 2008:

- our current executive officers and directors beneficially owned 13.3% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2008, and 28.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2008; and

- our five largest shareholders plus Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, beneficially owned 55.9% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2008. In addition, these six shareholders held 59.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, 2008.

Pursuant to an investor agreement, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

***The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.***

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining

directors;

- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to “business combinations” involving the Company and an “interested shareholder”, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned “*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.*”

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain “standstill” provisions, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a “change in control” of our company, as defined in the plan.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 2. PROPERTIES

We conduct our research, development, manufacturing, and administrative activities at our owned and leased facilities. Under our main operating lease, as amended, we currently lease approximately 248,000 square feet of laboratory and office facilities in Tarrytown, New York.

In December 2006, we entered into a new operating lease agreement (as amended in October 2007 and September 2008) to lease approximately 348,000 square feet of laboratory and office space at our current Tarrytown location, which includes approximately 118,000 square feet retained from our current space and approximately 230,000 square feet in new facilities that are under construction and expected to be completed in mid-2009. The term of the lease commenced effective June 2008 and will expire in June 2024. Under the new lease, we also have various options and rights on additional space at the Tarrytown site, and will continue to lease our present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for our retained facilities only. The lease provides for monthly payments over the term of the lease related to our retained facilities, the costs of construction and tenant improvements for our new facilities, and additional charges for utilities, taxes, and operating expenses.

In November 2007, we entered into a new operating sublease for approximately 10,000 square feet of office space in Tarrytown, New York. The lease expires in September 2009 and we have the option to extend the term for two additional terms of three months each. In April 2008, we entered into a new operating sublease for approximately 16,200 square feet of office space in Tarrytown, New York. The lease expires in March 2010 and we have the option to extend the term one additional term of six months. In October 2008, we entered into a new operating sublease for approximately 14,100 square feet of office space in Bridgewater, New Jersey. The lease commences in January 2009 and expires in July 2011.

We own facilities in Rensselaer, New York, consisting of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space.

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

Location	Square Footage	Expiration	Current Monthly Base Rental Charges <sup>(1)</sup>	Renewal Option Available
Tarrytown, New York <sup>(2)</sup>	130,000	June, 2009	\$171,300	None
Tarrytown, New York <sup>(2)</sup>	230,000	June, 2024	— <sup>(3)</sup>	Three 5-year terms
Tarrytown, New York <sup>(2)</sup>	118,000	June, 2024	\$212,200	Three 5-year terms
Tarrytown, New York <sup>(4)</sup>	10,000	September, 2009	\$ 22,000	Two 3-month terms
Tarrytown, New York <sup>(4)</sup>	16,200	March, 2010	\$ 32,700	One 6-month term
Bridgewater, New Jersey <sup>(5)</sup>	14,100	July, 2011	\$ 21,700	None

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

(2) Upon completion of the new facilities, as described above, we will retain 118,000 square feet of space in our current facility and take over 230,000 square feet in the newly constructed buildings.

(3) Rental payments will commence in August 2009.

(4) Relates to sublease in Tarrytown, New York as described above.

(5) Relates to sublease in Bridgewater, New Jersey as described above.

We believe that our existing owned and leased facilities are adequate for ongoing research, development, manufacturing, and administrative activities. In the future, we may lease, operate, or purchase additional facilities in which to conduct expanded research and development activities and manufacturing and commercial operations.

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### ITEM 3. LEGAL PROCEEDINGS

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

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our security holders during the last quarter of the fiscal year ended December 31, 2008.

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## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

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

The following table sets forth, for the periods indicated, the range of high and low sales prices for the Common Stock as reported by The NASDAQ Global Select Market:

	High	Low
<b>2007</b>		
First Quarter	\$22.84	\$17.87
Second Quarter	28.74	17.55
Third Quarter	21.78	13.55
Fourth Quarter	24.90	16.77
<b>2008</b>		
First Quarter	\$25.25	\$15.61
Second Quarter	21.68	13.75
Third Quarter	24.00	13.29
Fourth Quarter	22.82	12.62

As of February 13, 2009, there were 479 shareholders of record of our Common Stock and 42 shareholders of record of our Class A Stock.

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

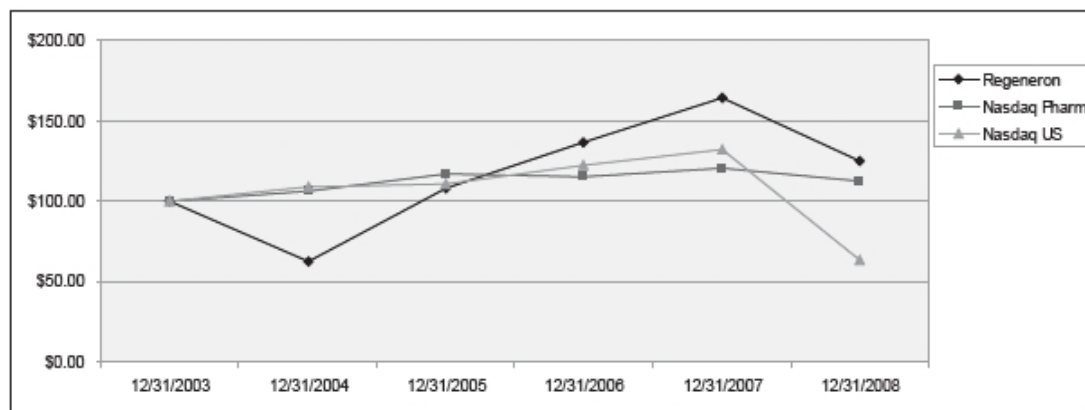
The information under the heading "Equity Compensation Plan Information" in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC is incorporated by reference into Item 12 of this Report on Form 10-K.

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### STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total shareholder return on Regeneron's Common Stock with the cumulative total return of (i) The Nasdaq Pharmaceuticals Stocks Index and (ii) The Nasdaq Stock Market (U.S.) Index for the period from December 31, 2003 through December 31, 2008. The comparison assumes that \$100 was invested on December 31, 2003 in our Common Stock and in each of the foregoing indices. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices. The historical stock price performance of our Common Stock shown in the graph below is not necessarily indicative of future stock price performance.



	12/31/2003	12/31/2004	12/31/2005	12/31/2006	12/31/2007	12/31/2008
Regeneron	\$100.00	\$ 62.61	\$108.09	\$136.44	\$164.17	\$124.81
Nasdaq Pharm	100.00	106.51	117.29	114.81	120.74	112.34
Nasdaq US	100.00	108.84	111.16	122.11	132.42	63.80

## ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2008, 2007, and 2006 and at December 31, 2008 and 2007 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, 2005 and 2004 and at December 31, 2006, 2005, and 2004 are derived from our audited financial statements not included in this report.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
<i>(In thousands, except per share data)</i>					
<b>Statement of Operations Data</b>					
<b>Revenues</b>					
Contract research and development	\$ 192,208	\$ 96,603	\$ 51,136	\$ 52,447	\$ 113,157
Research progress payments					42,770
Contract manufacturing			12,311	13,746	18,090
Technology licensing	40,000	28,421			
Net product sales	6,249				
	<u>238,457</u>	<u>125,024</u>	<u>63,447</u>	<u>66,193</u>	<u>174,017</u>
<b>Expenses</b>					
Research and development	278,016	201,613	137,064	155,581	136,095
Contract manufacturing			8,146	9,557	15,214
Selling, general, and administrative	49,348	37,865	25,892	25,476	17,062
Cost of goods sold	923				
	<u>328,287</u>	<u>239,478</u>	<u>171,102</u>	<u>190,614</u>	<u>168,371</u>
Income (loss) from operations	<u>(89,830)</u>	<u>(114,454)</u>	<u>(107,655)</u>	<u>(124,421)</u>	<u>5,646</u>
<b>Other income (expense)</b>					
Other contract income				30,640	42,750
Investment income	18,161	20,897	16,548	10,381	5,478
Interest expense	(7,752)	(12,043)	(12,043)	(12,046)	(12,175)
Loss on early extinguishment of debt	(938)				
	<u>9,471</u>	<u>8,854</u>	<u>4,505</u>	<u>28,975</u>	<u>36,053</u>
Net income (loss) before income tax expense and cumulative effect of a change in accounting principle	<u>(80,359)</u>	<u>(105,600)</u>	<u>(103,150)</u>	<u>(95,446)</u>	<u>41,699</u>
Income tax expense	<u>2,351</u>				
Net income (loss) before cumulative effect of a change in accounting principle	<u>(82,710)</u>	<u>(105,600)</u>	<u>(103,150)</u>	<u>(95,446)</u>	<u>41,699</u>
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")			813		
Net income (loss)	<u>\$ (82,710)</u>	<u>\$ (105,600)</u>	<u>\$ (102,337)</u>	<u>\$ (95,446)</u>	<u>\$ 41,699</u>
<b>Net income (loss) per share, basic:</b>					
Net income (loss) before cumulative effect of a change in accounting principle	\$ (1.05)	\$ (1.59)	\$ (1.78)	\$ (1.71)	\$ 0.75
Cumulative effect of adopting SFAS 123R			0.01		
Net income (loss)	<u>\$ (1.05)</u>	<u>\$ (1.59)</u>	<u>\$ (1.77)</u>	<u>\$ (1.71)</u>	<u>\$ 0.75</u>
Net income (loss) per share, diluted	<u>\$ (1.05)</u>	<u>\$ (1.59)</u>	<u>\$ (1.77)</u>	<u>\$ (1.71)</u>	<u>\$ 0.74</u>

	At December 31,				
	2008	2007	2006	2005	2004
	<i>(In thousands)</i>				
<b>Balance Sheet Data</b>					
Cash, cash equivalents, restricted cash, and marketable securities (current and non-current)	\$ 527,461	\$ 846,279	\$ 522,859	\$ 316,654	\$ 348,912
Total assets	670,038	936,258	585,090	423,501	473,108
Notes payable - current portion		200,000			
Notes payable - long-term portion			200,000	200,000	200,000
Stockholders' equity	418,852	460,267	216,624	114,002	182,543

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

### Overview

We are a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST<sup>®</sup> (riloncept) Injection for Subcutaneous Use, which is now available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We also have six clinical development programs, including three late-stage clinical programs. Our late stage programs are aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group, VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC, and ARCALYST which is being developed for the treatment of gout. Our earlier stage clinical programs are REGN88, an antibody to the interleukin-6 receptor (IL-6R), REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in rheumatoid arthritis, and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All three of these antibodies are being developed with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through December 31, 2008, we had a cumulative loss of \$875.9 million. In the absence of significant revenues from the commercialization of ARCALYST or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST; advance new product candidates into clinical development from our existing research programs utilizing our technologies for designing fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

As a company that does not expect to be profitable over the next several years, management of cash flow is extremely important. The most significant use of our cash is for research and development activities, which include drug discovery, preclinical studies, clinical trials, and the manufacture of drug supplies for preclinical studies and clinical trials. We are reimbursed for some of these research and development activities by our collaborators. Our principal sources of cash to-date have been from (i) sales of common equity, both in public offerings and to our

collaborators, including sanofi-aventis, (ii) a private placement of convertible debt, which was repaid in full during 2008, and (iii) funding from our collaborators in the form of up-front payments, research progress payments, and payments for our research and development activities.

In 2008, our research and development expenses totaled \$278.0 million. In 2009, we expect these expenses to increase substantially as we (i) continue to expand our research and preclinical and clinical development activities in connection with our antibody collaboration with sanofi-aventis, (ii) expand our VEGF Trap-Eye, ARCALYST, and aflibercept clinical programs, and (iii) increase our research and development headcount.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2008 was 810 compared with 627 in 2007 and 573 in 2006. In 2008 our average headcount increased primarily to support our expanded research and development activities in connection with our antibody collaboration with sanofi-aventis. In 2007 our average headcount increased primarily to support our expanded development programs for VEGF Trap-Eye and ARCALYST and our plans to move our first antibody candidate into clinical trials. In 2009, we expect our average headcount to increase to approximately 950-1,000, primarily to support the further expansion of our research, development, and marketing activities as described above, especially in connection with our antibody collaboration with sanofi-aventis.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2008 and plans for 2009 are as follows:

Clinical Program	2008 Events	2009 Plans
ARCALYST® (rilonacept; also known as IL-1 Trap)	<ul style="list-style-type: none"> <li>Received FDA approval for CAPS</li> <li>Launched ARCALYST commercially in CAPS</li> <li>Reported data from a Phase 2 study in the prevention of gout flares in patients initiating urate-lowering drug therapy</li> </ul>	<ul style="list-style-type: none"> <li>Initiate Phase 3 development program of ARCALYST in the prevention of gout flares in patients initiating urate-lowering drug therapy and in acute gout</li> </ul>
Aflibercept (VEGF Trap – Oncology)	<ul style="list-style-type: none"> <li>Reported final data from Phase 2 single-agent trial in advanced ovarian cancer</li> <li>Reported results from four Phase 1 dose-escalation studies in combination with chemotherapy in solid tumors</li> <li>Completed enrollment of Phase 2 single-agent study in symptomatic malignant ascites (SMA)</li> </ul>	<ul style="list-style-type: none"> <li>Initiate Phase 2 1st-line study in metastatic colorectal cancer in combination with chemotherapy</li> <li>Report results of Phase 2 single-agent study in SMA</li> <li>Continue enrollment of four Phase 3 studies</li> </ul>
VEGF Trap-Eye (intravitreal injection)	<ul style="list-style-type: none"> <li>Presented positive final data through 52 weeks from the Phase 2 trial in wet AMD</li> <li>Bayer HealthCare initiated second Phase 3 trial (VIEW 2) in wet AMD outside the United States</li> <li>Initiated a Phase 2 study in DME</li> </ul>	<ul style="list-style-type: none"> <li>Complete enrollment in VIEW 1 and VIEW 2 trials</li> <li>Continue enrolling patients in the Phase 2 DME trial</li> </ul>
Monoclonal Antibodies	<ul style="list-style-type: none"> <li>Filed IND for REGN421 (anti-DII4)</li> <li>Filed IND for REGN475 (anti-NGF)</li> </ul>	<ul style="list-style-type: none"> <li>Initiate Phase 1 trial for REGN421 in oncology</li> <li>Initiate Phase 1 trial for REGN475</li> <li>Report data from Phase 1 trial of REGN88 (anti-IL-6R) in rheumatoid arthritis</li> <li>Advance additional antibody candidate(s) into clinical development</li> </ul>

### Critical Accounting Policies and Use of Estimates

A summary of the significant accounting policies that impact us is provided in Note 2 to our Financial Statements, beginning on page F-7. The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- It requires an assumption (or assumptions) regarding a future outcome; and
- Changes in the estimate or the use of different assumptions to prepare the estimate could have a material effect on our results of operations or financial condition.

Management believes the current assumptions used to estimate amounts reflected in our financial statements are appropriate. However, if actual experience differs from the assumptions used in estimating amounts reflected in our financial statements, the resulting changes could have a material adverse effect on our results of operations, and in certain situations, could have a material adverse effect on our liquidity and financial condition. The critical accounting estimates that impact our financial statements are described below.

### Revenue Recognition

#### Contract Research and Development Revenue

We recognize contract research and development revenue and research progress payments in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and Emerging Issues Task Force 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). We earn contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize our technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of us, are deferred and recognized over the related performance period. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve

the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

We enter into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. We may share the costs of research and development activities with our collaborator, such as in our VEGF Trap-Eye collaboration with Bayer HealthCare, or we may be reimbursed for all or a significant portion of the costs of our research and development activities, such as in our aflibercept and antibody collaborations with sanofi-aventis. We record our internal and third-party development costs associated with these collaborations as research and development expenses. When we are entitled to reimbursement of all or a portion of the research and development expenses that we incur under a collaboration, we record those reimbursable amounts as contract research and development revenue proportionately as we recognize our expenses. If the collaboration is a cost-sharing arrangement in which both we and our collaborator perform development work and share costs, in periods when our collaborator incurs development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of the collaborator's development expenses that we are obligated to reimburse. In addition, we record revenue in connection with a government research grant using a proportional performance model as we incur expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically and could result in material changes to the amount of revenue recognized each year in the future. In addition, our estimated performance periods may change if development programs encounter delays or we and our collaborators decide to expand or contract our clinical plans for a drug candidate in various disease indications. For example, for the year ended December 31, 2007, we recognized \$2.6 million less in contract research and development revenue, compared to amounts recognized in 2006, in connection with non-refundable up-front payments previously received from sanofi-aventis pursuant to the companies' aflibercept collaboration, due to an extension of our estimated performance period. In addition, during the fourth quarter of 2008, we extended our estimated performance period in connection with the up-front and milestone payments previously received from Bayer HealthCare pursuant to the companies' VEGF Trap-Eye collaboration and shortened our estimated performance period in connection with up-front payments from sanofi-aventis pursuant to the companies' aflibercept collaboration. The net effect of these changes in our estimates resulted in the recognition of \$0.4 million less in contract research and development revenue in the fourth quarter of 2008, compared to amounts recognized in connection with these deferred payments in each of the prior three quarters of 2008. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

#### *Product Revenue*

In March 2008, ARCALYST<sup>®</sup> (riloncept) became available for prescription in the United States for the treatment of CAPS. We recognize revenue from product sales in accordance with SAB 104. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and we have no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distributor fees, and other sales-related costs. We account for these reductions in accordance with Emerging Issues Task Force Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)* (EITF 01-9), and Statement of Financial Accounting Standards No. (SFAS) 48, *Revenue Recognition When Right of Return Exists*, as applicable. In accordance with EITF 01-9 and SFAS 48, since we currently have limited historical return and rebate experience for ARCALYST, product sales revenues are deferred until (i) the right of return no longer exists or we can reasonably estimate returns and (ii) rebates have been processed or we can reasonably estimate rebates. We review our estimates of rebates payable each period and record any necessary adjustments in the current period's net product sales.

#### *Clinical Trial Expenses*

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations (CROs). CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of our contracts with CROs are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient

monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Our estimates and assumptions for clinical expense recognition could differ significantly from our actual results, which could cause material increases



or decreases in research and development expenses in future periods when the actual results become known. No material adjustments to our past clinical trial accrual estimates were made during the years ended December 31, 2008 or 2007.

### **Stock-based Employee Compensation**

We account for stock-based employee compensation under the provisions of SFAS 123R, *Share-Based Payment*. We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with previously issued employee and board of director option grants. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future.

The assumptions used in computing the fair value of option awards reflect our best estimates but involve uncertainties related to market and other conditions, many of which are outside of our control. Changes in any of these assumptions may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in future periods.

In addition, we have granted performance-based stock option awards which vest based upon the optionee satisfying certain performance and service conditions as defined in the agreements. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, these options' performance conditions are considered to be probable of attainment.

### **Marketable Securities**

We consider our marketable securities, which consist primarily of U.S. government, corporate, and asset-backed securities, to be "available-for-sale," as defined by SFAS 115, *Accounting for Certain Investments in Debt and Equity Securities*. These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a marketable security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that is charged against income.

On a quarterly basis, we review our portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. Such factors include the length of time and the extent to which market value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. This review process also includes an evaluation of our ability and intent to hold individual securities until they mature or their full value can be recovered. This review is subjective and requires a high degree of judgment.

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As a result of our quarterly reviews of our marketable securities portfolio, during 2008 and 2007, we recorded charges for other-than-temporary impairment of our marketable securities totaling \$2.5 million and \$5.9 million, respectively. However, the current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in our investment portfolio and that such declines could result in additional charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

### **Depreciation of Property, Plant, and Equipment**

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. In some situations, the life of the asset may be extended or shortened if circumstances arise that would lead us to believe that the estimated life of the asset has changed. The life of leasehold improvements may change based on the extension of lease contracts with our landlords. Changes in the estimated lives of assets will result in an increase or decrease in the amount of depreciation recognized in future periods.

### **Results of Operations**

#### **Years Ended December 31, 2008 and 2007**

#### **Net Loss**

Regeneron reported a net loss of \$82.7 million, or \$1.05 per share (basic and diluted), for the year ended December 31, 2008, compared to a net loss of \$105.6 million, or \$1.59 per share (basic and diluted) for 2007. The decrease in net loss was principally due to revenues earned in 2008 in connection with our November 2007 antibody collaboration with sanofi-aventis, partly offset by higher research and development expenses.

#### **Revenues**

Revenues for the years ended December 31, 2008 and 2007 consist of the following:

<i>(In millions)</i>	2008	2007
Contract research & development revenue		
Sanofi-aventis	\$154.0	\$ 51.7
Bayer HealthCare	31.2	35.9
Other	7.0	9.0
Total contract research & development revenue	192.2	96.6
Technology licensing revenue	40.0	28.4
Net product sales	6.3	

The contract research and development revenue we earn from sanofi-aventis, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

<b>Sanofi-aventis Contract Research &amp; Development Revenue</b> <i>(In millions)</i>	<b>Years ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Aflibercept:</b>		
Regeneron expense reimbursement	\$ 35.6	\$ 38.3
Recognition of deferred revenue related to up-front payments	8.8	8.8
<b>Total aflibercept</b>	<b>44.4</b>	<b>47.1</b>
<b>Antibody:</b>		
Regeneron expense reimbursement	97.9	3.7
Recognition of deferred revenue related to up-front payment	10.5	0.9
Recognition of revenue related to <i>VelociGene</i> <sup>®</sup> agreement	1.2	
<b>Total antibody</b>	<b>109.6</b>	<b>4.6</b>
<b>Total sanofi-aventis contract research &amp; development revenue</b>	<b>\$154.0</b>	<b>\$51.7</b>

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in 2008 compared to 2007, primarily due to lower costs related to manufacturing aflibercept clinical supplies. Recognition of deferred revenue relates to sanofi-aventis' up-front aflibercept payments. As of December 31, 2008, \$52.4 million of the original \$105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In 2008, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of \$72.2 million under the discovery agreement and \$25.7 million of development costs, related primarily to REGN88, under the license agreement, compared to \$3.0 million and \$0.7 million respectively, in 2007. Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' \$85.0 million up-front payment. As of December 31, 2008, \$73.6 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, in August 2008, we entered into a separate *VelociGene* agreement with sanofi-aventis. For the year ended December 31, 2008, we recognized \$1.2 million in revenue related to this agreement.

The contract research and development revenue we earn from Bayer HealthCare, as detailed below, consists partly of cost sharing of Regeneron VEGF Trap-Eye development expenses and partly of recognition of revenue related to a non-refundable \$75.0 million up-front payment and \$20.0 million milestone payment.

<b>Bayer HealthCare Contract Research &amp; Development Revenue</b> <i>(In millions)</i>	<b>Years ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	\$ 18.8	\$ 20.0
Recognition of deferred revenue related to up-front and milestone payments	12.4	15.9
<b>Total Bayer HealthCare contract research &amp; development revenue</b>	<b>\$31.2</b>	<b>\$35.9</b>

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue. In the fourth quarter of 2007, we and Bayer HealthCare approved a global development plan for VEGF Trap-Eye in wet AMD. The plan included estimated development steps, timelines, and costs, as well as the projected responsibilities of each of the companies. In addition, in the fourth quarter of 2007, we and Bayer HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. The \$75.0 million up-front licensing payment and the \$20.0 million milestone payment (which was received in August 2007 and not considered substantive) from Bayer HealthCare are being recognized as contract research and development revenue

over the related estimated performance period. In periods when we recognize VEGF Trap-Eye development expenses that we incur under the collaboration, we also recognize, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, we commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up.

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare decreased in 2008 compared to 2007. Under the terms of the collaboration, in 2008, the first \$70.0 million of agreed-upon VEGF Trap-Eye development expenses incurred by Regeneron and Bayer HealthCare under a global development plan were shared equally, and we were solely responsible for up to the next \$30.0 million. Since both we and Bayer HealthCare incurred higher VEGF Trap-Eye development expenses in 2008 compared to 2007, during the fourth quarter of 2008, we were solely responsible for most of the collaboration's VEGF Trap-Eye development expenses, which partly contributed to the revenue decrease in 2008 compared to 2007. In addition, the decrease was due in part to

the cumulative catchup recognized in 2007 from the inception of the collaboration in October 2006, as described above. Recognition of deferred revenue related to Bayer HealthCare's \$75.0 million up-front and \$20.0 million milestone payments also decreased in 2008 from 2007 as a result of the cumulative catch-up. As of December 31, 2008, \$66.7 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes \$4.9 million and \$5.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

In connection with our *VelocImmune*<sup>®</sup> license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. For the years ended December 31, 2008 and 2007, we recognized \$40.0 million and \$28.4 million, respectively, of technology licensing revenue related to these agreements.

For the year ended December 31, 2008, we recognized as revenue \$6.3 million of ARCALYST<sup>®</sup> (riloncept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated. At December 31, 2008, deferred revenue related to ARCALYST net product sales totaled \$4.0 million.

### Expenses

Total operating expenses increased to \$328.3 million in 2008 from \$239.5 million in 2007. Our average headcount in 2008 increased to 810 from 627 in the same period of 2007 principally as a result of our expanding research and development activities which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2008 and 2007 include a total of \$32.5 million and \$28.1 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

Expenses (In millions)	For the year ended December 31, 2008		
	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
	Research and development	\$259.0	\$19.0
Selling, general, and administrative	35.9	13.5	49.4
Cost of goods sold	0.9		0.9
Total operating expenses	<u>\$295.8</u>	<u>\$32.5</u>	<u>\$328.3</u>

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Expenses (In millions)	For the year ended December 31, 2007		
	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
	Research and development	\$185.4	\$16.2
Selling, general, and administrative	26.0	11.9	37.9
Total operating expenses	<u>\$211.4</u>	<u>\$28.1</u>	<u>\$239.5</u>

The increase in total Non-cash Compensation Expense in 2008 was partly attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2007 in comparison to the fair market value of annual employee option grants made in recent years prior to 2006. In addition, Non-cash Compensation Expense in 2008 and 2007 included \$2.2 million and \$0.1 million, respectively, in connection with a December 2007 Restricted Stock award.

### Research and Development Expenses

Research and development expenses increased to \$278.0 million for the year ended December 31, 2008 from \$201.6 million for 2007. The following table summarizes the major categories of our research and development expenses for the years ended December 31, 2008 and 2007:

Research and Development Expenses (In millions)	Year Ended December 31,		
	2008	2007	Increase
Payroll and benefits <sup>(1)</sup>	\$ 81.7	\$ 60.6	\$ 21.1
Clinical trial expenses	49.3	37.6	11.7
Clinical manufacturing costs <sup>(2)</sup>	53.8	47.0	6.8
Research and preclinical development costs	29.6	23.2	6.4
Occupancy and other operating costs	33.6	22.6	11.0
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses <sup>(3)</sup>	30.0	10.6	19.4
Total research and development	<u>\$ 278.0</u>	<u>\$ 201.6</u>	<u>\$ 76.4</u>

(1) Includes \$16.7 million and \$13.2 million of Non-cash Compensation Expense for the years ended December 31, 2008 and 2007, respectively.

- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$2.3 million and \$3.0 million of Non-cash Compensation Expense for the years ended December 31, 2008 and 2007, respectively.
- (3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, we commenced recognizing cost-sharing of our and Bayer Healthcare's VEGF Trap-Eye development expenses.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, which includes our VIEW 1 trial in wet AMD, (ii) ARCALYST<sup>®</sup> (rilonacept), which includes our Phase 2 gout flare prevention clinical study, and (iii) monoclonal antibodies, which includes REGN88 as well as clinical-related preparatory activities for REGN421. Clinical manufacturing costs increased due primarily to higher expenses related to VEGF Trap-Eye and monoclonal antibodies, including REGN88. These increases were partially offset by a reduction in manufacturing costs associated with ARCALYST and aflibercept. Research and preclinical development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new operating lease for our Tarrytown, New York facilities, which commenced in June 2008. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD, which Bayer HealthCare initiated in 2008.

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We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs (In millions)	Year ended December 31,		
	2008	2007	Increase (Decrease)
ARCALYST <sup>®</sup> (rilonacept)	\$ 39.2	\$ 38.1	\$ 1.1
Aflibercept	32.1	33.7	(1.6)
VEGF Trap-Eye	82.7	53.7	29.0
REGN88	21.4	13.6	7.8
Other research programs & unallocated costs	102.6	62.5	40.1
Total research and development expenses	<u>\$278.0</u>	<u>\$201.6</u>	<u>\$ 76.4</u>

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators, where applicable, continue to explore further development of ARCALYST, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors", under "Risks Related to ARCALYST<sup>®</sup> (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In the first quarter of 2008, we received FDA approval for ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. As a result, we can not predict whether the commercialization of ARCALYST in CAPS will result in a significant net cash benefit to us.

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Selling, general, and administrative expenses increased to \$49.4 million in 2008 from \$37.9 million in the same period of 2007. In 2008, we incurred \$5.2 million of selling expenses related to ARCALYST® (rilonacept) for the treatment of CAPS. General and administrative expenses increased in 2008 due to (i) higher compensation expense primarily resulting from increases in administrative headcount to support our expanded research and development activities, (ii) higher recruitment and related costs associated with expanding our headcount, (iii) higher fees for professional services related to various general corporate matters, and (iv) higher administrative facility-related costs.

#### Cost of Goods Sold

During the year ended December 31, 2008, we began recognizing revenue and cost of goods sold from net product sales of ARCALYST. We began capitalizing inventory costs associated with commercial supplies of ARCALYST subsequent to receipt of marketing approval from the FDA in February 2008. Costs for manufacturing supplies of ARCALYST prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not being included in cost of goods sold when revenue is recognized from the sale of those supplies of ARCALYST. Cost of goods sold for 2008 was \$0.9 million and consisted primarily of royalties and other period costs related to ARCALYST commercial supplies.

#### Other Income and Expense

Investment income decreased to \$18.2 million in 2008 from \$20.9 million in the 2007, due primarily to lower yields on our cash and marketable securities. In addition, in 2008 and 2007, deterioration in the credit quality of specific marketable securities in our investment portfolio subjected us to the risk of not being able to recover these securities' carrying values. As a result, in 2008 and 2007, we recognized charges of \$2.5 million and \$5.9 million related to securities from three issuers and two issuers, respectively, which we considered to be other than temporarily impaired. In 2008, these charges were partially offset by realized gains of \$1.2 million on sales of marketable securities during the year.

Interest expense of \$7.8 million and \$12.0 million for the years ended December 31, 2008 and 2007, respectively, was attributable to our 5.5% Convertible Senior Subordinated Notes due October 17, 2008. During the second and third quarters of 2008, we repurchased a total of \$82.5 million in principal amount of these convertible notes for \$83.3 million. In connection with these repurchases, we recognized a \$0.9 million loss on early extinguishment of debt, representing the premium paid on the notes plus related unamortized debt issuance costs. The remaining \$117.5 million of convertible notes were repaid in full upon their maturity in October 2008.

#### Income Tax Expense

In the third quarter of 2008, we implemented a tax planning strategy which resulted in the utilization of certain net operating loss carry-forwards, that would otherwise have expired over the next several years, to offset income for tax purposes. As a result, we incurred and paid income tax expense of \$3.1 million, which relates to U.S. federal and New York State alternative minimum tax and included \$0.2 million of interest and penalties. This expense was partly offset by a \$0.7 million income tax benefit, resulting from a provision in the Housing Assistance Tax Act of 2008 that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

#### Years Ended December 31, 2007 and 2006

#### Net Loss

Regeneron reported a net loss of \$105.6 million, or \$1.59 per share (basic and diluted), for the year ended December 31, 2007, compared to a net loss of \$102.3 million, or \$1.77 per share (basic and diluted), for 2006.

#### Revenues

Revenues for the years ended December 31, 2007 and 2006 consist of the following:

<i>(In millions)</i>	2007	2006
Contract research & development revenue		
Sanofi-aventis	\$ 51.7	\$47.8
Bayer HealthCare	35.9	
Other	9.0	3.3
Total contract research & development revenue	96.6	51.1
Contract manufacturing revenue		12.3
Technology licensing revenue	28.4	
Total revenue	<u>\$125.0</u>	<u>\$63.4</u>

We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

<u>Sanofi-aventis Contract Research &amp; Development Revenue</u> <i>(In millions)</i>	<u>Years ended</u> <u>December 31,</u>	
	2007	2006
Aflibercept:		
Regeneron expense reimbursement	\$38.3	\$36.4
Recognition of deferred revenue related to up-front payments	8.8	11.4
Total aflibercept	<u>47.1</u>	<u>47.8</u>

Antibody:

Regeneron expense reimbursement	3.7
Recognition of deferred revenue related to up-front payment	0.9
Total antibody	4.6
Total sanofi-aventis contract research & development revenue	<u>\$51.7</u> <u>\$47.8</u>

Sanofi aventis' reimbursement of Regeneron's aflibercept expenses increased in 2007 compared to 2006, primarily due to higher preclinical and clinical development costs. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments decreased in 2007 from 2006 due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of December 31, 2007, \$61.2 million of the original \$105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In 2007, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of \$3.0 million under the collaboration's discovery agreement and \$0.7 million of REGN88 development costs under the license agreement. Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' \$85.0 million up-front payment. As of December 31, 2007, \$84.1 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, in the fourth quarter of 2007, we commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up. As a result, in the fourth quarter of 2007, we recognized contract research and development revenue of \$35.9 million, consisting of (i) \$15.9 million related to the \$75.0 million up-front licensing payment and the \$20.0 million milestone payment, and (ii) \$20.0 million related to the portion of our 2007 VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. As of December 31, 2007, \$79.1 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes \$5.5 million and \$0.5 million in 2007 and 2006, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue in 2006 related to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in 2006 was \$1.2 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In connection with our license agreement with AstraZeneca, as described above, the \$20.0 million non-refundable, up-front payment, which we received in February 2007, was deferred and recognized as revenue ratably over the twelve month period beginning in February 2007. In connection with our license agreement with Astellas, as described above, the \$20.0 million non-refundable, up-front payment, which we received in April 2007, was deferred and recognized as revenue ratably over the twelve month period beginning in June 2007. For the year ended December 31, 2007, we recognized \$28.4 million of technology licensing revenue related to these agreements.

**Expenses**

Total operating expenses increased to \$239.5 million in 2007 from \$171.1 million in 2006. Our average employee headcount in 2007 increased to 627 from 573 in 2006, primarily to support our expanded development programs for VEGF Trap-Eye and ARCALYST® (riloncept) and our activities to move our first antibody candidate (REGN88) into clinical trials. Operating expenses in 2007 and 2006 include a total of \$28.1 million and \$18.6 million of Non-cash Compensation Expense, as detailed below:

Expenses (In millions)	For the year ended December 31, 2007		
	Expenses before inclusion of Non-cash Compensation	Non-cash Compensation	Expenses as
	Expense	Expense	Reported
Research and development	\$185.4	\$16.2	\$201.6
Selling, general, and administrative	26.0	11.9	37.9
Total operating expenses	<u>\$211.4</u>	<u>\$28.1</u>	<u>\$239.5</u>

Expenses (In millions)	For the year ended December 31, 2006		
	Expenses before inclusion of Non-cash Compensation	Non cash Compensation	Expenses as
	Expense	Expense	Reported
Research and development	\$126.7	\$10.4	\$137.1
Contract manufacturing	7.8	0.3	8.1
Selling, general, and administrative	18.0	7.9	25.9
Total operating expenses	<u>\$152.5</u>	<u>\$18.6</u>	<u>\$171.1</u>

The increase in total Non-cash Compensation Expense in 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

## Research and Development Expenses

Research and development expenses increased to \$201.6 million for the year ended December 31, 2007 from \$137.1 million for 2006. The following table summarizes the major categories of our research and development expenses for the years ended December 31, 2007 and 2006:

Research and Development Expenses (In millions)	Year Ended December 31,		
	2007	2006	Increase
Payroll and benefits <sup>(1)</sup>	\$ 60.6	\$ 44.8	\$15.8
Clinical trial expenses	37.6	14.9	22.7
Clinical manufacturing costs <sup>(2)</sup>	47.0	39.2	7.8
Research and preclinical development costs	23.2	17.5	5.7
Occupancy and other operating costs	22.6	20.7	1.9
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses <sup>(3)</sup>	10.6		10.6
Total research and development	<u>\$201.6</u>	<u>\$137.1</u>	<u>\$64.5</u>

(1) Includes \$13.2 million and \$8.6 million of Non-cash Compensation Expense for the years ended December 31, 2007 and 2006, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$3.0 million and \$1.8 million of Non-cash Compensation Expense for the years ended December 31, 2007 and 2006, respectively.

(3) In the fourth quarter of 2007, when we commenced recognizing cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, we recognized as additional research and development expense a cumulative catch-up of \$10.6 million of VEGF Trap-Eye development expenses that we were obligated to reimburse to Bayer HealthCare.

Payroll and benefits increased primarily due to the increase in employee headcount, as described above, annual compensation increases effective in 2007, and higher Non-cash Compensation Expense, as described above. Clinical trial expenses increased due primarily to higher costs related to our Phase 3 study of VEGF Trap-Eye in wet AMD, which we initiated in the third quarter of 2007, and our ongoing Phase 1 and 2 studies of VEGF Trap-Eye in wet AMD. Clinical manufacturing costs increased due primarily to higher costs related to manufacturing ARCALYST and preclinical and clinical supplies of REGN88, which were partly offset by lower costs related to manufacturing aflibercept and VEGF Trap-Eye. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs, including REGN88, and utilization of our proprietary technology platforms. Occupancy and other operating costs increased primarily as a result of higher Company headcount and our expanded research and development activities.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs (In millions)	Year ended December 31,		
	2007	2006	Increase
ARCALYST <sup>®</sup> (riloncept)	\$ 38.1	\$ 29.6	\$ 8.5
Aflibercept	33.7	30.7	3.0
VEGF Trap-Eye	53.7	21.9	31.8
REGN88	13.6		13.6
Other research programs & unallocated costs	62.5	54.9	7.6
Total research and development expenses	<u>\$201.6</u>	<u>\$137.1</u>	<u>\$64.5</u>

For the reasons described above in Results of Operations for the years ended December 31, 2008 and 2007, under the caption "Research and Development Expenses", and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In the first quarter of 2008, we received FDA approval for ARCALYST<sup>®</sup> (riloncept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. As a result, we can not predict whether the commercialization of ARCALYST in CAPS will result in a significant net cash benefit to us.

## Contract Manufacturing Expenses

We had no contract manufacturing expenses in 2007 compared to \$8.1 million in 2006, due to the expiration of our manufacturing agreement with Merck in October 2006.

## Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$37.9 million in 2007 from \$25.9 million in the same period of 2006 primarily due to (i) higher Non-cash Compensation Expense, as described above, (ii) higher compensation expense principally due to annual increases effective in 2007 and higher administrative headcount to support our expanded research and development activities, (iii) recruitment and related costs associated with expanding our headcount in 2007, (iv) higher fees for consultants and other professional services on various corporate matters, and (v) market research and related expenses incurred in 2007 in connection with our ARCALYST and VEGF Trap-Eye programs.

### ***Other Income and Expense***

Investment income increased to \$20.9 million in 2007 from \$16.5 million in 2006, resulting primarily from higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). This increase was partly offset by a \$5.9 million charge in 2007 related to marketable securities which we considered to be other than temporarily impaired in value. In the second half of 2007, deterioration in the credit quality of marketable securities from two issuers has subjected us to the risk of being unable to recover their full principal value, which totals \$14.0 million. Interest expense was \$12.0 million in 2007 and 2006. Interest expense was attributable primarily to our 5.5% Convertible Senior Subordinated Notes due October 17, 2008.

### **Liquidity and Capital Resources**

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, and our technology licensing agreements, ARCALYST product revenue, and investment income.

### ***Years Ended December 31, 2008 and 2007***

At December 31, 2008, we had \$527.5 million in cash, cash equivalents, restricted cash and marketable securities compared with \$846.3 million at December 31, 2007. Under the terms of our non-exclusive license agreements with AstraZeneca and Astellas, each company made two \$20.0 million annual, non-refundable payments to us, one in 2007 and the other in 2008. In August 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in our Phase 3 study of VEGF Trap-Eye in wet AMD. In December 2007, we received an \$85.0 million upfront payment in connection with our new antibody collaboration with sanofi-aventis. Sanofi-aventis also purchased 12 million newly issued, unregistered shares of our Common Stock in December 2007 for gross proceeds to us of \$312.0 million.

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### ***Cash (Used in) Provided by Operations***

Net cash used in operations was \$89.1 million in 2008, and net cash provided by operations was \$27.4 million in 2007 and \$23.1 million in 2006. Our net losses of \$82.7 million in 2008, \$105.6 million in 2007, and \$102.3 million in 2006 included \$32.5 million, \$28.1 million, and \$18.7 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of \$11.3 million, \$11.5 million, and \$14.6 million in 2008, 2007, and 2006, respectively.

At December 31, 2008, accounts receivable increased by \$16.9 million, compared to end-of-year 2007, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, prepaid expenses and other assets increased by \$6.6 million at December 31, 2008 compared to end-of-year 2007 due to a \$12.5 million payment to Collectis S.A. in July 2008, described below, which is being amortized in proportion to past and anticipated future revenues under our license agreements with AstraZeneca and Astellas and our antibody discovery agreement with sanofi-aventis. Our deferred revenue balances at December 31, 2008 decreased by \$26.8 million, compared to end-of-year 2007, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partly offset by the deferral of \$4.0 million of ARCALYST<sup>®</sup> (rilonacept) net product sales at December 31, 2008.

At December 31, 2007, accounts receivable increased by \$10.8 million compared to end-of-year 2006 due to higher receivable balances related to our collaborations with sanofi-aventis and Bayer HealthCare. Also, prepaid expenses and other assets increased \$9.6 million at December 31, 2007 compared to end-of-year 2006 due primarily to higher prepaid clinical trial costs. Our deferred revenue balances at December 31, 2007 increased by \$89.8 million, compared to end-of-year 2006, due primarily to (i) the \$85.0 million up-front payment received from sanofi-aventis, (ii) the \$20.0 million milestone payment from Bayer HealthCare which was deemed to be non-substantive and fully deferred, and (iii) the two \$20.0 million up-front payments received from each of AstraZeneca and Astellas, all as described above, partly offset by 2007 revenue recognition, principally from amortization of these deferred payments and prior year deferred payments from sanofi-aventis and Bayer HealthCare. Accounts payable, accrued expenses, and other liabilities increased \$18.2 million at December 31, 2007 compared to end-of-year 2006, primarily due to a \$4.9 million cost-sharing payment due to Bayer HealthCare in connection with the companies' VEGF Trap-Eye collaboration and higher accruals in 2007 for payroll costs and clinical-related expenses.

At December 31, 2006, accounts receivable balances decreased by \$29.0 million compared to end-of-year 2005, due to the January 2006 receipt of a \$25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, in connection with an amendment to our aflibercept collaboration to include Japan, and lower amounts due from sanofi-aventis for reimbursement of aflibercept development expenses. Also, our deferred revenue balances at December 31, 2006 increased by \$60.8 million compared to end-of-year 2005, due primarily to the October 2006 \$75.0 million up-front payment from Bayer, as described above, partly offset by 2006 revenue recognition from deferred sanofi-aventis up-front payments.

The majority of our cash expenditures in 2008, 2007, and 2006 were to fund research and development, primarily related to our clinical programs and, in 2008 and 2007, our preclinical human monoclonal antibody programs. In 2008, 2007, and 2006, we made interest payments totaling \$9.3 million, \$11.0 million, and \$11.0 million, respectively, on our convertible senior subordinated notes.

### ***Cash Provided by (Used in) Investing Activities***

Net cash provided by investing activities was \$30.8 million in 2008, and net cash used in investing activities was \$85.7 million and \$155.1 million in 2007 and 2006, respectively. In 2008, sales or maturities of marketable securities exceeded purchases by \$65.7 million, whereas in 2007 and 2006, purchases of marketable securities exceeded sales or maturities by \$67.3 million and \$150.7 million, respectively. Capital expenditures in 2008 include costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our December



*Cash (Used in) Provided by Financing Activities*

Net cash used in financing activities was \$192.9 million in 2008, and net cash provided by financing activities was \$319.4 million and \$185.4 million in 2007 and 2006, respectively. In the second and third quarters of 2008, we repurchased \$82.5 million in principal amount of our convertible senior subordinated notes for \$83.3 million. The remaining \$117.5 million of convertible notes were repaid in full upon their maturity in October 2008. In 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of our Common Stock for gross proceeds to us of \$312.0 million. In 2006, we completed a public offering of 7.6 million shares of our Common Stock and received proceeds, after expenses, of \$174.6 million. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were \$7.9 million in 2008, \$7.6 million in 2007, and \$10.4 million in 2006.

**Fair Value of Marketable Securities**

At December 31, 2008 and 2007, we held marketable securities whose aggregate fair value totaled \$278.0 million and \$345.7 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

Investment type	2008		2007	
	Fair Value	Percent	Fair Value	Percent
U.S. Treasury securities	\$113.9	41%		
U.S. government agency securities	58.3	21%	\$ 50.5	15%
U.S. government-guaranteed corporate bonds	29.8	11%		
U.S. government guaranteed collateralized mortgage obligations	17.4	6%	48.8	14%
Corporate bonds	37.1	13%	110.7	32%
Asset-backed securities	17.8	7%	45.2	13%
Commercial paper			72.8	21%
Other	3.7	1%	17.7	5%
<b>Total marketable securities</b>	<b>\$278.0</b>	<b>100%</b>	<b>\$345.7</b>	<b>100%</b>

In addition, at December 31, 2008 and 2007, we had \$249.5 million and \$500.6 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2008, as marketable securities in our portfolio matured or paid down, we purchased primarily U.S. Treasury securities, U.S. government agency obligations and U.S. government-guaranteed debt. This shift toward higher quality securities reduced the risk profile, as well as the overall yield, of our portfolio during 2008.

In particular, we reduced the proportion of asset-backed securities in the portfolio as they deteriorated in credit quality and declined in value due to higher delinquency rates on the underlying collateral supporting these securities. Of the \$17.8 million of asset-backed securities that we held at December 31, 2008, \$10.0 million were backed by prime and sub-prime residential mortgages and home equity loans. The remaining \$7.8 million were backed by automotive loans and credit card receivables, of which one \$4.9 million security matured in February 2009. The estimated fair value of our asset-backed securities generally ranged from 80% to 95% of par value at December 31, 2008. We purchased these securities in early 2007 when they were all rated triple-A by at least one of the major rating agencies. In addition, our asset-backed securities are all senior tranches that are paid-down before other subordinated tranches as the loans in the underlying collateral are repaid. Through December 31, 2008, we continued to receive monthly payments of principal and interest on our asset-backed securities holdings. If the monthly principal and interest payments continue at approximately the current rate, we anticipate that all of the asset-backed securities in our portfolio will be repaid within the next two years, and most would be repaid in 2009. However, further deterioration of the current economic environment and/or higher delinquency rates in the underlying collateral supporting an asset-backed security in our investment portfolio could result in future impairment charges related to these securities, which could be material.

In addition, we reduced the proportion of corporate bonds in our portfolio from 32% at December 31, 2007 to 13% at December 31, 2008, due to the deterioration of the credit quality of many corporate bond issuers. At the end of 2008, we held \$37.1 million of corporate bonds issued by financial services companies, of which \$5.1 million matured in January 2009 and another \$21.6 million are scheduled to mature by the end of 2009. During 2008, we recognized other-than-temporary impairment charges of \$2.5 million related to corporate securities in our portfolio. Further deterioration in the credit quality of financial services companies whose debt we hold could result in additional impairment charges, which could be material.

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. We adopted the provisions of SFAS 157 as of January 1, 2008, for financial instruments. Although the adoption of SFAS 157 did not materially impact our financial condition, results of operations, or cash flows, we are now required to provide additional disclosures as part of our financial statements. In addition, in October 2008, the FASB issued FASB Staff Position (FSP) 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, which clarifies the application of SFAS 157 in a market that is not active. FSP 157-3 also reaffirms the notion of fair value as an exit price as of the measurement date. FSP 157-3 was effective upon issuance for financial statements that had not yet been issued. We adopted FSP 157-3 for the quarter ended September 30, 2008.

SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers are Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. We

have determined that the provisions of SFAS 157 are applicable to our marketable securities, which totaled \$278.0 million as of December 31, 2008. At December 31, 2008, less than 1% of our marketable securities represented Level 3 assets.

Changes in Level 3 marketable securities during the year ended December 31, 2008 were as follows:

<i>(In millions)</i>	<b>Level 3 Marketable Securities</b>
Balance January 1, 2008	\$ 7.9
Settlements	(8.2)
Realized gain	1.1
Impairments	(0.7)
Balance December 31, 2008	<u>\$ 0.1</u>

During the year ended December 31, 2008, there were no transfers of marketable securities between Level 2 and Level 3 classifications.

Our methods for valuing our marketable securities are described in Note 2 to our financial statements included in this Annual Report on Form 10-K. With respect to valuations for pricing our Level 2 marketable securities, we consider quantitative and qualitative factors such as financial conditions and near term prospects of the issuer, recommendations of the investment advisors and forecasts of economic, market, or industry trends. We also review our investment advisors' policies and procedures for valuation and, for a sample of valuations, review the inputs supporting the valuations and independently test the valuations through the use of an alternative third-party vendor. For valuations that we determine for our Level 3 marketable securities, we regularly monitor these securities and adjust their valuations as deemed appropriate based on the facts and circumstances.

### ***Collaborations with the sanofi-aventis Group***

#### *Aflibercept*

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. Sanofi-aventis made a non-refundable up-front payment of \$80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for \$45.0 million.

In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In connection with this amendment, sanofi-aventis made a \$25.0 million non-refundable payment to us.

In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a \$25.0 million non-refundable up-front payment to us, which was

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received in January 2006. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

We have agreed to manufacture clinical supplies of aflibercept at our plant in Rensselaer, New York. Sanofi-aventis has agreed to be responsible for providing commercial scale manufacturing capacity for aflibercept.

Under the collaboration agreement, as amended, agreed upon worldwide aflibercept development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the \$25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of an aflibercept product for intraocular delivery to the eye predates the first commercial sale of an aflibercept product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to \$7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs. Since inception of the collaboration agreement through December 31, 2008, we and sanofi-aventis have incurred \$446.5 million in agreed upon development expenses related to aflibercept. Currently, multiple clinical studies to evaluate aflibercept as both a single agent and in combination with other therapies in various cancer indications are ongoing, and we and sanofi-aventis plan to initiate additional aflibercept clinical studies in 2009.

Sanofi-aventis funded \$35.6 million, \$38.3 million, and \$36.4 million, respectively, of our aflibercept development costs in 2008, 2007, and 2006, of which \$6.3 million, \$10.5 million, and \$6.8 million, respectively, were included in accounts receivable as of December 31, 2008, 2007, and 2006. In addition, the up-front payments of \$80.0 million in September 2003 and \$25.0 million in January 2006 from sanofi-aventis were recorded to deferred revenue and are being recognized as contract research and development revenue over the period during which we expect to perform services. In 2008, 2007, and 2006, we recognized \$8.8 million, \$8.8 million, and \$11.4 million of revenue, respectively, related to these up-front payments.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of aflibercept development expenses will terminate and we will retain all rights to aflibercept.

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$75 million of research from the collaboration's inception through December 31, 2008 and will fund up to \$100 million per year in 2009 through 2012. The discovery agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Under the license agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate (called Shared Phase 3 Trial Costs) will be shared 80% by sanofi-aventis and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of

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development expenses that were fully funded by sanofi-aventis (or half of \$27.8 million as of December 31, 2008) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and our share of the collaboration profits from commercialization of collaboration products. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the license agreement, we will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. The first three therapeutic antibodies to enter clinical development under the collaboration are REGN88, that is being evaluated in rheumatoid arthritis, REGN421, that is being evaluated in oncology in patients with advanced malignancies, and REGN475, that is being evaluated in pain.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the collaboration until commercial supplies of that drug candidate are being manufactured.

In 2008 and 2007, sanofi-aventis funded \$72.2 million and \$3.0 million, respectively, of our expenses under the collaboration's discovery agreement and \$25.7 million and \$0.7 million, respectively, of our development costs, primarily for REGN88, under the license agreement. Of these amounts, \$25.5 million and \$3.7 million were included in accounts receivable as of December 31, 2008 and 2007, respectively. In addition, the \$85.0 million up-front payment received from sanofi-aventis in December 2007 was recorded to deferred revenue and is being recognized as contract research and development revenue over the period during which we expect to perform services. In 2008 and 2007, we recognized \$10.5 million and \$0.9 million of revenue, respectively related to this up-front payment.

In connection with the collaboration, in August 2008, we entered into a separate agreement with sanofi-aventis to use our proprietary *VelociGene*<sup>®</sup> technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. The agreement provides for minimum annual order quantities for the term of the agreement which extends through December 2012, for which we expect to receive payments totaling a minimum of \$21.5 million, of which \$0.6 million had been received as of December 31, 2008.

With respect to each antibody product which enters development under the license agreement, sanofi-aventis or we may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. We may also opt-out of the further development of an antibody product if we give notice to sanofi-aventis within thirty days of the date that sanofi-aventis elects to jointly develop such antibody product under the license agreement. Each of the discovery agreement and the license agreement contains other termination provisions, including for material breach by the other party and, in the case of the discovery agreement, a termination right for sanofi-aventis under other limited defined circumstances. Prior to December 31, 2012, sanofi-aventis has the right to terminate the discovery agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to us the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, our obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate.

In December 2007, we sold sanofi-aventis 12 million newly issued, unregistered shares of Common Stock at an aggregate cash price of \$312.0 million, or \$26.00 per share of Common Stock. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with us, which contains certain demand rights, "standstill provisions", and other restrictions, which are more fully described in Note 8 to our Financial Statements.

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### ***Collaboration with Bayer HealthCare***

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, VEGF Trap-Eye. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to us of \$75.0 million. In August 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of VEGF Trap-Eye in wet AMD, and are eligible to receive up to \$90 million in additional development and regulatory milestones related to the VEGF Trap-Eye program. We are also eligible to receive up to an additional \$135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

We will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer HealthCare out of our share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred

(or half of \$63.0 million at December 31, 2008) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and our share of the collaboration profits, or at a faster rate at our option. Within the United States, we are responsible for any future commercialization of VEGF Trap-Eye and retain exclusive rights to any future profits from commercialization. In 2007, we initiated the VIEW 1 trial in wet AMD and, in 2008, Bayer HealthCare initiated the VIEW 2 trial in wet AMD. In addition, in late 2008, we initiated a Phase 2 study of VEGF Trap-Eye in patients with DME. We are also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

The \$75.0 million up-front payment and \$20.0 million non-substantive milestone payment from Bayer HealthCare were recorded to deferred revenue. In 2008 and 2007, we recognized \$12.4 million and \$15.9 million, respectively, of revenue related to these deferred payments. We did not recognize revenue in connection with our collaboration with Bayer HealthCare in 2006.

Under the terms of the agreement, in 2009 and thereafter, all agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared equally. In 2008, the first \$70.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next \$30.0 million, which resulted in a net payment of \$11.3 million to Bayer HealthCare by us in 2008. In 2007, the first \$50.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next \$40.0 million, which resulted in a net reimbursement of \$9.4 million from Bayer HealthCare to us in 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007. At December 31, 2008 and 2007, accrued expenses included \$9.8 million and \$4.9 million, respectively, due to Bayer HealthCare. In addition, at December 31, 2007, accounts receivable included \$2.8 million due from Bayer HealthCare.

Bayer HealthCare has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to VEGF Trap-Eye.

#### ***License Agreements with AstraZeneca and Astellas***

Under these non-exclusive license agreements, AstraZeneca and Astellas each made two \$20.0 million annual, non-refundable payments to us, one in 2007 and the other in 2008. AstraZeneca and Astellas are each required to make up to four additional annual payments of \$20.0 million, subject to each licensee's ability to terminate its license agreement with us after making two more payments or earlier if the technology does not meet minimum performance criteria.

#### ***National Institutes of Health Grant***

Under our five-year grant from the NIH, we are entitled to receive a minimum of \$24.5 million over a five-year period, subject to compliance with the grant's terms and annual funding approvals, including \$1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium. In 2008 and 2007, we recognized \$4.9 million and \$5.5 million, respectively, of revenue related to the NIH Grant, of which \$1.3 million and \$1.0 million, respectively, was receivable at the end of 2008 and 2007. In 2009, we expect to receive funding of approximately \$5 million for reimbursement of Regeneron expenses related to the NIH Grant.

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#### ***Convertible Debt***

In 2001, we issued \$200.0 million aggregate principal amount of convertible senior subordinated notes, which bore interest at 5.5% per annum, payable semi-annually, and that matured in October 2008. During the second and third quarters of 2008, we repurchased \$82.5 million in principal amount of our notes for \$83.3 million. The remaining \$117.5 million of outstanding convertible notes were repaid in full upon their maturity in October 2008.

#### ***License Agreement with Collectis***

In July 2008, we and Collectis S.A. entered into an Amended and Restated Non-Exclusive License Agreement. The amended license agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which we licensed certain patents and patent applications relating to a process for the specific replacement of a copy of a gene in the receiver genome by homologous recombination. Pursuant to the amended license agreement, in July 2008, we made a non-refundable \$12.5 million payment to Collectis and agreed to pay Collectis a low single-digit royalty based on revenue received by us from any future licenses or sales of our *VelociGene*<sup>®</sup> or *VelocImmune*<sup>®</sup> products and services. No royalties are payable with respect to our *VelocImmune* license agreements with AstraZeneca and Astellas or our November 2007 collaboration with sanofi-aventis. Moreover, no royalties are payable on any revenue from commercial sales of antibodies from our *VelocImmune* technology.

We are amortizing our \$12.5 million payment to Collectis in proportion to past and anticipated future revenues under our license agreements with AstraZeneca and Astellas and our antibody discovery agreement with sanofi-aventis. In 2008, we recognized \$2.7 million of expense related to this agreement.

In July 2008, we and Collectis also entered into a Subscription Agreement pursuant to which we purchased 368,301 ordinary shares of Collectis in November 2008 at a price of EUR 8.63 per share (which was equivalent to \$10.98 at the EUR exchange rate on the date of purchase).

#### ***Operating Lease – Tarrytown, New York Facilities***

Under our main operating lease, as amended, we currently lease approximately 248,000 square feet of laboratory and office facilities in Tarrytown, New York. In December 2006, we entered into a new operating lease agreement (as amended in October 2007) to lease approximately 257,000 square feet of laboratory and office space at our current Tarrytown location, which included approximately 27,000 square feet that we currently occupy (our retained facilities) and approximately 230,000 square feet in new facilities that are currently under construction and expected to be completed in mid-2009. In September 2008, we amended the operating lease agreement to increase the amount of retained space we will lease from approximately 27,000 square feet to approximately 118,000 square feet, for an amended total under the new lease of approximately 348,000 square feet. The term of the new lease commenced effective June 2008 and will expire in June 2024. Under the new lease we also have various options and rights on additional space at the Tarrytown site, and will continue to lease our present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for our retained facilities only. The lease provides for monthly payments over the term of the lease related to our retained facilities, the costs of construction and tenant improvements for our new facilities, and additional charges for utilities, taxes, and operating expenses.

In connection with the new lease agreement, in December 2006, we issued a letter of credit in the amount of \$1.6 million to our landlord, which is collateralized by a \$1.6 million bank certificate of deposit.

## Capital Expenditures

Our additions to property, plant, and equipment totaled \$34.9 million in 2008, \$19.6 million in 2007, and \$3.3 million in 2006. In 2009, we expect to incur approximately \$50 to \$60 million in capital expenditures (net of Tarrytown tenant improvement costs that will be reimbursed by our landlord in connection with our new operating lease), primarily in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and our new Tarrytown operating lease, as described above. We currently expect to incur approximately \$30 million in capital expenditures in 2010.

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## Funding Requirements

Our total expenses for research and development from inception through December 31, 2008 have been approximately \$1,630 million. We have entered into various agreements related to our activities to develop and commercialize product candidates and utilize our technology platforms, including collaboration agreements, such as those with sanofi-aventis and Bayer HealthCare, and agreements to use our *Velocigene*<sup>®</sup> technology platform. We incurred expenses associated with these agreements, which include an allocable portion of general and administrative costs, of \$230.6 million, \$108.2 million, and \$43.4 million in 2008, 2007, and 2006, respectively.

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 50-60% of our expenditures for 2009 will be directed toward the preclinical and clinical development of product candidates, including ARCALYST<sup>®</sup> (riloncept), aflibercept, VEGF Trap-Eye, and monoclonal antibodies (including REGN88, REGN421, and REGN475); approximately 25-30% of our expenditures for 2009 will be applied to our basic research and early preclinical activities and the remainder of our expenditures for 2009 will be used for the continued development of our novel technology platforms, capital expenditures, and general corporate purposes.

We currently anticipate that in 2009 the commercialization of ARCALYST for the treatment of CAPS will not materially enhance or otherwise materially impact our cash flows.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2008. These obligations and commitments assume non-termination of agreements and represent expected payments based on current operating forecasts, which are subject to change:

	Payments Due by Period				
	Total	Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
Operating leases <sup>(1)</sup>	\$230.1	\$ 9.1	\$26.8	\$27.2	\$167.0
Purchase obligations <sup>(2)</sup>	126.3	65.7	59.3	1.3	
Total contractual obligations	<u>\$356.4</u>	<u>\$74.8</u>	<u>\$86.1</u>	<u>\$28.5</u>	<u>\$167.0</u>

(1) Includes projected obligations based, in part, upon budgeted construction and tenant improvement costs related to our new operating lease for facilities under construction in Tarrytown, New York, as described above. Excludes future contingent rental costs for utilities, real estate taxes, and operating expenses. In 2008, these costs were \$8.4 million.

(2) Purchase obligations primarily relate to (i) research and development commitments, including those related to clinical trials, (ii) capital expenditures for equipment acquisitions, and (iii) license payments. Our obligation to pay certain of these amounts may increase or be reduced based on certain future events. Open purchase orders for the acquisition of goods and services in the ordinary course of business are excluded from the table above.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare will share agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, as described above. In addition, under our collaboration agreements with sanofi-aventis and Bayer HealthCare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse sanofi-aventis and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by sanofi-aventis and Bayer HealthCare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for our aflibercept collaboration with sanofi-aventis, royalties on product sales in Japan) otherwise payable to us unless we agree to reimburse these expenses at a faster rate at our option. Given the uncertainties related to drug development (including the development of aflibercept and co-developed antibody candidates in collaboration with sanofi-aventis and VEGF Trap-Eye in collaboration with Bayer HealthCare) such

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as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with sanofi-aventis and Bayer HealthCare will become profitable.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST<sup>®</sup> (riloncept) for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST for other indications or certain of our product

candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

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

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates.

Other than letters of credit totaling \$1.7 million, including a \$1.6 million letter of credit issued to our landlord in connection with our operating lease for facilities in Tarrytown, New York, as described above, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of December 31, 2008, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

### **Future Impact of Recently Issued Accounting Standards**

In November 2007, the Emerging Issues Task Force issued Statement No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and will be applied retrospectively as a change in accounting principle for collaborative arrangements existing at the effective date. We are required to adopt EITF 07-1 for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of EITF 07-1 will have a material impact on our financial statements.

In March 2008, the FASB issued SFAS 161, *Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement 133*. SFAS 161 enhances required disclosures regarding derivatives and hedging activities, including enhanced disclosures regarding how (a) an entity uses derivative instruments, (b) derivative

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instruments and related hedged items are accounted for under SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, and (c) derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for fiscal years and interim periods beginning after November 15, 2008. We are required to adopt SFAS 161 for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of SFAS 161 will have a material impact on our financial statements.

In April 2008, the FASB issued FASB Staff Position (FSP) FAS 142-3, *Determination of the Useful Life of Intangible Assets*. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, *Goodwill and Other Intangible Assets*. The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R, and other generally accepted accounting principles (GAAP). This FSP is effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. We are required to adopt FSP FAS 142-3 for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of this FSP will have a material impact on our financial statements.

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

#### *Interest Rate 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 U.S. government, corporate, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent unfavorable change in interest rates would result in approximately a \$1.9 million decrease in the fair value of our investment portfolio at both December 31, 2008 and 2007.

#### *Credit Quality Risk*

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. In the second half of 2007, we recognized a \$5.9 million charge related to marketable securities from two issuers which we considered to be other than temporarily impaired in value. In 2008, an additional \$0.7 million impairment charge was recognized related to one of these securities and a \$1.8 million charge was recognized related to another marketable security which we considered to be other than temporarily impaired in value.

### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements required by this Item are included on pages F-1 through F-34 of this report. The supplementary financial information required by this Item is included at pages F-34 of this report.

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

Not applicable.

## ITEM 9A. CONTROLS AND PROCEDURES

### *Evaluation of Disclosure Controls and Procedures*

The Company's management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that

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it files or submits under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to the Company's management, including the Company's chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

### ***Management Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation our management has concluded that our internal control over financial reporting was effective as of December 31, 2008. The effectiveness of our internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

### ***Changes in Internal Control over Financial Reporting***

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

## ITEM 9B. OTHER INFORMATION

None.

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## PART III

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our officers, directors and employees. The full text of our code of business conduct and ethics can be found on the Company's website (<http://www.regeneron.com>) under the "Corporate Governance" heading on the "About Us" page.

## ITEM 11. EXECUTIVE COMPENSATION

The information called for by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

## PART IV

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

### (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.

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### 3. Exhibits

Exhibit Number	Description
3.1	(p) - Restated Certificate of Incorporation, filed February 11, 2008 with the New York Secretary of State.
3.2	(a) - By-Laws of the Company, currently in effect (amended through November 9, 2007).
10.1 +	(b) - 1990 Amended and Restated Long-Term Incentive Plan.
10.2 +	(q) - Amended and Restated 2000 Long-Term Incentive Plan.
10.2.1 +	(c) - Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers.
10.2.2 +	(c) - Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10.2.3 +	(d) - Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers.
10.3 +	- Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Company and Leonard S. Schleifer, M.D., Ph.D.
10.4* +	(e) - Employment Agreement, dated as of December 31, 1998, between the Company and P. Roy Vagelos, M.D.
10.5 +	- Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008.
10.6*	(f) - IL-1 License Agreement, dated June 26, 2002, by and among the Company, Immunex Corporation, and Amgen Inc.
10.7*	(g) - Collaboration, License and Option Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and the Company.
10.8*	(h) - Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.8.1*	(e) - Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 31, 2004.
10.8.2	(i) - Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of January 7, 2005.
10.8.3*	(j) - Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 21, 2005.
10.8.4*	(j) - Amendment No. 4 to Collaboration Agreement, by and between sanofi-aventis U.S., LLC (successor in interest to Aventis Pharmaceuticals, Inc.) and Regeneron Pharmaceuticals, Inc., effective as of January 31, 2006.
10.9	(h) - Stock Purchase Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.10*	(k) - License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
10.11*	(l) - Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007 by and between AstraZeneca UK Limited and Regeneron Pharmaceuticals, Inc.
10.12	(m) - Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc.
10.12.1*	(o) - First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of October 24, 2007.
10.12.2	(s) - Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of September 30, 2008.
10.13*	(n) - Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and Regeneron Pharmaceuticals, Inc.
10.14*	(p) - Discovery and Preclinical Development Agreement, dated as of November 28, 2007, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.15*	(p) - License and Collaboration Agreement, dated as of November 28, 2007, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique Du Nord and Regeneron Pharmaceuticals, Inc.

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Exhibit Number	Description
10.16	(p) - Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amerique Du Nord, sanofi-aventis US LLC and Regeneron Pharmaceuticals, Inc.
10.17	(p) - Investor Agreement, dated as of December 20, 2007, by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and Regeneron Pharmaceuticals, Inc.
10.18*	(r) - Amended and Restated Non-Exclusive License Agreement, dated as of July 1, 2008 by and between Collectis, S.A. and Regeneron Pharmaceuticals, Inc.
10.19	(r) - Subscription Agreement, dated as of July 1, 2008 by and between Collectis, S.A. and Regeneron Pharmaceuticals, Inc.
12.1	- Statement re: computation of ratio of earnings to combined fixed charges of Regeneron Pharmaceuticals, Inc.
23.1	- Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

**Description:**

- (a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.
- (b) Incorporated by reference from the Company's registration statement on Form S-1 (file number 33-39043).
- (c) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.
- (d) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.
- (e) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2004, filed March 11, 2005.
- (f) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2002, filed August 13, 2002.
- (g) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended March 31, 2003, filed May 15, 2003.
- (h) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2003, filed November 12, 2003.
- (i) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.
- (j) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2005, filed February 28, 2006.
- (k) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2006, filed November 6, 2006.
- (l) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2006, filed March 12, 2007.
- (m) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.
- (n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended March 31, 2007, filed May 4, 2007.

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- (o) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended September 30, 2007, filed November 7, 2007.
  - (p) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2007, filed February 27, 2008.
  - (q) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc. filed June 17, 2008.
  - (r) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2008, filed August 1, 2008.
  - (s) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2008, filed November 5, 2008.

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

+ Indicates a management contract or compensatory plan or arrangement.

## SIGNATURES

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

REGENERON PHARMACEUTICALS, INC.

By: /s/ LEONARD S. SCHLEIFER  
Leonard S. Schleifer, M.D., Ph.D.  
*President and Chief Executive Officer*

Dated: New York, New York  
February 26, 2009

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leonard S. Schleifer, President and Chief Executive Officer, and Murray A. Goldberg, Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, and each of them, his true and lawful attorney-in-fact and agent, with the full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities therewith, to sign any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or either of them, or their 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 persons on behalf of the registrant and in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>
<u>/s/ LEONARD S. SCHLEIFER</u> Leonard S. Schleifer, M.D., Ph.D.	<i>President, Chief Executive Officer, and Director (Principal Executive Officer)</i>
<u>/s/ MURRAY A. GOLDBERG</u> Murray A. Goldberg	<i>Senior Vice President, Finance &amp; Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer)</i>
<u>/s/ DOUGLAS S. McCORKLE</u> Douglas S. McCorkle	<i>Vice President, Controller, and Assistant Treasurer (Principal Accounting Officer)</i>
<u>/s/ GEORGE D. YANCOPOULOS</u> George D. Yancopoulos, M.D., Ph.D.	<i>Executive Vice President, Chief Scientific Officer, President, Regeneron Research Laboratories, and Director</i>
<u>/s/ P. ROY VAGELOS</u> P. Roy Vagelos, M.D.	<i>Chairman of the Board</i>
<u>/s/ CHARLES A. BAKER</u> Charles A. Baker	<i>Director</i>
<u>/s/ MICHAEL S. BROWN</u> Michael S. Brown, M.D.	<i>Director</i>
<u>/s/ ALFRED G. GILMAN</u> Alfred G. Gilman, M.D., Ph.D.	<i>Director</i>
<u>/s/ JOSEPH L. GOLDSTEIN</u> Joseph L. Goldstein, M.D.	<i>Director</i>
<u>/s/ ERIC M. SHOOTER</u> Eric M. Shooter, Ph.D.	<i>Director</i>
<u>/s/ GEORGE L. SING</u> George L. Sing	<i>Director</i>

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REGENERON PHARMACEUTICALS, INC.

## INDEX TO FINANCIAL STATEMENTS

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
Regeneron Pharmaceuticals, Inc.:

In our opinion, 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. at December 31, 2008 and December 31, 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in note 2 to the financial statements, effective January 1, 2006, the Company changed its method of accounting for share-based payment, to conform with FASB Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-based Payment."

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP

New York, New York  
February 26, 2009

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**REGENERON PHARMACEUTICALS, INC.  
BALANCE SHEETS**

**December 31, 2008 and 2007**

	2008	2007
	<i>(In thousands, except share data)</i>	
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 247,796	\$ 498,925
Marketable securities	226,954	267,532
Accounts receivable from the sanofi-aventis Group	33,302	14,244
Accounts receivable - other	1,910	4,076
Prepaid expenses and other current assets	11,480	13,052
Total current assets	521,442	797,829
Restricted cash	1,650	1,600
Marketable securities	51,061	78,222
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	87,853	58,304

Other assets	8,032	303
Total assets	<u>\$ 670,038</u>	<u>\$ 936,258</u>
<b>LIABILITIES and STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 36,168	\$ 39,232
Deferred revenue from sanofi-aventis, current portion	21,390	18,855
Deferred revenue - other, current portion	26,114	25,577
Notes payable		200,000
Total current liabilities	<u>83,672</u>	<u>283,664</u>
Deferred revenue from sanofi-aventis	105,586	126,431
Deferred revenue - other	56,835	65,896
Other long term liabilities	5,093	
Total liabilities	<u>251,186</u>	<u>475,991</u>
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; shares issued and outstanding - 2,248,698 in 2008 and 2,260,266 in 2007	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 77,642,203 in 2008 and 76,592,218 in 2007	78	77
Additional paid-in capital	1,294,813	1,253,235
Accumulated deficit	(875,927)	(793,217)
Accumulated other comprehensive income (loss)	(114)	170
Total stockholders' equity	<u>418,852</u>	<u>460,267</u>
Total liabilities and stockholders' equity	<u>\$ 670,038</u>	<u>\$ 936,258</u>

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

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**REGENERON PHARMACEUTICALS, INC.  
STATEMENTS OF OPERATIONS**

**For the Years Ended December 31, 2008, 2007, and 2006**

	2008	2007	2006
<i>(In thousands, except per share data)</i>			
<b>Revenues</b>			
Contract research and development from sanofi-aventis	\$ 153,972	\$ 51,687	\$ 47,763
Other contract research and development	38,236	44,916	3,373
Contract manufacturing			12,311
Technology licensing	40,000	28,421	
Net product sales	6,249		
	<u>238,457</u>	<u>125,024</u>	<u>63,447</u>
<b>Expenses</b>			
Research and development	278,016	201,613	137,064
Selling, general, and administrative	49,348	37,865	25,892
Contract manufacturing			8,146
Cost of goods sold	923		
	<u>328,287</u>	<u>239,478</u>	<u>171,102</u>
Loss from operations	<u>(89,830)</u>	<u>(114,454)</u>	<u>(107,655)</u>
<b>Other income (expense)</b>			
Investment income	18,161	20,897	16,548
Interest expense	(7,752)	(12,043)	(12,043)
Loss on early extinguishment of debt	(938)		
	<u>9,471</u>	<u>8,854</u>	<u>4,505</u>
Net loss before income tax expense and cumulative effect of a change in accounting principle	<u>(80,359)</u>	<u>(105,600)</u>	<u>(103,150)</u>
Income tax expense	2,351		



connection with exercise of stock options, net of shares tendered	886	1	7,618					7,619		
Issuance of Common Stock to sanofi-aventis	12,000	12	311,988					312,000		
Cost associated with issuance of equity securities to sanofi-aventis			(219)					(219)		
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution	65		1,367					1,367		
Issuance of restricted Common Stock under Long-Term Incentive Plan	500	1	(1)							
Conversion of Class A Stock to Common Stock	(10)		10							
Stock-based compensation expense			28,075					28,075		
Net loss, 2007						(105,600)		(105,600)	\$(105,600)	
Change in net unrealized gain (loss) on marketable securities							401	401	401	
<b>Balance, December 31, 2007</b>	<b>2,260</b>	<b>2</b>	<b>76,592</b>	<b>77</b>	<b>1,253,235</b>	<b>—</b>	<b>(793,217)</b>	<b>170</b>	<b>460,267</b>	<b>\$(105,199)</b>

Issuance of Common Stock in connection with exercise of stock options, net of shares tendered	980	1	7,948					7,949		
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution	59		1,107					1,107		
Conversion of Class A Stock to Common Stock	(11)		11							
Stock-based compensation expense			32,523					32,523		
Net loss, 2008						(82,710)		(82,710)	\$(82,710)	
Change in net unrealized gain (loss) on marketable securities							(284)	(284)	(284)	
<b>Balance, December 31, 2008</b>	<b>2,249</b>	<b>\$ 2</b>	<b>77,642</b>	<b>\$78</b>	<b>\$1,294,813</b>	<b>—</b>	<b>\$(875,927)</b>	<b>\$(114)</b>	<b>\$ 418,852</b>	<b>\$(82,994)</b>

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

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**REGENERON PHARMACEUTICALS, INC.**  
**STATEMENTS OF CASH FLOWS**

**For the Years Ended December 31, 2008, 2007, and 2006**

	2008	2007	2006
	<i>( In thousands )</i>		
<b>Cash flows from operating activities</b>			
Net loss	\$ (82,710)	\$ (105,600)	\$ (102,337)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities			
Depreciation and amortization	11,287	11,487	14,592
Non-cash compensation expense	32,523	28,075	18,675
Loss on early extinguishment of debt	938		
Net realized loss on marketable securities	1,310	5,943	
Cumulative effect of a change in accounting principle			(813)
Changes in assets and liabilities			
(Increase) decrease in accounts receivable	(16,892)	(10,827)	29,028
(Increase) decrease in prepaid expenses and other assets	(6,560)	(9,649)	155
Decrease in inventory			3,594
(Decrease) increase in deferred revenue	(26,834)	89,764	60,833

(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(2,148)	18,179	(652)
Total adjustments	(6,376)	132,972	125,412
Net cash (used in) provided by operating activities	(89,086)	27,372	23,075
<b>Cash flows from investing activities</b>			
Purchases of marketable securities	(581,139)	(594,446)	(456,893)
Sales or maturities of marketable securities	646,861	527,169	306,199
Capital expenditures	(34,857)	(18,446)	(2,811)
Increase in restricted cash	(50)		(1,600)
Net cash provided by (used in) investing activities	30,815	(85,723)	(155,105)
<b>Cash flows from financing activities</b>			
Repurchases or repayment of notes payable	(200,807)		
Net proceeds from the issuance of Common Stock	7,949	319,400	185,008
Other			390
Net cash (used in) provided by financing activities	(192,858)	319,400	185,398
Net (decrease) increase in cash and cash equivalents	(251,129)	261,049	53,368
Cash and cash equivalents at beginning of period	498,925	237,876	184,508
Cash and cash equivalents at end of period	\$ 247,796	\$ 498,925	\$ 237,876
<b>Supplemental disclosure of cash flow information</b>			
Cash paid for interest	\$ 9,348	\$ 11,000	\$ 11,000
Cash paid for income taxes	\$ 3,079		

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

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**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**For the years ended December 31, 2008, 2007, and 2006**  
*(Unless otherwise noted, dollars in thousands, except per share data).*

**1. Organization and Business**

Regeneron Pharmaceuticals, Inc. (the “Company” or “Regeneron”) was incorporated in January 1988 in the State of New York. The Company is engaged in the research, development, and commercialization of therapeutics to treat human disorders and conditions. In 2008, the Company received marketing approval from the U.S. Food and Drug Administration (“FDA”) for the Company’s first commercial drug product, ARCALYST<sup>®</sup> (riloncept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (“CAPS”). The Company’s facilities are primarily 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**

***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.

***Marketable Securities***

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The Company generally invests its excess cash in obligations of the U.S. government and its agencies, investment grade debt securities issued by corporations, governments, and financial institutions, bank deposits, asset-backed securities, commercial paper, and money market funds that invest in these instruments. The Company considers its marketable securities to be “available-for-sale,” as defined by Statement of Financial Accounting Standards No. (“SFAS”) 115, *Accounting for Certain Investments in Debt and Equity Securities*. These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders’ equity. If the decline in the value of a marketable security in the Company’s investment portfolio is deemed to be other-than-temporary, the Company writes down the security to its current fair value and recognizes a loss that is charged against income. As described under “Use of Estimates” below, on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary.

***Capitalization of Inventory Costs***

The Company does not capitalize inventory costs associated with commercial supplies of drug product until it has received marketing approval from the FDA. Prior to receipt of FDA approval, costs for manufacturing supplies of drug product are recognized as research and development expenses in the period that the costs were incurred. Therefore, these pre-approval manufacturing costs are not included in cost of goods sold when revenue is recognized from the sale of those supplies of drug product.

In February 2008, the Company received marketing approval from the FDA for ARCALYST for the treatment of CAPS. In 2008, subsequent to receipt of such marketing approval, ARCALYST shipments to the Company's customers consisted of supplies of inventory manufactured and expensed prior to FDA approval. At December 31, 2008, the Company had no inventoried costs related to ARCALYST.

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**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**  
**For the years ended December 31, 2008, 2007, and 2006**  
***(Unless otherwise noted, dollars in thousands, except per share data)***

***Property, Plant, and Equipment***

Property, plant, and equipment are stated at cost, net of accumulated depreciation. 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	7-30 years
Laboratory and other equipment	3-5 years
Furniture and fixtures	5 years

Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the lease term, without assuming renewal features, if any, are exercised. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

***Accounting for the Impairment of Long-Lived Assets***

The Company periodically assesses the recoverability of long-lived assets, such as property, plant, and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Asset impairment is determined to exist if estimated future undiscounted cash flows are less than the carrying amount in accordance with SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. For all periods presented, no impairment losses were recorded.

***Patents***

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

***Leases***

The Company accounts for its lease agreements pursuant to SFAS 13, *Accounting for Leases*. On certain of its lease agreements, the Company may receive rent holidays and other incentives. The Company recognizes lease costs on a straight-line basis without regard to deferred payment terms, such as rent holidays that defer the commencement date of required payments. In addition, lease incentives that the Company receives are treated as a reduction of rent expense over the term of the related agreements.

***Revenue Recognition***

**a. Contract Research and Development Revenue**

The Company recognizes contract research and development revenue and research progress payments in accordance with Staff Accounting Bulletin No. ("SAB") 104, *Revenue Recognition* and Emerging Issues Task Force No. ("EITF") 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. The Company earns contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of the Company, are deferred and recognized over the related performance period. The Company estimates its performance period based on the specific terms of each agreement, and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation

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**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**  
**For the years ended December 31, 2008, 2007, and 2006**  
***(Unless otherwise noted, dollars in thousands, except per share data)***

associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.



The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, such as in the Company's VEGF Trap-Eye collaboration with Bayer HealthCare LLC, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities, such as in the Company's aflibercept and antibody collaborations with the sanofi-aventis Group. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as contract research and development revenue proportionately as the Company recognizes its expenses. If the collaboration is a cost-sharing arrangement in which both the Company and its collaborator perform development work and share costs, in periods when the Company's collaborator incurs development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of the collaborator's development expenses that the Company is obligated to reimburse. In addition, the Company records revenue in connection with a government research grant using a proportional performance model as it incurs expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, the Company's performance period estimates are principally based on projections of the scope, progress, and results of its research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, estimated performance periods may change if development programs encounter delays or the Company and its collaborators decide to expand or contract the clinical plans for a drug candidate in various disease indications. For example, for the year ended December 31, 2007, the Company recognized \$2.6 million less in contract research and development revenue, compared to amounts recognized in 2006, in connection with non-refundable up-front payments previously received from sanofi-aventis pursuant to the companies' aflibercept collaboration, due to an extension of the Company's estimated performance period. In addition, during the fourth quarter of 2008, the Company extended its estimated performance period in connection with the up-front and milestone payments previously received from Bayer HealthCare pursuant to the companies' VEGF Trap-Eye collaboration and shortened its estimated performance period in connection with up-front payments from sanofi-aventis pursuant to the companies' aflibercept collaboration. The net effect of these changes in the Company's estimates resulted in the recognition of \$0.4 million less in contract research and development revenue in the fourth quarter of 2008, compared to amounts recognized in connection with these deferred payments in each of the prior three quarters of 2008. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, the Company would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

#### b. Contract Manufacturing

The Company manufactured product and performed services for a third party under a contract manufacturing agreement which expired in October 2006. Contract manufacturing revenue was recognized as product was shipped and as services were performed.

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#### c. *VelocImmune*<sup>®</sup> Technology Licensing

The Company enters into non-exclusive license agreements with third parties that allow the third party to utilize the Company's *VelocImmune* technology in its internal research programs. The terms of these agreements include annual, non-refundable payments and entitle the Company to receive royalties on any future sales of products discovered by the third party using the Company's *VelocImmune* technology. Annual, non-refundable payments under these agreements, where continuing involvement is required of the Company, are deferred and recognized ratably over their respective annual license periods.

#### d. Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST<sup>®</sup> (riloncept) for the treatment of CAPS. The Company recognizes revenue from product sales in accordance with SAB 104. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and the Company has no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distribution fees, and other sales-related costs. The Company accounts for these reductions in accordance with EITF 01-9, *Accounting for Considerations Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*, and SFAS 48, *Revenue Recognition When Right of Return Exists*, as applicable. In accordance with EITF 01-9 and SFAS 48, since the Company currently has limited historical return and rebate experience for ARCALYST, product sales revenues are deferred until (i) the right of return no longer exists or the Company can reasonably estimate returns and (ii) rebates have been processed or the Company can reasonably estimate rebates. The Company reviews its estimates of rebates payable each period and records any necessary adjustments in the current period's net product sales.

#### **Investment Income**

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

#### **Research and Development Expenses**

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research collaboration and licensing agreements, the cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, amounts that the Company is obligated to reimburse to collaborators for research and development expenses that they incur, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by contract research organizations ("CROs"). CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these startup costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be

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significantly wider, as many of the Company's contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, the Company accrues on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, the Company adjusts its rate of clinical expense recognition if actual results differ from the Company's estimates. The Company's estimates and assumptions for clinical expense recognition could differ significantly from its actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known.

***Stock-based Employee Compensation***

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123, *Accounting for Stock-Based Compensation*. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate, at the time of grant, the number of awards that are expected to be forfeited and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Effective January 1, 2005 and prior to the Company's adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that were not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by \$0.8 million and is included in the Company's operating results in 2006 as a cumulative-effect adjustment of a change in accounting principle.

***Income Taxes***

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

***Comprehensive Income (Loss)***

The Company presents comprehensive income (loss) in accordance with SFAS 130, *Reporting Comprehensive Income*. Comprehensive income (loss) of the Company includes net income (loss) adjusted for the change in net unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive income (loss) is immaterial. Comprehensive losses for the years ended December 31, 2008, 2007, and 2006 have been included in the Statements of Stockholders' Equity.

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***Concentration of Credit Risk***

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities (see Note 3), and receivables from sanofi-aventis and Bayer HealthCare (see Note 4).

***Per Share Data***

Net income (loss) per share, basic and diluted, is computed on the basis of the net income (loss) for the period divided by the weighted average number of shares of Common Stock and Class A Stock outstanding during the period. Basic net income (loss) per share excludes restricted stock awards until vested. Diluted net income per share is based upon the weighted average number of shares of Common Stock and Class A Stock outstanding, and of common stock equivalents outstanding when dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock awards under the Company's Long-Term Incentive Plans, which are included under the "treasury stock method" when dilutive, and (ii) Common Stock to be issued under the assumed conversion of the Company's formerly outstanding convertible senior subordinated notes, which are included under the "if-converted method" when dilutive. The computation of diluted net loss per share for the years ended December 31, 2008, 2007, and 2006 does not include common stock equivalents, since such inclusion would be antidilutive.

### **Risks and Uncertainties**

Developing and commercializing new medicines entails significant risk and expense. Since its inception, the Company has not generated any significant sales or profits from the commercialization of ARCALYST<sup>®</sup> (rilonacept) or any of the Company's other product candidates. Before revenues from the commercialization of the Company's current or future product candidates can be realized, the Company (or its collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render the Company's products and technologies uncompetitive or obsolete. The Company may be subject to legal claims by third parties seeking to enforce patents to limit or prohibit the Company from marketing or selling its products. The Company is also dependent upon the services of its employees, consultants, collaborators, and certain third-party suppliers, including single-source unaffiliated third-party suppliers of certain raw materials and equipment. Regeneron, as licensee, licenses certain technologies that are important to the Company's business which impose various obligations on the Company. If Regeneron fails to comply with these requirements, licensors may have the right to terminate the Company's licenses.

The Company has generally incurred net losses and negative cash flows from operations since its inception. Revenues to date have principally been limited to (i) up-front, license, milestone, and reimbursement payments from the Company's collaborators and other entities related to the Company's development activities and technology platforms, (ii) payments for past contract manufacturing activities, (iii) ARCALYST product sales, and (iv) investment income. Contract research and development revenue in 2008 was primarily earned from sanofi-aventis and Bayer HealthCare under collaboration agreements (see Note 10 for the terms of these agreements). These collaboration agreements contain early termination provisions that are exercisable by sanofi-aventis or Bayer HealthCare, as applicable.

### **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. Estimates which could have a significant impact on the Company's financial statements include:

- Periods over which payments, including non-refundable up-front, license, and milestone payments, are recognized as revenue in connection with collaboration and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms.

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- Product rebates and returns in connection with the recognition of revenue from product sales.
- Periods over which certain clinical trial costs, including costs for clinical activities performed by contract research organizations, are recognized as research and development expenses.
- The fair value of stock options on their date of grant using the Black-Scholes option-pricing model, based on assumptions with respect to (a) expected volatility of the Company's Common Stock price, (b) the periods of time for which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (c) expected dividend yield on the Company's Common Stock, and (d) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. In addition, in connection with the recognition of stock-based employee compensation expense, the Company is required to estimate, at the time of grant, the number of stock option awards that are expected to be forfeited.
- The Company's determination of whether marketable securities are other than temporarily impaired. The Company conducts a quarterly review of its portfolio of marketable securities, using both quantitative and qualitative factors, to determine, for securities whose current fair value is less than their cost, whether the decline in fair value below cost is other-than-temporary. In making this determination, the Company considers factors such as the length of time and the extent to which fair value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. This review process also includes an evaluation of the Company's ability and intent to hold individual securities until they mature or their full value can be recovered. This review is subjective and requires a high degree of judgment.
- Useful lives of property, plant, and equipment.
- The extent to which deferred tax assets and liabilities are offset by a valuation allowance.

### **Future Impact of Recently Issued Accounting Standards**

In November 2007, the Emerging Issues Task Force issued Statement No. 07-1, *Accounting for Collaborative Arrangements* ("EITF 07-1"). EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years

beginning after December 15, 2008, and will be applied retrospectively as a change in accounting principle for collaborative arrangements existing at the effective date. The Company is required to adopt EITF 07-1 for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of EITF 07-1 will have a material impact on the Company's financial statements.

In March 2008, the Financial Accounting Standards Board ("FASB") issued SFAS 161, *Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement 133*. SFAS 161 enhances required disclosures regarding derivatives and hedging activities, including enhanced disclosures regarding how (a) an entity uses derivative instruments, (b) derivative instruments and related hedged items are accounted for under SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, and (c) derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for fiscal years and interim periods beginning after November 15, 2008. The Company is required to adopt SFAS 161 for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of SFAS 161 will have a material impact on the Company's financial statements.

In April 2008, the FASB issued FASB Staff Position ("FSP") FAS 142-3, *Determination of the Useful Life of Intangible Assets*. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, *Goodwill and Other Intangible Assets*. The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset

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under SFAS 141R under this and other generally accepted accounting principles ("GAAP"). This FSP is effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. The Company is required to adopt FSP FAS 142-3 for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of this FSP will have a material impact on the Company's financial statements.

**3. Marketable Securities**

Marketable securities at December 31, 2008 and 2007 consisted of debt securities, as detailed below, and, in 2008, equity securities whose fair value was \$3.7 million and cost was \$4.1 million. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized holding gains and losses on those securities at December 31, 2008 and 2007:

At December 31, 2008	Amortized	Fair	Unrealized Holding		
	Cost Basis	Value	Gains	(Losses)	Net
<b>Maturities within one year</b>					
U.S. government obligations	\$ 170,993	\$ 172,253	\$ 1,260		\$ 1,260
Corporate bonds	26,893	26,661	25	\$ (257)	(232)
Asset-backed securities	16,939	16,248		(691)	(691)
U.S. government guaranteed collateralized mortgage obligations	11,742	11,792	50		50
	<u>226,567</u>	<u>226,954</u>	<u>1,335</u>	<u>(948)</u>	<u>387</u>
<b>Maturities between one and three years</b>					
U.S. government guaranteed corporate bonds	29,853	29,811	82	(124)	(42)
Corporate bonds	10,446	10,414	77	(109)	(32)
Asset-backed securities	1,821	1,556		(265)	(265)
U.S. government guaranteed collateralized mortgage obligations	5,296	5,569	273		273
	<u>47,416</u>	<u>47,350</u>	<u>432</u>	<u>(498)</u>	<u>(66)</u>
	<u>\$ 273,983</u>	<u>\$ 274,304</u>	<u>\$ 1,767</u>	<u>\$ (1,446)</u>	<u>\$ 321</u>
<b>At December 31, 2007</b>					
<b>Maturities within one year</b>					
U.S. government obligations	\$ 50,386	\$ 50,475	\$ 89		\$ 89
Corporate and municipal bonds	69,213	69,263	74	\$ (24)	50
Asset-backed securities	32,671	32,388	42	(325)	(283)
U.S. government guaranteed collateralized mortgage obligations	41,268	41,318	57	(7)	50
Commercial paper	64,846	64,870	25	(1)	24
Certificates of deposit	9,220	9,218		(2)	(2)
	<u>267,604</u>	<u>267,532</u>	<u>287</u>	<u>(359)</u>	<u>(72)</u>
<b>Maturities between one and two years</b>					
Corporate and municipal bonds	49,724	49,947	289	(66)	223
Asset-backed securities	12,949	12,838	34	(145)	(111)
U.S. government guaranteed collateralized mortgage obligations	7,346	7,485	139		139
Commercial paper	7,952	7,952			
	<u>77,971</u>	<u>78,222</u>	<u>462</u>	<u>(211)</u>	<u>251</u>
	<u>\$ 345,575</u>	<u>\$ 345,754</u>	<u>\$ 749</u>	<u>\$ (570)</u>	<u>\$ 179</u>

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At December 31, 2008, marketable securities included an additional unrealized holding loss of \$0.4 million related to one equity security in the Company's marketable securities portfolio. At December 31, 2007, cash equivalents included an unrealized holding loss of \$9 thousand.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at December 31, 2008 and 2007. The debt securities listed at December 31, 2008 mature at various dates through December 2011.

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
<b>At December 31, 2008</b>						
Corporate bonds	\$15,559	\$(287)	\$ 2,933	\$ (79)	\$18,492	\$ (366)
Government guaranteed						
corporate bonds	11,300	(124)			11,300	(124)
Asset-backed securities	8,700	(87)	9,104	(869)	17,804	(956)
Equity securities	3,608	(436)			3,608	(436)
	<u>\$39,167</u>	<u>\$(934)</u>	<u>\$12,037</u>	<u>\$(948)</u>	<u>\$51,204</u>	<u>\$(1,882)</u>
<b>At December 31, 2007</b>						
Corporate and municipal bonds	\$36,979	\$ (89)	\$ 3,056	\$ (1)	\$40,035	\$ (90)
Asset backed securities	18,674	(360)	5,566	(109)	24,240	(469)
U.S. government guaranteed						
collateralized mortgage						
obligation			6,824	(7)	6,824	(7)
Commercial paper	14,950	(2)			14,950	(2)
Certificates of deposit	9,218	(2)			9,218	(2)
	<u>\$79,821</u>	<u>\$(453)</u>	<u>\$15,446</u>	<u>\$(117)</u>	<u>\$95,267</u>	<u>\$ (570)</u>

Realized gains and losses are included as a component of investment income. For the year ended December 31, 2008, realized gains on sales of marketable securities totaled \$1.2 million and realized losses on sales of marketable securities were not significant. For the years ended December 31, 2007 and 2006, realized gains and losses on sales of marketable securities 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 security, adjusted for the amortization of any discount or premium.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. The Company adopted the provisions of SFAS 157 for financial instruments as of January 1, 2008. Although the adoption of SFAS 157 did not materially impact the Company's financial condition, results of operations, or cash flows, the Company is now required to provide additional disclosures as part of its financial statements. In addition, in October 2008, the FASB issued FSP 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, which clarifies the application of SFAS 157 in a market that is not active. FSP 157-3 also reaffirms the notion of fair value as an exit price as of the measurement date. FSP 157-3 was effective upon issuance for financial statements that had not yet been issued and adopted by the Company for the year ended December 31, 2008.

SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers are Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

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The Company's assets that are measured at fair value on a recurring basis, and that are subject to the disclosure requirements of SFAS 157 at December 31, 2008, were as follows:

Description	Fair Value Measurements at Reporting Date Using			
	Fair Value at December 31, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale marketable securities	\$278,015	\$3,608	\$274,307	\$100

Marketable securities included in Level 2 above were valued using a market approach utilizing prices and other relevant information generated by market transactions involving identical or comparable assets. During the year ended December 31, 2008, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the security's principal value. As a result, the Company recognized a \$1.8 million charge related to this Level 2 marketable security, which the Company considered to be other than temporarily impaired.

Marketable securities included in Level 3 above were valued using information provided by the Company's investment advisors, including quoted bid prices which take into consideration the securities' current lack of liquidity. During the year ended December 31, 2007, deterioration in the credit quality of marketable securities from two issuers subjected the Company to the risk of not being able to recover the full principal value of these securities. As a result, the Company recognized a \$5.9 million charge related to these marketable securities, which the Company considered to be other than temporarily impaired. During the year ended December 31, 2008, the Company recognized an additional \$0.7 million other-than-temporary impairment charge related to one of these marketable securities.

Changes in marketable securities included in Level 3 above during the twelve month period ended December 31, 2008 were as follows:

	Level 3 Marketable Securities
Balance, January 1, 2008	\$7,950
Settlements	(8,194)
Realized gain	1,044
Impairments	(700)
Balance, December 31, 2008	<u>\$ 100</u>

There were no unrealized gains or losses related to the Company's Level 3 marketable securities for the year ended December 31, 2008. In addition, there were no purchases of Level 3 marketable securities and no transfers of marketable securities between the Level 2 and Level 3 classifications during the period.

As described in Note 2 above under "Use of Estimates", on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. As a result of these quarterly reviews, in 2008 and 2007, the Company recorded charges for other-than-temporary impairment of its marketable securities totaling \$2.5 million and \$5.9 million, respectively, as described above, which are included as a component of investment income. However, the current economic environment, the deterioration in the credit quality of some of the issuers of securities that the Company holds, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in the Company's investment portfolio and that such declines could result in additional charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

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**4. Accounts Receivable**

Accounts receivable as of December 31, 2008 and 2007 consist of the following:

	2008	2007
Receivable from sanofi-aventis (see Note 10)	\$33,302	\$14,244
Receivable from Bayer HealthCare (see Note 10)		2,797
Other	1,910	1,279
	<u>\$35,212</u>	<u>\$18,320</u>

**5. Property, Plant, and Equipment**

Property, plant, and equipment as of December 31, 2008 and 2007 consist of the following:

	2008	2007
Land	\$ 2,117	\$ 2,117
Building and improvements	74,343	66,208
Leasehold improvements	2,720	13,982
Construction-in-progress	24,520	4,677
Laboratory and other equipment	75,935	61,717
Furniture, computer and office equipment, and other	7,501	6,080
	<u>187,136</u>	<u>154,781</u>
Less, accumulated depreciation and amortization	(99,283)	(96,477)
	<u>\$ 87,853</u>	<u>\$ 58,304</u>

Construction-in-progress at December 31, 2008 included \$13.4 million of tenant improvement and equipment costs in connection with the Company's new leased facilities in Tarrytown, New York that are currently under construction. See Note 9a.

Depreciation and amortization expense on property, plant, and equipment amounted to \$10.6 million, \$10.4 million, and \$14.3 million for the years ended December 31, 2008, 2007, and 2006, respectively. Included in these amounts was \$0.7 million of depreciation and amortization expense related to contract manufacturing that was capitalized into inventory for the year ended December 31, 2006.

## 6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2008 and 2007 consist of the following:

	2008	2007
Accounts payable	\$ 6,268	\$ 8,128
Payable due to Bayer HealthCare (see Note 10)	9,799	4,892
Accrued payroll and related costs	5,948	14,514
Accrued clinical trial expense	4,273	5,609
Accrued expenses, other	9,880	3,797
Interest payable on convertible notes		2,292
	<u>\$36,168</u>	<u>\$39,232</u>

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## 7. Deferred Revenue

Deferred revenue as of December 31, 2008 and 2007 consists of the following:

	2008	2007
<b>Current portion:</b>		
Received from sanofi-aventis (see Note 10)	\$ 21,390	\$ 18,855
Received from Bayer HealthCare (see Note 10)	9,884	13,179
Received for technology license agreements (see Note 11)	11,579	11,579
Other	4,651	819
	<u>\$ 47,504</u>	<u>\$ 44,432</u>
<b>Long-term portion:</b>		
Received from sanofi-aventis (see Note 10)	\$105,586	\$126,431
Received from Bayer HealthCare (see Note 10)	56,835	65,896
	<u>\$162,421</u>	<u>\$192,327</u>

## 8. Stockholders Equity

The Company's Restated Certificate of Incorporation provides for the issuance of up to 40 million shares of Class A Stock, par value \$0.001 per share, and 160 million shares of Common Stock, par value \$0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that each share of Class A is entitled to ten votes per share, while each share of Common Stock is entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, 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.

In November 2006, the Company completed a public offering of 7.6 million shares of Common Stock at a price of \$23.03 per share and received proceeds, after expenses, of \$174.6 million.

In September 2003, sanofi-aventis purchased 2,799,552 newly issued, unregistered shares of the Company's Common Stock for \$45.0 million. See Note 10.

In December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for an aggregate cash price of \$312.0 million. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with the Company. Under the investor agreement, sanofi-aventis has three demand rights to require the Company to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the Company's Common Stock beneficially owned by sanofi-aventis immediately after the closing of the transaction. Until the later of the fifth anniversaries of the expiration or earlier termination of the License and Collaboration Agreement under the Company's antibody collaboration with sanofi-aventis (see Note 10) and the Company's collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept (see Note 10), sanofi-aventis will be bound by certain "standstill" provisions. These provisions include an agreement not to acquire more than a specified percentage of the outstanding shares of the Company's Class A Stock and Common Stock. The percentage is currently 25% and will increase to 30% after December 20, 2011. Sanofi-aventis has also agreed not to dispose of any shares of the Company's Common Stock that were beneficially owned by sanofi-aventis immediately after the closing of the transaction until December 20, 2012, subject to certain limited exceptions. Following December 20, 2012, sanofi-aventis will be permitted to sell shares of the Company's Common Stock (i) in a registered underwritten public offering undertaken pursuant to the demand registration rights granted to sanofi-aventis and described above, subject to the underwriter's broad distribution of securities sold, (ii) pursuant to Rule 144 under the Securities Act and transactions exempt from registration under the Securities Act, subject to a volume limitation of one million shares of the Company's Common Stock every three months and a prohibition on selling to beneficial owners, or persons that would become beneficial owners as a result of such sale, of 5% or

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more of the outstanding shares of the Company's Common Stock, and (iii) into an issuer tender offer, or a tender offer by a third party that is recommended or not opposed by the Company's Board of Directors. Sanofi-aventis has agreed to vote, and cause its affiliates to vote, all shares of the Company's voting securities they are entitled to vote, at sanofi-aventis' election, either as recommended by the Company's Board of Directors or proportionally with the votes cast by the Company's other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of the Company's Class A Stock and Common Stock, and new equity compensation plans or amendments if not materially consistent with the Company's historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events.

**9. Commitments and Contingencies**

**a. Operating Leases**

The Company currently leases laboratory and office facilities in Tarrytown, New York under operating lease agreements. In December 2006, the Company entered into a new operating lease agreement to lease laboratory and office space that is now under construction and expected to be completed in mid-2009 at the Company's current Tarrytown location, plus retain a portion of the Company's existing space. In October 2007 and September 2008, the Company amended the December 2006 operating lease agreement to increase the amount of new and existing space to be leased. The term of the lease commenced effective June 30, 2008 and will expire in June 2024. Under the new lease the Company also has various options and rights on additional space at the Tarrytown site, and will continue to lease its present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for the Company's retained facilities only. The lease provides for monthly payments over the term of the lease related to the Company's retained facilities, the costs of construction and tenant improvements for the Company's new facilities, and additional charges for utilities, taxes, and operating expenses.

In connection with the new lease agreement, in December 2006, the Company issued a letter of credit in the amount of \$1.6 million to its landlord, which is collateralized by a \$1.6 million bank certificate of deposit. The certificate of deposit has been classified as restricted cash at December 31, 2008 and 2007.

In November 2007, the Company entered into a new operating sublease for additional office space in Tarrytown, New York. The lease expires in September 2009 and contains two renewal options to extend the term of the sublease by three months each. In April 2008, the Company entered into a new operating sublease for additional office space located in Tarrytown, New York. The lease expires in March 2010 and contains one renewal option to extend the term of the sublease by six months. In October 2008 the Company entered into a new sublease with sanofi-aventis U.S. Inc. for office space in Bridgewater, New Jersey. The lease commences in January 2009 and expires in July 2011.

The Company formerly leased manufacturing, office, and warehouse facilities in Rensselaer, New York under an operating lease agreement. The lease provided for base rent plus additional rental charges for utilities, taxes, and operating expenses, as defined. In June 2007, the Company exercised a purchase option under the lease and, in October 2007, purchased the land and building.

The Company leases certain laboratory and office equipment under operating leases which expire at various times through 2011.

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Based, in part, upon budgeted construction and tenant improvement costs related to our new operating lease for facilities that are under construction in Tarrytown, New York, as described above, at December 31, 2008, the estimated future minimum noncancelable lease commitments under operating leases were as follows:

<u>December 31,</u>	<u>Facilities</u>	<u>Equipment</u>	<u>Total</u>
2009	\$ 8,707	\$419	\$ 9,126
2010	13,121	241	13,362
2011	13,252	146	13,398
2012	13,428		13,428
2013	13,764		13,764
Thereafter	166,973		166,973
	<u>\$229,245</u>	<u>\$806</u>	<u>\$230,051</u>

Rent expense under operating leases was:

<u>Year Ending December 31,</u>	<u>Facilities</u>	<u>Equipment</u>	<u>Total</u>
2008	\$10,111	\$416	\$10,527
2007	4,632	363	4,995
2006	4,492	307	4,799



As described above, the term of the Company's operating lease for its new facilities in Tarrytown, New York commenced in mid-2008; as a result, the Company began recognizing rent expense in connection with this new lease, even though actual rent payments will not commence until August 2009. In addition to its rent expense for various facilities, the Company paid additional rental charges for utilities, real estate taxes, and operating expenses of \$8.4 million, \$8.8 million, and \$8.7 million for the years ended December 31, 2008, 2007, and 2006, respectively.

#### **b. Convertible Debt**

In October 2001, the Company issued \$200.0 million aggregate principal amount of convertible senior subordinated notes ("Notes") in a private placement for proceeds to the Company of \$192.7 million, after deducting the initial purchasers' discount and out-of-pocket expenses (collectively, "Deferred Financing Costs"). The Notes bore interest at 5.5% per annum, payable semi-annually, and matured on October 17, 2008. Deferred Financing Costs, which were included in other assets, were amortized as interest expense over the period from the Notes' issuance to stated maturity. During the second and third quarters of 2008, the Company repurchased \$82.5 million in principal amount of the Notes for \$83.3 million and recognized a \$0.9 million loss on early extinguishment of debt, representing the premium paid on the Notes plus related unamortized Deferred Financing Costs. The remaining \$117.5 million of outstanding Notes were repaid in full upon their maturity in October 2008.

#### **c. Research Collaboration and Licensing Agreements**

As part of the Company's research and development efforts, the Company enters into research collaboration and licensing agreements with related and unrelated companies, scientific collaborators, universities, and consultants. These agreements contain varying terms and provisions which include fees and milestones to be paid by the Company, services to be provided, and ownership rights to certain proprietary technology developed under the agreements. Some of the agreements contain provisions which require the Company to pay royalties, as defined, at rates that range from 0.25% to 16.5%, in the event the Company sells or licenses any proprietary products developed under the respective agreements.

Certain agreements under which the Company is required to pay fees permit 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 \$3.5 million, \$1.0 million, and \$1.1 million for the years ended December 31, 2008, 2007, and 2006, respectively.

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In connection with the Company's receipt of marketing approval from the FDA for ARCALYST<sup>®</sup> (rilonacept) for the treatment of CAPS, in 2008, the Company commenced paying royalties under various licensing agreements based on ARCALYST net product sales. For the year ended December 31, 2008, ARCALYST royalties totaled \$0.6 million and are included in cost of goods sold.

In July 2008, the Company and Collectis S.A. ("Collectis") entered into an Amended and Restated Non-Exclusive License Agreement (the "Collectis Agreement"). The Collectis Agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which the Company licensed certain patents and patent applications from Collectis. Pursuant to the Collectis Agreement, in July 2008, the Company made a non-refundable \$12.5 million payment to Collectis (the "Collectis Payment") and agreed to pay Collectis a low single-digit royalty based on revenue received by the Company from any future licenses or sales of the Company's *VelociGene*<sup>®</sup> or *VelocImmune*<sup>®</sup> products and services. No royalties are payable with respect to the Company's *VelocImmune* license agreements with AstraZeneca UK Limited ("AstraZeneca") and Astellas Pharma Inc. ("Astellas") or the Company's November 2007 collaboration with sanofi-aventis. Moreover, no royalties are payable on any revenue from commercial sales of antibodies from the Company's *VelocImmune* technology.

The Company began amortizing the Collectis Payment in the second quarter of 2008 in proportion to past and future anticipated revenues under the Company's license agreements with AstraZeneca and Astellas and the Discovery and Preclinical Development Agreement under the Company's November 2007 collaboration with sanofi-aventis. In 2008, the Company recognized \$2.7 million of expense in connection with the Collectis Payment.

### **10. Research and Development Agreements**

The Company has entered into various agreements related to its activities to develop and commercialize product candidates and utilize its technology platforms. Amounts earned by the Company in connection with these agreements, which were recognized as contract research and development revenue, totaled \$192.2 million, \$96.6 million, and \$51.1 million in 2008, 2007, and 2006, respectively. Total Company incurred expenses associated with these agreements, which include reimbursable and non-reimbursable amounts, an allocable portion of general and administrative costs, and cost-sharing of a collaborator's development expenses, where applicable (see Bayer HealthCare below), were \$230.6 million, \$108.2 million and \$43.4 million in 2008, 2007, and 2006, respectively. Significant agreements of this kind are described below.

#### **a. The sanofi-aventis Group**

##### *Aflibercept*

In September 2003, the Company entered into a collaboration agreement (the "Aventis Agreement") with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.), to jointly develop and commercialize aflibercept. In connection with this agreement, sanofi-aventis made a non-refundable up-front payment of \$80.0 million and purchased 2,799,552 newly issued unregistered shares of the Company's Common Stock for \$45.0 million.

In January 2005, the Company and sanofi-aventis amended the Aventis Agreement to exclude intraocular delivery of aflibercept to the eye ("Intraocular Delivery") from joint development under the agreement, and product rights to aflibercept in Intraocular Delivery reverted to Regeneron. In connection with this amendment, sanofi-aventis made a \$25.0 million non-refundable payment to Regeneron (the "Intraocular Termination Payment") in January 2005.

In December 2005, the Company and sanofi-aventis amended the Aventis Agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a \$25.0 million non-refundable up-front payment to the Company, which was received in January 2006. Under the Aventis Agreement, as amended, the Company and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan, for disease indications included in the companies' collaboration. The Company is entitled to a royalty of approximately 35% on annual sales of aflibercept in Japan, subject to certain potential adjustments. The Company may also receive up to \$400 million in milestone

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payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

Under the Aventis Agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of these development expenses, or half of \$446.5 million as of December 31, 2008, in accordance with a formula based on the amount of development expenses and Regeneron's share of the collaboration profits and Japan royalties, or at a faster rate at Regeneron's option. Regeneron has the option to conduct additional pre-Phase III studies at its own expense. In connection with the January 2005 amendment to the Aventis Agreement, the Intraocular Termination Payment of \$25.0 million will be considered an aflibercept development expense and will be subject to 50% reimbursement by Regeneron to sanofi-aventis, as described above, if the collaboration becomes profitable. In addition, if the first commercial sale of an aflibercept product in Intraocular Delivery predates the first commercial sale of an aflibercept product under the collaboration by two years, Regeneron will begin reimbursing sanofi-aventis for up to \$7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, Regeneron's obligation to reimburse sanofi-aventis, for 50% of aflibercept development expenses will terminate, and the Company will retain all rights to aflibercept.

Revenue related to payments from sanofi-aventis under the Aventis Agreement, as amended, is being recognized in accordance with SAB 104 and EITF 00-21 (see Note 2). The up-front payments received in September 2003 and January 2006, of \$80.0 million and \$25.0 million, respectively, and reimbursement of Regeneron-incurred development expenses, are being recognized as contract research and development revenue over the related performance period. The Company recognized \$44.4 million, \$47.1 million, and \$47.8 million of contract research and development revenue in 2008, 2007, and 2006, respectively, in connection with the Aventis Agreement, as amended. At December 31, 2008 and 2007, amounts receivable from sanofi-aventis totaled \$6.3 million and \$10.5 million, respectively, and deferred revenue was \$52.4 million and \$61.2 million, respectively, in connection with the Aventis Agreement.

#### *Antibodies*

In November 2007, the Company entered into a global, strategic collaboration (the "Antibody Collaboration") with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. In connection with the collaboration, in December 2007, sanofi-aventis purchased 12 million newly issued; unregistered shares of the Company's Common Stock for \$312.0 million (see Note 8).

The Antibody Collaboration is governed by a Discovery and Preclinical Development Agreement (the "Discovery Agreement") and a License and Collaboration Agreement (the "License Agreement"). The Company received a non-refundable up-front payment of \$85.0 million from sanofi-aventis under the Discovery Agreement. In addition, sanofi-aventis will fund up to \$475 million of the Company's research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against such targets through December 31, 2012, subject to specified funding limits of \$75 million for the period from the collaboration's inception through December 31, 2008, and \$100 million annually in each of the next four years. The Discovery Agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the Discovery Agreement, sanofi-aventis has the option to license rights to the candidate under the License Agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with the Company through product approval. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the License Agreement, the Company will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. The first three therapeutic antibodies that are being co-developed by the Company and sanofi-aventis under the License Agreement are REGN88, REGN421, and REGN475.

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Under the License Agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") will be shared 80% by sanofi-aventis and 20% by Regeneron. If the Antibody Collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of \$27.8 million as of December 31, 2008) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and the Company's share of collaboration profits from commercialization of collaboration products.

Sanofi-aventis will lead commercialization activities for products developed under the License Agreement, subject to the Company's right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (Regeneron) and ending at 55% (sanofi-aventis)/45% (Regeneron), and losses outside the United States at 55% (sanofi-aventis)/45% (Regeneron). In addition to profit sharing, the Company is entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the Antibody Collaboration until commercial supplies of that drug candidate are being manufactured.

With respect to each antibody product which enters development under the License Agreement, sanofi-aventis or the Company may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. The Company may also opt-out of the further development of an antibody product if it gives notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the License Agreement. Each of the Discovery Agreement and the License Agreement contains other termination provisions, including for material breach by the other party and, in the case of the Discovery Agreement, a termination right for sanofi-aventis under certain circumstances, including if certain minimal criteria for the discovery program are not achieved. Prior to December 31, 2012, sanofi-aventis has the right to terminate the Discovery Agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to the Company the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, the Company's obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate. Upon expiration of the Discovery Agreement, sanofi-aventis has an option to license the Company's *VelocImmune*<sup>®</sup> technology for agreed upon consideration.

In connection with the Antibody Collaboration, in August 2008, the Company entered into a separate agreement with sanofi-aventis to use Regeneron's proprietary *VelociGene*<sup>®</sup> technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease (the "*VelociGene* Agreement"). The *VelociGene* Agreement provides for minimum annual order quantities for the term of the agreement which extends through December 2012, for which the Company expects to receive payments totaling a minimum of \$21.5 million.

Revenue related to payments from sanofi-aventis under the Antibody Collaboration is being recognized in accordance with SAB 104 and EITF 00-21 (see Note 2). The (i) \$85.0 million up-front payment received in December 2007, (ii) reimbursement of Regeneron-incurred expenses under the Discovery and License Agreements, and (iii) \$21.5 million of aggregate minimum payments under the *VelociGene* Agreement are being recognized as contract research and development revenue over the related performance period. In connection with the Antibody Collaboration, the Company recognized \$109.6 million and \$4.6 million of contract research and development revenue in 2008 and 2007, respectively. In addition, at December 31, 2008 and 2007, amounts receivable from sanofi-aventis totaled \$27.0 million and \$3.7 million and deferred revenue was \$74.6 million and \$84.1 million, respectively.

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***b. Bayer HealthCare LLC***

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the United States, the Company's VEGF Trap for the treatment of eye disease by local administration ("*VEGF Trap-Eye*"). Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to the Company of \$75.0 million. In addition, the Company is eligible to receive up to \$110 million in development and regulatory milestones related to the VEGF Trap-Eye program, of which the Company received a \$20.0 million milestone payment in August 2007 in connection with the initiation of a Phase 3 trial of VEGF Trap-Eye in the neovascular form of age-related macular degeneration ("*wet AMD*"). The Company is also eligible to receive up to an additional \$135 million in sales milestones when and if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

The Company will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer HealthCare out of its share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of \$63.0 million as of December 31, 2008) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. Within the United States, the Company is responsible for any future commercialization of VEGF Trap-Eye and retains exclusive rights to any future profits from commercialization.

Agreed upon VEGF Trap-Eye development expenses incurred by both companies in 2007 and 2008 under a global development plan, were shared as follows:

2007: The first \$50.0 million was shared equally and the Company was solely responsible for up to the next \$40.0 million.

2008: The first \$70.0 million was shared equally and the Company was solely responsible for up to the next \$30.0 million.

In 2009 and thereafter, all development expenses will be shared equally. Neither party was reimbursed for any development expenses that it incurred prior to 2007. The Company is also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

Bayer HealthCare has the right to terminate the Bayer Agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to VEGF Trap-Eye.

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue for financial statement purposes. In the fourth quarter of 2007, Regeneron and Bayer HealthCare approved a global development plan for VEGF Trap-Eye in wet AMD. The plan included estimated development steps,

timelines, and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. In addition, in the fourth quarter of 2007, Regeneron and Bayer HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's VEGF Trap-Eye development expenses. The \$75.0 million up-front licensing payment and \$20.0 million milestone payment (which was not considered substantive) from Bayer HealthCare are being recognized as contract research and development revenue over the related estimated performance period in accordance with SAB 104 and EITF 00-21 (see Note 2). In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration, the Company also recognizes, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron,

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the Company also recognizes, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that the Company is obligated to reimburse. In the fourth quarter of 2007, the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up.

In 2008, the Company recognized \$31.2 million of contract research and development revenue from Bayer HealthCare, consisting of \$12.4 million related to the up-front licensing and milestone payments and \$18.8 million related to the portion of the Company's 2008 VEGF Trap-Eye development expenses that was reimbursable from Bayer HealthCare. In 2007, the Company recognized \$35.9 million of contract research and development revenue from Bayer HealthCare, consisting of \$15.9 million related to the up-front licensing and milestone payments and \$20.0 million related to the portion of the Company's 2007 VEGF Trap-Eye development expenses that was reimbursable from Bayer HealthCare. In addition, in 2008 and 2007, the Company recognized as additional research and development expense \$30.0 million and \$10.6 million, respectively, of VEGF Trap-Eye development expenses that the Company was obligated to reimburse to Bayer HealthCare.

In connection with cost-sharing of VEGF Trap-Eye development expenses under the collaboration, \$9.8 million and \$4.9 million was payable to Bayer HealthCare at December 31, 2008 and 2007, respectively, and \$2.8 million was receivable from Bayer HealthCare at December 31, 2007. In addition, at December 31, 2008 and 2007, deferred revenue from the Company's collaboration with Bayer HealthCare was \$66.7 million and \$79.1 million, respectively.

***c. Serono, S.A. (now part of Merck KGaA)***

In December 2002, the Company entered into an agreement (the "Serono Agreement") with Serono S.A. to use Regeneron's proprietary *VelociGene*<sup>®</sup> technology platform to provide Serono with knock-out and transgenic mammalian models of gene function ("Materials"). The Serono Agreement contains provisions for minimum yearly order quantities. In connection with its orders for Materials, Serono makes advance payments to Regeneron, which are accounted for as deferred revenue. Regeneron recognizes revenue and reduces the deferred revenue balance as Materials are shipped to and accepted by Serono. In 2008, 2007, and 2006, the Company recognized \$0.9 million, \$2.4 million, and \$1.8 million, respectively, of contract research and development revenue in connection with the Serono Agreement.

***d. National Institutes of Health***

In September 2006, the Company was awarded a grant from the National Institutes of Health ("NIH") as part of the NIH's Knockout Mouse Project. As amended, the NIH grant provides a minimum of \$24.5 million in funding over a five-year period, including \$1.5 million in funding to optimize certain existing technology, subject to compliance with its terms and annual funding approvals, for the Company's use of its *VelociGene* technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells which can be used to produce knockout mice. In 2008, 2007, and 2006, the Company recognized contract research and development revenue of \$4.9 million, \$5.5 million, and \$0.5 million, respectively, from the NIH Grant.

**11. Technology Licensing Agreements**

In February 2007, the Company entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize the Company's *VelocImmune*<sup>®</sup> technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made two \$20.0 million annual, non-refundable payments to the Company, one in 2007 and the other in 2008. Each annual payment is deferred and recognized as revenue ratably over approximately the ensuing twelve-month period. AstraZeneca is required to make up to four additional annual payments of \$20.0 million, subject to their ability to terminate the agreement after making two such additional payments or earlier if the technology does not meet minimum performance criteria. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company's *VelocImmune* technology. In connection with the AstraZeneca license agreement, for the years ended December 31, 2008 and 2007, the Company recognized \$20.0 million and \$17.1 million of revenue. In addition, deferred revenue at both December 31, 2008 and 2007 was \$2.9 million.

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**REGENERON PHARMACEUTICALS, INC.**  
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In March 2007, the Company entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's *VelocImmune*<sup>®</sup> technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made two \$20.0 million annual, non-refundable payments to the Company, one in 2007 and the other in 2008. Each annual payment is deferred and, recognized as revenue ratably over approximately the ensuing twelve-month period. Astellas is required to make up to four additional annual payments of \$20.0 million, subject to their ability to terminate the agreement after making two such additional payments or earlier if the technology does not meet minimum performance criteria. The

Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's *VelocImmune* technology. In connection with the Astellas license agreement, for the years ended December 31, 2008 and 2007, the Company recognized \$20.0 million and \$11.3 million of revenue. In addition, deferred revenue at both December 31, 2008 and 2007 was \$8.7 million.

## 12. Manufacturing Agreement

During 1995, the Company entered into a long-term manufacturing agreement with Merck & Co., Inc., as amended, (the "Merck Agreement") to produce an intermediate (the "Intermediate") for a Merck pediatric vaccine at the Company's Rensselaer, New York facility. The Company modified portions of its facility for manufacture of the Intermediate and assisted Merck in securing regulatory approval for such manufacture in the Company's facility. The Merck Agreement called for the Company to manufacture Intermediate for Merck for a specified period of time (the "Production Period"), with certain minimum order quantities each year. The Production Period commenced in November of 1999 and, as amended, extended through October 2006, at which time the Merck Agreement terminated.

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 miscellaneous costs during the Production Period ("Internal Costs"). These payments were recognized as contract manufacturing revenue as follows: (i) payments for Internal Costs were recognized as the activities were performed, (ii) the Facility Fee and Additional Payments were recognized over the period to which they related, (iii) payments for Capital Costs were deferred and recognized as Intermediate was shipped to Merck, and (iv) payments related to the manufacture of Intermediate during the Production Period were recognized after the Intermediate was tested and approved by, and shipped (FOB shipping point) to, Merck. In 2006, Merck contract manufacturing revenue totaled \$12.3 million, which included \$1.2 million of previously deferred Capital Costs.

## 13. ARCALYST® (riloncept) Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST for the treatment of CAPS. For the year-ended December 31, 2008, the Company recognized as revenue \$6.3 million of ARCALYST net product sales for which the right of return no longer existed and rebates could be reasonably estimated. At December 31, 2008, deferred revenue related to ARCALYST net product sales totaled \$4.0 million.

Cost of goods sold related to ARCALYST sales totaled \$0.9 million for the year ended December 31, 2008 and consisted primarily of royalties (see Note 9c). In 2008, ARCALYST shipments to the Company's customers consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST; therefore, the costs of these supplies were not included in costs of goods sold. At December 31, 2008, the Company had no inventoried costs related to ARCALYST.

## 14. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan which, as amended and restated (the "2000 Incentive Plan"), provides for the issuance of up to 28,816,184 shares of Common Stock in respect of awards. In addition, shares of Common Stock previously approved by shareholders for

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**REGENERON PHARMACEUTICALS, INC.**  
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issuance under the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, (collectively, "Participants") may receive awards as determined by a committee of independent directors ("Committee"). The awards that may be made under the 2000 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

Stock Option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the Option is granted. Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three to five year period. The Committee also determines the expiration date of each Option; however, no ISO is exercisable more than ten years after the date of grant. The maximum term of options that have been awarded under the 2000 Incentive Plan is ten years.

Restricted Stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as defined by the 2000 Incentive Plan, the ownership of the Restricted Stock, which has not vested, will be transferred to the Company, except under defined circumstances with Committee approval, in consideration of amounts, if any, paid by the Participant to acquire such shares. In addition, if the Company requires a return of the Restricted Shares, it also has the right to require a return of all dividends paid on such shares.

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

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

During 1990, the Company established the 1990 Incentive Plan which, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, received awards as determined by a committee of independent directors. Under the provisions of the 1990 Incentive Plan, there will be no future awards from the plan. Awards under the 1990 Incentive Plan consisted of Incentive Stock Options and Nonqualified Stock Options which generally vested 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.

As of December 31, 2008, there were 6,912,833 shares available for future grants under the 2000 Incentive Plan.

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**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**  
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**a. Stock Options**

Transactions involving stock option awards during 2006, 2007, and 2008 under the 1990 and 2000 Incentive Plans are summarized in the table below.

	Number of Shares	Weighted-Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Intrinsic Value (in thousands)
<b>Stock Options:</b>				
Outstanding at December 31, 2005	14,719,492	\$14.23		
<b>2006:</b> Granted	2,742,260	\$19.59		
Forfeited	(338,122)	\$10.51		
Expired	(172,218)	\$24.23		
Exercised	<u>(1,408,907)</u>	\$ 9.84		
Outstanding at December 31, 2006	15,542,505	\$15.54		
<b>2007:</b> Granted	3,415,743	\$21.78		
Forfeited	(220,342)	\$14.43		
Expired	(50,759)	\$13.73		
Exercised	<u>(1,014,791)</u>	\$10.58		
Outstanding at December 31, 2007	17,672,356	\$17.05		
<b>2008:</b> Granted	4,126,600	\$17.38		
Forfeited	(515,298)	\$16.58		
Expired	(34,242)	\$26.81		
Exercised	<u>(1,115,506)</u>	\$ 9.61		
Outstanding at December 31, 2008	<u>20,133,910</u>	\$17.53	6.62	\$59,268
Vested and expected to vest at December 31, 2008	19,596,843	\$17.52	6.57	\$58,354
Exercisable at December 31, 2006	7,890,856	\$17.41		
Exercisable at December 31, 2007	9,369,665	\$17.02		
Exercisable at December 31, 2008	10,994,371	\$17.43	5.08	\$42,791

The Company satisfies stock option exercises with newly issued shares of the Company's Common Stock. The total intrinsic value of stock options exercised during 2008, 2007, and 2006 was \$11.9 million, \$12.6 million, and \$13.2 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

The Company grants stock options with exercise prices that are equal to or greater than the market price of the Company's Common Stock on the date of grant. The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2006, 2007, and 2008. The fair value of each option granted under the 2000 Incentive Plan during 2008, 2007, and 2006 was estimated on the date of grant using the Black-Scholes option-pricing model.

	Number of Options Granted	Weighted- Average Exercise Price	Weighted- Average Fair Value
<b>2006:</b>			
Exercise price equal to market price	2,742,260	\$19.59	\$12.82
<b>2007:</b>			
Exercise price equal to market price	3,415,743	\$21.78	\$11.13
<b>2008:</b>			
Exercise price equal to market price	4,126,600	\$17.38	\$ 8.45

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The following table summarizes stock option information as of December 31, 2008:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted-	Weighted- Average Exercise Price	Number Exercisable	Weighted-
		Average Remaining Contractual Life			Average Exercise Price
\$4.83 to \$9.49	3,721,142	4.02	\$ 8.95	2,815,152	\$ 9.10
\$9.53 to \$13.00	3,588,129	5.93	\$12.25	3,069,391	\$12.36
\$13.05 to \$16.80	3,832,641	9.57	\$16.53	287,491	\$15.26
\$17.33 to \$20.32	3,508,707	6.95	\$19.90	2,076,331	\$19.85
\$20.37 to \$22.12	3,193,837	8.91	\$21.68	752,577	\$21.79
\$22.25 to \$37.94	2,229,454	3.38	\$31.41	1,933,429	\$32.56
\$51.56 to \$51.56	60,000	1.16	\$51.56	60,000	\$51.56
\$4.83 to \$51.56	<u>20,133,910</u>	6.62	\$17.53	<u>10,994,371</u>	\$17.43

For the years ended December 31, 2008, 2007, and 2006, \$30.3 million, \$28.0 million, and \$18.4 million, respectively, of non-cash stock-based employee compensation expense related to stock option awards was recognized in operating expenses. As of December 31, 2008, there was \$46.3 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 2.0 years. In addition, there were 1,302,260 performance-based options which were unvested as of December 31, 2008 of which, subject to the optionee satisfying certain service conditions, 664,760 options would vest upon achieving certain defined sales targets for the Company's products and 637,500 options would vest upon achieving certain development milestones for the Company's product candidates. Potential compensation cost, measured on the grant date, related to these performance options totals \$9.1 million and will begin to be recognized only if, and when, these options' performance conditions are considered to be probable of attainment.

**Fair value Assumptions:**

Using the Black-Scholes option-pricing model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with previously issued employee and board of director option grants. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future.

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2008, 2007, and 2006.

	2008	2007	2006
Expected volatility	53%	53%	67%
Expected lives from grant date	5.5 years	5.6 years	6.5 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	1.73%	3.60%	4.51%

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**b. Restricted Stock**

A summary of the Company's activity related to Restricted Stock awards for the years ended December 31, 2006, 2007, and 2008 is summarized below:

Restricted Stock:	Number of Shares	Weighted-
		Average Grant Date Fair Value
Outstanding at December 31, 2005	95,188	\$11.16
2006: Forfeited	(1,703)	\$ 9.74

Released	(93,485)	\$11.18
Outstanding at December 31, 2006	—	
<b>2007: Granted</b>	500,000	\$21.92
Outstanding at December 31, 2007	500,000	\$21.92
<b>2008: Outstanding at December 31, 2008</b>	500,000	\$21.92

In December 2007, the Company awarded a grant of Restricted Stock to the Company's executive vice president. In accordance with generally accepted accounting principles, the Company records unearned compensation in Stockholders' Equity related to grants of Restricted Stock awards. This amount is based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restriction on these shares lapse, which is five years for the grant made in 2007. In addition, unearned compensation in Stockholders' Equity is reduced due to forfeitures of Restricted Stock resulting from employee terminations. Prior to the adoption of SFAS 123R, unearned compensation was included as a separate component of Stockholders' Equity. Effective January 1, 2006, unearned compensation is combined with additional paid-in capital in accordance with the provisions of SFAS 123R.

In connection with the 2007 grant of Restricted Stock, the Company recorded unearned compensation in Stockholders' Equity of \$11.0 million, which was combined with additional paid-in capital. In connection with forfeitures of past Restricted Stock awards, the Company reduced unearned compensation by \$17 thousand in 2006. The Company recognized non-cash stock-based employee compensation expense from Restricted Stock awards of \$2.2 million, \$0.1 million, and \$0.3 million in 2008, 2007, and 2006, respectively. As of December 31, 2008, there were 500,000 unvested shares of Restricted Stock outstanding and \$8.7 million of stock-based compensation cost related to these unvested shares which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 4.0 years.

### 15. 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, 2008, there were 44,246 shares available for future grants under the Plan.

### 16. 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, provides for

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the Company to make discretionary contributions ("Contribution"), as defined. The Company recorded Contribution expense of \$1.5 million in 2008, \$1.4 million in 2007, and \$1.3 million in 2006; such amounts were accrued as liabilities at December 31, 2008, 2007, and 2006, respectively. During the first quarter of 2009, 2008, and 2007, the Company contributed 81,086, 58,575, and 64,532 shares, respectively, of Common Stock to the Savings Plan in satisfaction of these obligations.

### 17. Income Taxes

For the year ended December 31, 2008, the Company incurred a net loss for tax purposes and recognized a full tax valuation against deferred taxes. During 2008, the Company implemented a tax planning strategy to utilize net operating loss carry-forwards (which were otherwise due to expire in 2008 through 2012) on its 2007 U.S. federal and New York State income tax returns that were filed in September 2008. The tax planning strategy included electing, for tax purposes only, to capitalize \$142.1 million of 2007 research and development ("R&D") costs and amortize these costs over ten years for tax purposes. By capitalizing these R&D costs, the Company was able to generate taxable income for tax year 2007 and utilize the net operating loss carry-forwards to offset this taxable income. As a result, the Company incurred and paid income tax expense of \$3.1 million in 2008, which related to U.S. federal and New York State alternative minimum tax ("AMT") and included \$0.2 million of interest and penalties. This expense was partly offset by the Company's recognition of a \$0.7 million income tax benefit for the year ended December 31, 2008, resulting from a provision in the Housing Assistance Tax Act of 2008 that allows the Company to claim a refund for a portion of its unused pre-2006 research tax credits on its 2008 U.S. federal income tax return.

For the year ended December 31, 2007, the Company had projected to incur a net loss for tax purposes and recognized a full tax valuation against deferred taxes. Accordingly, no provision or benefit for income taxes was recorded in 2007. Subsequently, the Company implemented the tax planning strategy described above, which resulted in taxable income in 2007 on which the Company recognized and paid U.S. federal and New York State AMT in 2008. For the year ended December 31, 2006, the Company incurred a net loss for tax purposes and recognized a full tax valuation against deferred taxes. Accordingly, no provision or benefit for income taxes was recorded in 2006.

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2008 and 2007 is as follows:

	2008	2007
Deferred tax assets:		



Net operating loss carry-forward	\$ 161,790	\$ 166,714
Fixed assets	18,612	17,245
Deferred revenue	85,251	96,148
Deferred compensation	22,942	15,159
Research and experimental tax credit carry-forward	22,295	25,446
Capitalized research and development costs	59,661	15,236
Other	9,825	7,036
Valuation allowance	(380,376)	(342,984)
	<u>—</u>	<u>—</u>

The Company's valuation allowance increased by \$37.4 million in 2008, due primarily to the increase in the temporary difference related to capitalized research and development costs, resulting from the implementation of the tax planning strategy described above. In 2007, the Company's valuation allowance increased by \$30.7 million, due primarily to the temporary difference related to deferred revenue, principally resulting from the non-refundable, up-front payment received from sanofi-aventis in December 2007 (see Note 10).

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*. The implementation of FIN 48 had no impact on the Company's financial statements as the Company has not recognized any income tax positions that were deemed uncertain under the recognition thresholds and measurement attributes prescribed by FIN 48.

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The Company is primarily subject to U.S. federal and New York State income tax. The Company's effective income tax rate is generally zero for all years presented. The difference between the Company's effective income tax rate and the U.S. 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. The Company's 1998 and subsequent tax years remain open to examination by U.S. federal and state tax authorities.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2008 and 2007, the Company had no accruals for interest or penalties related to income tax matters.

As of December 31, 2008, the Company had available for tax purposes unused net operating loss carry-forwards of \$415.4 million which will expire in various years from 2018 to 2028 and included \$17.0 million of net operating loss carry-forwards related to exercises of Nonqualified Stock Options and disqualifying dispositions of Incentive Stock Options, the tax benefit from which, if realized, will be credited to additional paid-in capital. The Company's research and experimental tax credit carry-forwards expire in various years from 2009 to 2028. Under the Internal Revenue Code and similar state provisions, substantial changes in the Company's ownership have resulted in an annual limitation on the amount of net operating loss and tax credit carry-forwards that can be utilized in future years to offset future taxable income. This annual limitation may result in the expiration of net operating losses and tax credit carry-forwards before utilization.

**18. Legal Matters**

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition. Legal costs associated with the Company's resolution of legal proceedings are expensed as incurred.

**19. Net Loss Per Share Data**

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. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. In 2008, 2007, and 2006, the Company reported net losses; 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:

	December 31,		
	2008	2007	2006
Net loss (Numerator)	\$(82,710)	\$(105,600)	\$(102,337)
Weighted-average shares, in thousands (Denominator)	78,827	66,334	57,970
Basic and diluted net loss per share	\$ (1.05)	\$ (1.59)	\$ (1.77)

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

	December 31,		
	2008	2007	2006
Options:			
Weighted average number, in thousands	17,598	15,385	14,139
Weighted average exercise price	\$ 17.31	\$ 15.97	\$ 14.41

Restricted Stock:			
Weighted average number, in thousands	500	21	23
Convertible Debt:			
Weighted average number, in thousands		6,611	6,611
Conversion price		\$ 30.25	\$ 30.25

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**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**  
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**20. Statement of Cash Flows**

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at December 31, 2008, 2007, and 2006 were \$7.0 million, \$1.7 million, and \$0.8 million of accrued capital expenditures, respectively.

Included in accounts payable and accrued expenses at December 31, 2007, 2006, and 2005 were \$1.1 million, \$1.4 million, and \$1.9 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2008, 2007, and 2006, the Company contributed 58,575, 64,532, and 120,960 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at December 31, 2008, 2007, and 2006 were \$1.7 million, \$2.2 million, and \$1.5 million of accrued interest income, respectively.

**21. Segment Information**

In 2008 and 2007, the Company managed its business as one segment which included all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. This segment also included revenues and expenses related to (i) research and development activities conducted under the Company's collaboration agreements with third parties and the Company's grant from the NIH, (ii) ARCALYST® (rilonacept) product sales for the treatment of CAPS, and (iii) the supply of specified, ordered research materials using Regeneron-developed proprietary technology. In 2006, the Company's operations were managed in two business segments: research and development, and contract manufacturing; therefore, segment information has only been provided for 2006 in the table below. In 2006, the contract manufacturing segment included all revenues and expenses related to the commercial production of a product under a contract with Merck, which expired in October 2006. The accounting policies for the segments are the same as those described above in Summary of Significant Accounting Policies.

The following table presents information about reported segments for the year ended December 31, 2006.

<u>2006</u>	<u>Research &amp; Development</u>	<u>Contract Manufacturing</u>	<u>Reconciling Items</u>	<u>Total</u>
Revenues	\$ 51,136	\$ 12,311	—	\$ 63,447
Depreciation and amortization	13,549	— <sup>(1)</sup>	\$ 1,043	14,592
Non-cash compensation expense	18,357	318	(813) <sup>(2)</sup>	17,862
Interest expense		—	12,043	12,043
Net income (loss)	(111,820)	4,165	5,318 <sup>(3)</sup>	(102,337)
Capital expenditures	3,339	—	—	3,339
Total assets	56,843	3	528,244 <sup>(4)</sup>	585,090

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

(2) Represents the cumulative effect of adopting SFAS 123R.

(3) Represents investment income net of interest expense related to convertible notes issued in October 2001 (see Note 9). For the year ended December 31, 2006, also includes the cumulative effect of adopting SFAS 123R (see Note 2).

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

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**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**  
**For the years ended December 31, 2008, 2007, and 2006**  
*(Unless otherwise noted, dollars in thousands, except per share data).*

## 22. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2008 and 2007 are set forth in the following tables.

	First Quarter Ended <u>March 31, 2008</u>	Second Quarter Ended <u>June 30, 2008</u>	Third Quarter Ended <u>September 30, 2008</u>	Fourth Quarter Ended <u>December 31, 2008</u>
	<i>(Unaudited)</i>			
Revenues	\$ 56,383	\$ 60,653	\$ 65,584	\$ 55,837
Net loss	(11,618)	(18,459)	(21,115)	(31,518)
Net loss per share, basic and diluted:	\$ (0.15)	\$ (0.23)	\$ (0.27)	\$ (0.40)

	First Quarter Ended <u>March 31, 2007</u>	Second Quarter Ended <u>June 30, 2007</u>	Third Quarter Ended <u>September 30, 2007</u>	Fourth Quarter Ended <u>December 31, 2007<sup>(1)</sup></u>
	<i>(Unaudited)</i>			
Revenues	\$ 15,788	\$ 22,195	\$ 22,311	\$ 64,730
Net loss	(29,917)	(26,774)	(35,838)	(13,071)
Net loss per share, basic and diluted:	\$ (0.46)	\$ (0.41)	\$ (0.54)	\$ (0.19)

- <sup>(1)</sup> As described above in Note 10, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. As a result, in the fourth quarter of 2007, when the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, the Company recognized contract research and development revenue from Bayer HealthCare of \$35.9 million and additional research and development expense of \$10.6 million.

As of November 14, 2008

Leonard S. Schleifer, M.D., Ph.D.  
 President and Chief Executive Officer,  
 Regeneron Pharmaceuticals, Inc.  
 777 Old Saw Mill River Road  
 Tarrytown, New York 10591-6707

Dear Len:

This employment agreement will replace and update the agreement dated December 20, 2002 between Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") and you. The compensation obligations of the Company under this agreement (the "Agreement") will be reduced by any amounts actually paid by any affiliate, subsidiary, and related entity controlled by or under common control with the Company ("Related Entity").

1. Employment.

- (a) You will continue to serve, during the Employment Term, as President and Chief Executive Officer of the Company with the customary responsibilities and authority of such positions and in accordance with the Company's By-Laws. You will report directly and only to the Board of Directors. If elected, you will also continue to serve as a Director of the Company. The Company shall during the Employment Term recommend and propose you as a Director of the Company and any Related Entity and, if the Chairman of the Board of Directors as of the date hereof at any time ceases to serve as such, as Chairman of the Board of Directors. To the extent you are not elected Chief Executive Officer of any Related Entity, such Chief Executive Officer shall report to you.
- (b) During the Employment Term, you shall devote substantially all of your business time and attention to the performance of your duties for the Company and serve the Company diligently and to the best of your ability. You may, however, perform teaching, consulting, patient care, and other activities as you have done from time to time in the past, provided that they do not materially conflict with the performance of your duties to the Company. In addition, you may manage your personal investments and be involved in civic and charitable activities so long as such activities do not materially interfere with your providing services hereunder. During the Employment Term, you shall not serve as a member of a board of directors of any other for-profit corporation (other than a Related Entity) without the prior written consent of the Board of Directors (which consent shall not be unreasonably withheld). In no event will the provisions of this Agreement in any way modify, alter, reduce, or limit the fiduciary obligations you owe to the Company as an officer and Director of the Company.

2. Term. Except for earlier termination as provided in paragraph 4 hereof, your employment under this Agreement (the "Employment Term") is for an initial term that commenced on February 12, 1998 and ended on December 31, 2003 (the "Initial Term") and automatically extended since then. Unless notice is given of an intent not to extend the Initial Term or any extension thereof, by you or by the Company by written notice at least ninety (90) days prior to each December 31 during the Employment Term, the Employment Term shall be deemed as of such 90th day to have been extended and continue until the end of the following calendar year unless otherwise terminated as provided in paragraph 4 hereof.

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3. Compensation/Benefits.

- (a) During the Employment Term, you have received base salary at an annual rate of not less than \$575,000, paid currently at periodic intervals in accordance with the Company's payroll practices for salaried employees. Adjustments in your base salary during the term of this Agreement (which shall thereafter be your "Base Salary") have been and may be effected from time to time upon the recommendation of the Compensation Committee and the approval of the Board of Directors based upon an annual review by the Compensation Committee, but your Base Salary, once increased, shall in no event be decreased; provided, however, that in the event there is a general reduction of compensation applicable to senior executives generally, nothing herein shall preclude the Board of Director's ability to reduce your Base Salary consistent with this reduction. You shall also participate in and be the beneficiary of any cash bonus payments, stock option and other equity programs, incentive programs, pension plans, profit sharing plans and other benefit programs and fringe benefit programs implemented by the Company and otherwise available to executive officers, nonindependent directors, and employees of the Company, at a level commensurate with your position, in accordance with the terms and conditions of such programs.
- (b) You have separately entered into one or more stock purchase agreements and stock option award agreements with the Company. With the sole exception of the provisions in this Agreement regarding vesting and exercisability of stock options, nothing in this Agreement will affect any term or provision of any stock purchase or stock option award agreement you have entered into or will enter into with the Company under any stock purchase or incentive plan of the Company and the stock options to purchase common shares previously granted to you shall remain outstanding, and in effect, in accordance with their respective terms.
- (c) The Company will during the Employment Term maintain insurance on your life in the amount of \$1,000,000 payable to such beneficiary as you designate. You may change the designated beneficiary of this policy at any time. The Company will not borrow against or otherwise encumber the policy or proceeds thereof. The Company will also during the Employment Term maintain for your benefit a long term disability policy that will pay you at least 65 percent of your Base Salary during such period as you are unable, for physical or mental reasons, to perform the responsibilities of your current position, with such benefits commencing no later than six (6) months after incurrence of the disability.

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- (d) During the Employment Term, subject to paragraph 14(o)(i), the Company will pay for or will reimburse the reasonable costs of your medical malpractice insurance and all customary, ordinary, and necessary business expenses incurred by you in the performance of your duties (including expenses related to equipment you customarily and normally use in connection with the performance of your duties to the Company), provided that you present such vouchers, receipts, or other documentation as are required by the regular procedures of the Company for the reimbursement of such

expenses. In addition, during the Employment Term, the Company will pay you a monthly automobile cash allowance of \$1,500 plus all expenses of maintaining and operating your automobile in accordance with current policy.

- (e) You shall be entitled to at least four (4) weeks of vacation per year, which vacation may be taken at such times as you elect with due regard to the needs of the Company.
- (f) Subject to paragraph 14(o)(i), the Company will pay, or will reimburse the reasonable costs of any legal, accounting or other professional services you incur in connection with your tax preparation and financial planning to an annual maximum of (i) the amount for financial planning and similar benefits generally made available to other senior executives of the Company for such year, plus (ii) \$12,500 per year (together, the "Maximum Annual Professional Services Reimbursement Amount"), including, without limitation, a tax gross-up reimbursement, so long as the total direct reimbursement and tax gross-up reimbursement is no more than the Maximum Annual Professional Services Reimbursement Amount per year. For calendar years commencing after December 31, 2004, any accrued unused amount that would have been reimbursed under this paragraph 3(f) during such year will be forfeited to the extent reimbursable expenses are not incurred during the applicable year. For calendar years prior to 2004, any unused amounts under the annual reimbursable cap (the "Grandfathered Reimbursements") under this Agreement and the February 12, 1998 agreement between you and the Company shall continue to be available to you for reimbursement of legal, accounting or other professional service expenses (and tax gross ups) you incur in connection with your tax preparation and financial planning under the terms of this Section 3(f). For the avoidance of doubt, all reimbursements shall first be deemed to come from the annual allowance that, if unused, is subject to forfeiture.
- (g) During the Employment Term (and, subject to the terms of this paragraph, thereafter), the Company will continue to designate you as its nominee at the club at which you are currently designated as the nominee of the Company (the "Club") and, subject to paragraph 14(o)(i), pay any dues or other expenses incurred with regard to your use of the Club. After your termination of employment with the Company, you shall, at your election made to the Company within 45 days thereafter: (i) elect not to be designated by the Company as the nominee for the Company's Club membership; (ii) if permitted by the Club, have the Company transfer the Company's Club membership to you, with the Company having its bond either returned or assumed by you (in which case you would pay the Club any dues or other Club expenses incurred thereafter and, if you assumed the bond, would pay the Company the amount of the bond); or (iii) have the Company continue your designation as nominee for the Company's Club membership (in which case you would pay the dues and other Club expenses incurred thereafter and deposit the amount of the Club bond with the Company, with such amount (as adjusted in the same manner as the bond) returned to you by the Company at the earlier of such time as it receives a refund of the bond or you elect to cease being designated as the Company's nominee at the Club). Notwithstanding anything else herein, this obligation shall survive any termination of your employment with the Company.

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- (h) Following any termination of your employment with the Company, if and to the extent the Company maintains any health benefit plans (and without any obligation to do so), you and your (and, after your death, your wife's) dependents shall be entitled to continue to participate therein by paying an amount equal to the COBRA cost thereof for the remainder of your life and that of your spouse at the time of such termination of employment. Notwithstanding anything else herein, this provision shall survive any termination of your employment with the Company.

4. Termination. Except as otherwise provided in paragraph 2, the Employment Term shall end upon the earliest of the following to occur:

- (a) Your death.
- (b) Upon a vote of the Board of Directors and notice to you of termination as a result of your Permanent Disability. Permanent Disability means your inability, by reason of any physical or mental impairment, to substantially perform the significant aspects of your regular duties as contemplated by this Agreement and which inability is reasonably contemplated to continue for at least one (1) year from its incurrence and at least ninety (90) days from the date of such vote. Any question as to the existence, extent, or potentiality of your Permanent Disability shall be determined by a qualified independent physician selected by you (or, if you are unable to make such selection, by an adult member of your immediate family), and reasonably acceptable to the Company. Such physician's written determination of your Permanent Disability shall, upon delivery to the Company, be final and conclusive for purposes of this Agreement; provided, however, that no such determination shall be final and conclusive with respect to any disability coverage under paragraph 3(c).
- (c) Your Involuntary Termination, as set forth in paragraph 6 below.
- (d) Your Removal for Cause, as set forth in paragraph 7(a) below.
- (e) Your voluntary termination (other than termination on account of death, Permanent Disability or termination by you for Good Reason) upon ninety (90) days prior written notice; provided, however, that the Company may waive such notice requirement in a written waiver delivered to you.

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5. Death and Disability.

- (a) If the Employment Term terminates by reason of your death or your Permanent Disability as provided in paragraph 4, then, except as provided in this paragraph 5(a), no further compensation will become payable to you under this Agreement, other than any earned but unpaid Base Salary, earned but unpaid bonuses, the pro rata portion of incentive compensation earned for services rendered through the date of your death or Permanent Disability, any deferred compensation and all other payments, benefits or fringe benefits to which you may be entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant (other than any severance plan) or this Agreement (collectively, "Entitlements"). Entitlements shall be calculated and paid as set forth in paragraph 5(c) below. You shall also be entitled to the Stock Option Treatment (as set forth in paragraph 8(f) below). In the event of your termination on account of your Permanent Disability, the Company shall pay you 100% of your Base Salary which you would have received during the eighteen (18) month period following your date of termination, such payment to be made in lump sum on the sixtieth (60th) day following termination, reduced by the projected amount of disability payments you are expected to receive during such period, calculated at the time of your termination, and assuming your continuous disability for the full (18) month

period, and the Company shall also (i) continue to provide for insurance and other payments that are to be made under disability policies or plans paid for or maintained by the Company, (ii) continue to provide life insurance at a level of coverage comparable to the coverage in effect for you at the time of your termination on account of Permanent Disability, and (iii) pay you a monthly amount equal to COBRA premiums for medical and dental coverage as set forth in subparagraph (b) below, in each case upon the same terms and conditions (except for the requirement of your continued employment) for a period of eighteen (18) months following your date of termination.

- (b) With respect to monthly amount for medical and dental coverage provided under paragraph 5(a), you shall be required to pay the applicable COBRA premium for you and your dependents, or to obtain coverage for you and your dependents under substitute arrangements, and you shall be paid a monthly amount by the Company equal to such amount, and to the extent you incur tax that you would not have incurred as an active employee as a result of the aforementioned coverage, you shall receive from the Company an additional gross-up payment in the amount necessary, subject to paragraph 14(o)(i), so that you will have no additional cost for receiving such items or any additional payment.
- (c) Earned but unpaid bonus shall mean any declared but unpaid bonus for any prior bonus period and, if the bonus for the current bonus period is other than totally discretionary, a pro rata portion of the calculated bonus for the bonus period based on days in the bonus period prior to termination of your services compared to total days in the bonus period. Any incentive compensation shall be deemed earned and shall be paid based on actual results during the measuring period and a pro rata measurement of the days in the incentive period prior to termination of your services compared to total days in the incentive period. Such pro rata bonus and incentive compensation shall be paid to you at the same time and form that bonuses and incentive compensation are paid to other active participants. Any deferred compensation shall be paid in accordance with the terms of the applicable plan. Base Salary shall be paid in accordance with normal payroll practice.

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## 6. Involuntary Termination.

- (a) Involuntary Termination shall mean either your termination by the Company in accordance with paragraph 6(b) hereof, or your resignation in accordance with paragraph 6(c) hereof.
- (b) Termination By The Company Without Cause: Your termination by the Company shall be considered to be "without cause" if (i) you are terminated or dismissed, for reasons other than your death, Permanent Disability or "Removal for Cause," as President or Chief Executive Officer, unless you have previously consented in writing to such removal or dismissal (which consent may be given or withheld in your sole discretion); provided, however, that your termination or dismissal as President shall not be a Termination by the Company without Cause if the person appointed President reports to you, or (ii) prior to your sixty-fifth (65th) birthday, the Company gives notice of nonextension of the Employment Term pursuant to paragraph 2 hereof.
- (c) Termination By You For Good Reason: Your resignation shall be considered to be for Good Reason if you resign as President and Chief Executive Officer (whether or not you resign as a Director and, if Chairman of the Board, as Chairman of the Board) upon ninety (90) days' prior written notice within ninety (90) days after the occurrence of one of the following events: (i) your removal, dismissal or failure to be re-elected as President or Chief Executive Officer (other than on account of your termination for some other reason) or a de jure or de facto material reduction in your duties, title, responsibilities, authority, status, or reporting responsibilities (other than in connection with the appointment of a Chief Operating Officer or President who reports to you), unless you have previously consented in writing to such removal, dismissal or reduction (which consent may be given or withheld in your sole discretion); (ii) the failure to elect you, or your removal, dismissal or failure to be re-elected, as Chairman of the Board if the current Chairman of the Board ceases to serve as such; (iii) the failure of the Company to pay to you any amount due under this Agreement within ten (10) days after the later of its due date or your written demand for payment of such amount; (iv) any material breach by the Company of any provision of this Agreement which is not cured within thirty (30) days after your giving of written notice of such breach to the Company; (v) one year after a Change of Control, as defined in Exhibit A hereto, to the extent you are employed hereunder at that time; (vi) the relocation of the Company's principal executive office more than fifty (50) miles from the current location; or (vii) the failure of the Company to obtain and deliver to you a reasonably satisfactory written agreement from any successor to the Company as provided in paragraph 14(l).

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- (d) Upon an Involuntary Termination, you will become entitled to the benefits specified in paragraph 8 of this Agreement. In addition, you will be entitled to your Entitlements as calculated and paid in accordance with paragraph 5(c) above.

## 7. Removal for Cause.

- (a) Removal for Cause shall mean the termination of your duties as President, Chief Executive Officer and, if you are then serving in such capacity, Chairman of the Board, effected by the Board of Directors of the Company (after a Board of Directors meeting for which you had at least ten (10) days prior written notice and at which you had the opportunity to have counsel present to represent you in connection with issues concerning your removal for cause) by reason of any one or more of the following, which individually or in the aggregate has a material adverse effect on the aggregate business or affairs of the Company and any Related Entity:
  - (i) your gross neglect of your duties, your willful and continuing refusal to perform your duties (other than, in any such case, because of a reasonably documented mental or physical illness), your refusal to obey any lawful order of the Board of Directors, or any material breach by you of any provision of paragraphs 11 or 12 of this Agreement, which, in any of the foregoing events, continues for more than thirty (30) days following your receipt of written notice from the Board of Directors that describes such breach or other event
  - (ii) your willful misconduct with respect to the business or affairs of the Company or of any Related Entity
  - (iii) your conviction of, or your plea of nolo contendere to, a misdemeanor involving embezzlement or fraud or other offense involving money or other property of the Company (other than a good faith dispute over expense account items), any criminal violation of the Securities Act of

1933 or the Securities Exchange Act of 1934, or any felony, provided your rights of appeal with respect to such matter have either lapsed or been exercised

- (b) Upon your Removal for Cause, you will be entitled to your Entitlements as calculated and paid in accordance with paragraph 5(c) above. In such case, no amounts will be payable to you under paragraph 8 of this Agreement for any reason whatsoever.
- (c) In the event of your voluntary termination in accordance with paragraph 4(e), you shall receive the same amounts as if you were Removed for Cause plus the Stock Option Treatment (as set forth in paragraph 8(f)).

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8. Severance Benefits.

- (a) Subject to paragraphs 8(b) and 8(e), upon an Involuntary Termination, you will become entitled to the following severance benefits:
  - (i) The Company will pay you an amount equal to one and one-quarter (1-1/4) times the sum of (x) your Base Salary in effect (or, if improperly reduced, required to be in effect) at the time of your Involuntary Termination and (y) the average of the annual bonuses paid or payable to you during the three (3) completed fiscal years prior to your Involuntary Termination; and such payment shall be made to you in lump sum on the date specified in paragraph 8(g) below.
  - (ii) With respect to medical and dental coverage, you shall be required to pay the applicable COBRA premium for you and your dependents, or to obtain covering for you and your dependents under substitute arrangements, for eighteen (18) months, and you shall be reimbursed monthly by the Company for such amount, and to the extent you incur tax that you would not have incurred as an active employee as a result of the aforementioned coverage, you shall receive from the Company, subject to paragraph 14(o)(i), an additional gross-up payment in the amount necessary so that you will have no additional cost for receiving such items or any additional payment. The Company shall continue to provide you and your eligible dependents, upon the same terms and conditions (except for the requirement of your continued employment), with life insurance at a level of coverage comparable to the coverage in effect for you at the time of your Involuntary Termination for the eighteen (18) month period following your Involuntary Termination.
- (b) Notwithstanding paragraph 8(a), upon your Involuntary Termination within three (3) years after a Change of Control, as defined in Exhibit A hereto, or within three (3) months prior thereto in anticipation of a Change of Control, you will become entitled to the following severance benefits in lieu of the amounts under paragraph 8(a) above:
  - (i) The Company will make a lump sum payment to you at on the date specified in paragraph 8(g) below of an amount equal to three (3) times the sum of (x) your Base Salary in effect (or, if improperly reduced, required to be in effect) at the time of your Involuntary Termination and (y) the average of the annual bonuses paid or payable to you during the three (3) completed fiscal years prior to your Involuntary Termination or, if higher, the three (3) completed fiscal years prior to the Change of Control.
  - (ii) Any bonus, vacation pay or other compensation accrued or earned under law or in accordance with the Company's policies applicable to you but not yet paid and any incurred but unreimbursed business expenses for the period prior to termination shall be payable, subject to paragraph 14(o)(i), in accordance with the Company's policies and the terms of the applicable plan

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- (iii) With respect to medical and dental coverage, you shall be required to pay the applicable COBRA premium for you and your dependents, or to obtain covering for you and your dependents under substitute arrangements, for the thirty-six (36) month period following your Involuntary Termination, and you shall be reimbursed monthly by the Company for such amount, and to the extent you incur tax that you would not have incurred as an active employee as a result of the aforementioned coverage, you shall receive from the Company, subject to paragraph 14(o)(i), an additional gross-up payment in the amount necessary so that you will have no additional cost for receiving such items or any additional payment. The Company shall continue to provide you and your eligible dependents, upon the same terms and conditions (except for the requirement of your continued employment), with life insurance at a level of coverage comparable to the coverage in effect for you at the time of your Involuntary Termination for the thirty-six (36) month period following your Involuntary Termination.
  - (iv) All stock options, whether heretofore or hereafter, granted to you shall become fully vested and immediately exercisable and, if the basis were an action in anticipation of the Change of Control, the option shall remain exercisable (unless the original terms would otherwise end) at least through the Change of Control
- (c) Each of your outstanding loans from the Company will become due and payable in accordance with their existing terms and provisions, and none of these loans will be forgiven or otherwise canceled in whole or in part.
  - (d) The Company agrees that if your employment with the Company is terminated during the Employment Term for any reason whatsoever, you are not required to seek other employment or to attempt in any way to reduce any amounts payable to you by the Company pursuant to this Agreement. Further, the amount of any payment or benefit provided for in this Agreement shall not be reduced by any compensation earned by you or benefit provided to you as the result of employment by another employer or otherwise. In addition, the amounts payable hereunder shall not be subject to setoff, counterclaim, recoupment, defense or other right which the Company may have against you or others, except upon obtaining by the Company of a final nonappealable judgment against you.
  - (e) In the event that you have received or commenced receipt of any payments or other rights under paragraphs 5(a) or 8(a), you shall not be entitled to any additional payments or rights under paragraphs 5(a), 8(a), or 8(b) with respect to any subsequent occurrence which might otherwise give rise to such payments or rights under such paragraphs, except as specifically provided with regard to paragraph 8(b).

- (f) Notwithstanding anything to the contrary in this Agreement or any other agreement between you and the Company, the Company agrees that if your employment with the Company terminates during the Employment Term for any reason (other than a Removal for Cause), including a termination of employment pursuant to paragraphs 4(a), 4(b), 4(c) and 4(e), (i) all of your stock options and other equity awards shall continue to vest in accordance with the terms of the applicable grant agreement notwithstanding the employment termination, (ii) you (or your executors or administrators of your estate, in the case of your death) shall be entitled to exercise any of your stock options at any time during the original term of such options, and (iii) all agreements relating to your stock options or other equity shall be deemed amended to the extent inconsistent with the foregoing (such continued vesting and exercisability, the "Stock Option Treatment").

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- (g) Any amounts payable and benefits or additional rights provided pursuant to paragraphs 8(a) or 8(b) beyond Entitlements ("Release Conditioned Amounts") shall be payable only if you deliver to the Company a release of all claims that you have or may have (and you do not revoke the release within the revocation period) within sixty (60) days after your termination in a form substantially in the form of Exhibit B hereto. Release Conditioned Amounts shall be paid to you in a lump sum, or shall commence if in installments, on the sixtieth (60th) day following your date of termination, with any missed installment payments paid in a lump sum on such date.

9. Excise Tax. In the event that you become entitled to payments and/or benefits which would constitute "parachute payments" within the meaning of Section 280G(b)(2) of the Internal Revenue Code of 1986, as amended, (the "Code"), the provisions of Exhibit C shall apply.

10. Proprietary Information and Inventions. You understand and acknowledge that:

- (a) The Company is and will be engaged in a continuous program of research, design, development, production, and marketing with respect to its business.
- (b) Your employment by the Company creates a relationship of confidence and trust between the Company and you with respect to certain information relating to the business and affairs of the Company or applicable to the business of any client, customer, consultant, partner, external collaborator, or service provider of the Company, which may be made known to you by the Company or by any client, customer, consultant, partner, external collaborator, or service provider of the Company, or learned by you during the period of your affiliation with the Company.
- (c) The Company will possess information created, discovered, or developed by, or otherwise become known to, the Company (including, without limitation, information created, discovered, developed, or made known to you during the Employment Term) or in which property rights have been or may be assigned or otherwise conveyed to the Company (whether or not the information has commercial value in the business in which the Company is or proposes to be engaged) and is treated by the Company as confidential. All this information is "Proprietary Information," which includes, but is not limited to, systems, processes, formulae, data, functional specifications, computer software, programs and displays, know-how, improvements, discoveries, inventions, developments, designs, techniques, marketing plans, strategies, forecasts, new and proposed products, unpublished financial statements, budgets, projections, licenses, prices, costs, and customer, external collaborator, partner, client, and supplier lists, and any and all intellectual properties. The foregoing, however, shall not cover information generally known in the industry or which hereafter become generally known in the industry.

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11. Ownership of Proprietary Information and Inventions.

- (a) All Proprietary Information shall be the sole property of the Company and its assigns, and the Company and its assigns will be the sole owners of all inventions, patents, copyrights, trademarks, and other rights in connection therewith. You hereby assign to the Company any right you may have or acquire in such Proprietary Information. At all times, you will keep in strictest confidence and trust all Proprietary Information and you will not use or disclose any Proprietary Information without the written consent of the Company.
- (b) If your employment with the Company is terminated for any reason, you will deliver to the Company all documents, notes, drawings, specifications, computer software, data, inventions, organisms, and other materials of any nature pertaining to any Proprietary Information, and will not take any of the foregoing, or any reproduction of any of the foregoing, that is embodied in any tangible medium of expression. This shall not limit you from retaining your personal phone directories and rolodexes.
- (c) You will promptly disclose to the Company (or any persons designated by it) all discoveries, developments, designs, improvements, inventions, formulae, processes, techniques, computer software, strategies, know-how, and data, whether or not patentable or registrable under copyright or similar statutes, made or conceived or reduced to practice or learned by you, either alone or jointly with others, during your employment by the Company, which result from carrying out your responsibilities to the Company, or result from the use of premises or property owned, leased, or contracted for by the Company (all such discoveries, developments, designs, improvements, inventions, formulae, processes, techniques, computer software, know-how, and data are referred to in this Agreement as Inventions). You will also promptly disclose to the Company, and the Company agrees to receive all such disclosures in confidence, all other discoveries, developments, designs, improvements, inventions, formulae, processes, techniques, computer software, strategies, know-how, and data, whether or not patentable or registrable under copyright or similar statutes, made or conceived or reduced to practice or learned by you, either alone or jointly with others, during your employment by the Company for the purpose of determining whether they are Inventions, as that term is used in this Agreement. At all times during your employment by the Company you will use your reasonable business efforts to avoid conflicts of interest involving potential rights and claims of the Company and of third parties to Inventions, including those that might arise by virtue of your affiliation with a university or other medical institution concurrently with your employment by the Company and will take all action reasonably necessary and or desirable to minimize the probability of any such conflicts of interest and to maximize the likelihood that any Inventions made, conceived or developed or reduced to practice by you (alone or jointly with others) during your employment by the Company and which reasonably relate to the business of the Company will be and become the sole, unencumbered property of the Company, and no other third party (including, without limitation, any such university or other institution with whom you may also be affiliated) will have any rights thereto and that any such conflicts of interest be resolved in favor of the Company.

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- (d) All Inventions shall be the sole property of the Company and its assigns, and the Company and its assigns shall be the sole owner of all patents, copyrights, trademarks, and other rights in connection therewith. You hereby assign to the Company any rights you may have or acquire in such Inventions. You will assist the Company in every proper way as to all such Inventions (but at the Company's expense) to obtain and from time to time enforce patents, copyrights, trademarks, and other rights and protections on and enforcing such Inventions, as the Company may desire, together with any assignments thereof to the Company or persons designated by it. Your obligation to assist the Company in obtaining and enforcing patents, copyrights, trademarks, and other rights and protections relating to such Inventions in any and all countries shall continue beyond the Employment Term. If the Company is unable, after reasonable effort, to secure your signature on any document or documents needed to apply for or prosecute any patent, copyright, or other right or protection relating to an Invention, for any other reason whatsoever, you hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as your agent and attorney-in-fact, to act for and on your behalf to execute and file any such application or applications and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights, or similar protections thereon with the same legal force and effect as if executed by you and you hereby ratify, affirm, and approve all such lawfully permitted acts accordingly.

12. Restricted Covenant.

- (a) You are aware that the services you perform for the Company are of a special, unique character. You also acknowledge your possession and future possession of Proprietary Information and the highly competitive nature of the business of the Company. Accordingly, you agree that, for the consideration set forth in this Agreement, you will not, without the written permission of the Company pursuant to Board of Directors authorization, during your employment under this Agreement and, if your employment ends as a result of your voluntary termination of employment pursuant to paragraph 4(e), for a period of one (1) year thereafter (six (6) months, in the event of any such termination after the occurrence of a Change of Control): (i) directly or indirectly engage or become interested or involved in any Competitive Business (as defined in subparagraph (b) below), whether such engagement, interest, or involvement shall be as an employer, officer, director, owner shareholder, employee, partner, consultant, or in any other capacity or relationship; provided, however, that this shall not preclude a passive investment of less than one (1%) of the stock of any publicly traded company; or (ii) materially assist others in engaging in any Competitive Business in the manner described in the foregoing clause (i); provided, further, that this shall not preclude you from providing investment banking services to or on behalf of an entity after your termination of employment that might otherwise be a Competitive Business so long as such services are to arrange a purchase, sale or other business combination for or with such entity or to arrange financing for such entity (including, without limitation, obtaining a bank loan for such entity or participating in the sale of the debt or equity securities of such entity).

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You understand that this provision is not meant to prevent you from earning a living or fostering your career. It does intend, however, to prevent Competitive Businesses from gaining any unfair advantage from your knowledge of Proprietary Information. You understand that by making any other employer aware of this provision, that employer can take such action as to avoid your breach of this provision and to indemnify you in the event of a breach.

- (b) The term "Competitive Business" means:

- (i) For the period commencing on the date of this Agreement and ending on the date of your termination of employment any business or activity that is substantially the same as any business or activity of the Company as conducted by the Company or any Related Entity during such period; and
- (ii) For the period thereafter, any business or activity described in subparagraph (i) above to the extent that on the date of your termination of employment such business or activity represents at least 10% of the research and development budget of the Company for the fiscal year in which your termination occurs; provided, however, that any business or activity of the Company shall be deemed to have been conducted by the Company at the time of your termination of employment if the Company has undertaken steps to commence such business or activity prior to your termination of employment. Notwithstanding the foregoing, the provisions of this paragraph shall not operate to preclude your employment with (or providing consulting services to) any company that has a market capitalization at the time of your termination of employment of at least \$500 million.

13. Litigation Support. Subject to your other commitments, following the Employment Term, you shall make yourself reasonably available to cooperate (but only truthfully) with the Company and provide information as to matters with which you were personally involved, or have information on, while you were an officer of the Company and which are or become the subject of litigation or other dispute.

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14. General Provisions.

- (a) Death. Should you die before receipt of any or all severance payments to which you became entitled under paragraph 8, then the balance of the payments to which you are entitled shall continue to be paid in accordance with the terms hereof to the executors or administrators of your estate.
- (b) General Creditor Status. The amounts to which you may become entitled hereunder shall be paid, when due, from the general assets of the Company, and no trust fund, escrow arrangements, or other segregated account shall be established as a funding vehicle for such payment. Accordingly, your right (or the right of the executors or administrators of your estate) to receive such benefits shall at all times be that of a general creditor of the Company and shall have no priority over the claims of other general creditors.
- (c) Indemnification. During the Employment Term and thereafter, the Company shall indemnify you and hold you harmless to the fullest extent permitted by law against any judgments, fines, amounts paid in settlement and reasonable expenses (including reasonable attorneys' fees), and advance amounts necessary to pay the foregoing at the earliest time and to the fullest extent permitted by law, in connection with any claim, action or proceeding (whether civil or criminal) against you as a result of you serving as an officer or Director of the Company or in any capacity at the

request of the Company in or with regard to any other entity, employee benefit plan or enterprise. This indemnification is in addition to and not in lieu of any other indemnification rights you may otherwise have.

- (d) Remedies. Your obligations under paragraphs 11 or 12 of this Agreement will survive termination of your employment by the Company. You acknowledge that a remedy at law for any breach or threatened breach of such provisions would be inadequate and therefore agree that the Company may be entitled to injunctive relief and any other available rights and remedies in case of any such breach or threatened breach; provided, however, that nothing contained in this subparagraph (d) will be construed as prohibiting the Company from pursuing any other remedies available for any such breach or threatened breach.
- (e) Interpretation. This Agreement shall be interpreted under the laws of the State of New York without regard to conflict of law provisions thereof.
- (f) Notices. Any notice which a party is required or may desire to give under this Agreement will be given by personal delivery, air courier, or registered or certified mail, return receipt requested, addressed to you at the address of record with the Company and addressed to the Secretary of the Company at its principal office, or at such other place as either party may from time to time designate in writing given as aforesaid. The date of delivery of any notice or communication will be deemed to be (i) the date of delivery thereof, in the case of personal delivery; (ii) the day after the date when dispatched, in the case of air courier; and (iii) the date of receipt, in the case of mailing.

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- (g) Waivers. If either party shall waive any breach of any provision of this Agreement, he or it will not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.
  - (h) Headings. The paragraph headings of this Agreement are for convenience only and will not be deemed to affect the meaning of the Agreement.
  - (i) Superseding. This Agreement supersedes all prior agreements between you and the Company relating to the subject of your personal services and severance benefits, including the letter agreement dated September 14, 1993, which is hereby terminated. The provisions of this Agreement may only be amended by written instrument signed by you and a member of the Board of Directors.
  - (j) No Guarantee of Employment or Service. Nothing in this Agreement is intended to provide you with any right to continue in the service of the Company for any period of specific duration, nor, except as specifically provided herein, to provide the Company with any right to require you to continue in the service of the Company.
  - (k) Amendment or Termination. This Agreement may not be amended or terminated orally, but only by a writing executed by the party to be charged.
  - (l) Assignment. None of the benefits to which you may become entitled hereunder may be assigned, transferred, pledged, or otherwise encumbered by you, and to the maximum extent permissible under law, such benefits will not be subject to the claims of your creditors or to levy, attachment, execution, or other legal process. This Agreement shall be binding upon and inure to the benefit of the Company, its successors and permitted assigns and your executors and heirs, provided that the Company may not assign the Agreement except in connection with a sale of all or substantially all of its assets and then only if said acquiror assumes in a writing delivered to you the obligations of the Company hereunder.
  - (m) Costs of Collection. In the event either party collects any part or all of the payments provided for hereunder or otherwise successfully enforces the terms of this Agreement by or through a lawyer or lawyers, the losing party shall pay all costs of such collection or enforcement, including reasonable legal fees and other fees and expenses which the successful party may incur plus interest ("Costs"); provided, however, that the Company shall not be entitled to recover any Costs from you unless an arbitrator determines that your action to recover any payment or to enforce the terms of this Agreement was not grounded on a reasonable good faith interpretation of the Agreement or that the action was undertaken for the primary purpose of harassing the Company. Interest shall be calculated at the prime rate as announced from time to time by Citibank, N.A. on all or any part of any amount to be paid to you hereunder that is not paid when due. The prime rate for each calendar quarter shall be the prime rate in effect on the first day of the calendar quarter. Any amounts due and payable to you on a favorable award of the arbitrator, pursuant to this paragraph 14(m) and paragraph 14(n), shall be paid within sixty (60) days following the date the arbitrator's decision becomes final.

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- (n) Arbitration. Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration, conducted before a panel of three (3) arbitrators in New York, New York, in accordance with the rules of the American Arbitration Association then in effect, and judgment may be entered on the arbitrators' award in any court having jurisdiction. The Company shall pay all costs of the American Arbitration Association and the arbitrator. The decision upon arbitration shall be final and binding upon both you and the Company. Notwithstanding the foregoing, you shall be entitled to seek specific performance from a court of your right to be paid until the date of termination during the pendency of any dispute or controversy arising under or in connection with this Agreement and the Company shall have the right to obtain injunctive relief from a court pursuant to subparagraph (d) above.
  - (o) Section 409A. It is the intention of the parties hereto that the provisions of this Agreement comply with or be exempt from Section 409A of the Code and the regulations and guidance promulgated thereunder ("Section 409A") and that the Agreement shall be construed in accordance with such intention. Without limiting the generality of the foregoing, the Company and you agree as follows:
    - (i) Reimbursements payable to you as a result of the operation of paragraph 3(c), paragraph 3(d), paragraph 3(f) (other than the "Grandfathered Reimbursements"), paragraph 3(g), paragraph 3(h), paragraph 5, paragraph 8 (including paragraphs 8(b)(iii) and 8(f)), paragraph 14(c) or paragraph 14(m) hereof, or any other provision in this Agreement regarding reimbursement, shall be paid to you within sixty (60) days following the date upon which you become entitled to the reimbursement (or such earlier date specified in this Agreement), but in no event later than the end of the calendar year following the year in which the expenses to be reimbursed are incurred (or, in the case of payments under paragraph 14(m), the year following the year in which you become entitled to reimbursement). Tax gross-up payments (and related reimbursements) payable to you as a result of the operation of paragraph 3(f), paragraph 5(b), paragraph 8(f), paragraph 9 or Exhibit C hereof,

or any other provision in this Agreement regarding tax gross-up payments, shall be paid to you within sixty (60) days following the date upon which the tax resulting in the gross-up is paid, but in no event later than the end of the calendar year following the year in which the tax resulting in the gross-up is paid. With regard to such reimbursements and payments under this paragraph or elsewhere in the Agreement, except as permitted by Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, and (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year, provided that the foregoing clause (ii) shall not be violated without regard to expenses reimbursed under any arrangement covered by Section 105(b) of the Code solely because such expenses are subject to a limit related to the period the arrangement is in effect.

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- (ii) Notwithstanding anything to the contrary herein, if you are a "specified employee" (within the meaning of Section 409A(a)(2)(B)(i) of the Code) with respect to the Company, (1) any amounts (or benefits) otherwise payable to or in respect of you under this Agreement pursuant to your termination of employment with the Company, which are deferred compensation under Section 409A, shall be delayed for a period of six months following such termination (or until death if earlier), so that taxes are not imposed on you pursuant to the operation of Section 409A, and shall be paid on first business day following the expiration such six month period and (2) any payments and benefits not required to be so delayed shall be paid or provided in accordance with this Agreement.
  - (iii) For purposes of amounts under this Agreement which are subject to Section 409A, your employment with the Company will not be treated as terminated unless and until such termination of employment constitutes a "separation from service" for purposes of Section 409A.
  - (iv) For purposes of Section 409A, to the extent that any payment payable under the Agreement is to be paid in installments, each such payment shall be treated as a separate identified payment for purposes of Section 409A. To the extent that the Agreement provides for a payment to be made on or before a specified date, the decision with respect to when to make such payment within the specified period shall be made in the sole discretion of the Company.
  - (v) The Company shall gross you up for any taxes, interest or penalties incurred by you under Section 409A as a result of any payments or benefits hereunder or otherwise due from the Company in such a manner that you will have no after tax cost as a result thereof, as soon as practicable but in no event later than the last day of the calendar year following the calendar year in which such tax, interest or penalty is paid. You agree to reasonably cooperate with the Company in order to avoid the imposition of such taxes, it being understood that such cooperation shall not require you to forgo receipt or receive a reduced amount of payments or benefits due hereunder.

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Please indicate your acceptance by signing the enclosed copy of this letter and returning it to the Company.

Very truly yours,

REGENERON PHARMACEUTICALS, INC.

/s/ Arthur F. Ryan  
Chairman of the Compensation  
Committee of the Board of Directors

AGREED TO AND ACCEPTED BY:  
LEONARD S. SCHLEIFER, M.D., Ph.D.

/s/ Leonard Schleifer

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#### EXHIBIT A

#### CHANGE OF CONTROL

For purposes of this Agreement, "Change of Control" shall be deemed to have occurred if the event set forth in any one of the following paragraphs shall have occurred:

- (i) any "Person" (as defined in Section 3(a)(9) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as modified and used in Sections 13(d) and 14(d) thereof, except that such term shall not include (1) the Company, (2) a trustee or other fiduciary holding securities under an employee benefit plan of the Company, (3) an underwriter temporarily holding securities pursuant to an offering of such securities, or (4) a corporation owned, directly or indirectly, by the shareholders of the Company in substantially the same proportions as their ownership of stock of the Company) is or becomes the "Beneficial Owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company (not including in the securities Beneficially Owned by such Person any securities acquired directly from the Company) representing 20% or

more of the Company's then outstanding securities, excluding any Person who is an officer or director of the Company or who becomes such a Beneficial Owner in connection with a transaction described in clause (A) of paragraph (iii) below; or

- (ii) the following individuals cease for any reason to constitute a majority of the number of directors then serving: individuals who, on the date hereof, constitute the Board of Directors and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including but not limited to a consent solicitation, relating to the election of directors of the Company) whose appointment or election by the Board of Directors or nomination for election by the Company's shareholders was approved or recommended by a vote of at least two-thirds (2/3) of the directors then still in office who either were directors on the date hereof or whose appointment, election or nomination for election was previously so approved or recommended; or
- (iii) there is consummated a merger or consolidation of the Company with any other corporation other than (A) a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) at least 60% of the combined voting power of the voting securities of the Company or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no Person is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company (not including in the securities Beneficially Owned by such Person any securities acquired directly from the Company) representing 20% or more of the combined voting power of the Company's then outstanding securities; or
- (iv) the shareholders of the Company approve a plan of complete liquidation or dissolution of the Company or there is consummated an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets, other than a sale or disposition by the Company of all or substantially all of the Company's assets to an entity at least 75% of the combined voting power of the voting securities of which are owned by Persons in substantially the same proportions as their ownership of the Company immediately prior to such sale.

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## EXHIBIT B

### FORM OF RELEASE

To: Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591-6707  
Attention: [General Counsel]

**1. Termination.** (a) I hereby acknowledge that my employment with Regeneron Pharmaceuticals, Inc. (the "Company") [will terminate] [has terminated] on, (the "Termination Date") pursuant to provisions of paragraphs 8 of my employment agreement dated as of December 20, 2002 with the Company (the "Employment Agreement"), that the Company will not have an obligation to rehire me or to consider me for reemployment after the Termination Date and that my employment with the Company is permanently and irrevocably severed.

(b) I hereby confirm my resignation from my position as President and Chief Executive Officer of the Company and that I will not be eligible for any benefits or compensation after the Termination Date, other than as specifically provided hereunder and in paragraphs 3 and 8 of the Employment Agreement [or in any capacity as a director of the Company]. In addition, effective as of the Termination Date, I hereby resign from all offices, directorships, trusteehips, committee memberships and fiduciary capacities held with, or on behalf of, the Company or any of its affiliates or any benefit plans of the Company or any of its affiliates [other than as a director]. These resignations will become irrevocable on the Effective Date of this Agreement, as defined in Section 6 below.

**2. Consideration.** I acknowledge that this General Release is being executed in accordance with paragraph 8(g) of the Employment Agreement.

**3. General Release.** (a) For and in consideration of the payments to be made and the promises set forth under the Employment Agreement, I, for myself and for my heirs, dependents, executors, administrators, trustees, legal representatives and assigns (collectively referred to as "Releasers"), hereby forever release, waive and discharge the Company, its affiliates, employee benefit and/or pension plans or funds, insurers, successors and assigns, and all of its or their past, present and/or future directors, officers, trustees, agents, members, partners, counsel, employees, fiduciaries, administrators, representatives, successors and assigns, whether acting on behalf of the Company or its affiliates or in their individual capacities (collectively referred to as "Releasees"), from any and all claims, demands, causes of action, fees and liabilities of any kind whatsoever, whether known or unknown, which Releasers ever had, now have, or hereafter may claim to have against Releasees by reason of any actual or alleged act, omission, transaction, practice, policy, procedure, conduct, occurrence, or other matter up to and including the date of my execution of this General Release, in connection with, or in any way related to or arising out of, my employment, service as a director, service as a trustee, service as a fiduciary or termination of any of the foregoing with the Company.

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(b) Without limiting the generality of the foregoing, this General Release is intended and shall release the Releasees from any and all claims, whether known or unknown, which Releasers ever had, now have, or may hereafter claim to have against the Releasees including, but not limited to, (i) any claim of discrimination or retaliation under the Age Discrimination in Employment Act ("ADEA"), Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act ("ADA"), the Employee Retirement Income Security Act of 1974 or the Family and Medical Leave Act; (ii) any claim under the New York State Human Rights Law and the New York City Administrative Code; (iii) any other claim (whether based on federal, state or local law, statutory or decisional) relating to or arising out of my employment, the terms and conditions of such employment, the termination of such employment and/or any of the events relating directly or indirectly to or surrounding the termination of such employment, including, but not limited, breach of contract (express or implied), wrongful discharge, tortious interference, detrimental reliance, defamation, emotional distress or compensatory or punitive damages; and (iv) any claim for attorney's fees, costs, disbursements and the like.

(c) I further acknowledge and agree that by virtue of the foregoing, I have waived all relief available to me (including without limitation, monetary damages, equitable relief and reinstatement) under any of the claims and/or causes of action waived in Sections 3(a) and (b) above. Therefore I agree that I will not seek or accept any award or settlement from any source or proceeding (including, but not limited to, any proceeding brought by any other person or by any government agency) with respect to any claim or right waived in this General Release. I further agree, to the maximum extent permitted by law, that I will not sue or commence any proceeding (judicial or administrative), or participate in any action, suit or proceeding (unless compelled by legal process or court order), against the Company (or any of its affiliates), with respect to any claim released by Sections 3(a) and (b) above, other than a claim contesting the validity of the release under applicable provisions of the ADEA. I also warrant and represent that as of the date I sign this Agreement, I have not taken or engaged in any of the acts described in the foregoing sentences. I understand that this release has neither the purpose nor intent of interfering with my protected right to file a charge with or participate in an investigation or proceeding pursuant to the statutes administered and enforced by the EEOC, specifically: the ADEA, the Equal Pay Act, Title VII of the Civil Rights Act of 1964 and the ADA. I understand that I will not breach this release if I file a charge with or participate in an investigation or proceeding pursuant to the statutes administered and enforced by the EEOC. However, by signing this release, I understand that I waive any right I may have to recover money or other relief in any lawsuit or proceeding brought by me or by an agency or third party, including the EEOC, on my behalf. If, notwithstanding the foregoing promises and understandings, I violate this Section 3(c), I shall be required, to the maximum extent permitted by law, to indemnify and hold harmless the Company (and its affiliates) from and against any and all demands, assessments, judgments, costs, damages, losses and liabilities, and attorneys' fees and other expenses which result from, or are incident to, such violation.

(d) Notwithstanding anything herein to the contrary, the sole matters to which the release and covenants in this Section 3 do not apply are: (i) my rights of indemnification and directors and officers liability insurance coverage which I was entitled immediately prior to the Termination Date under the Company's By-laws or otherwise with regard to my service as an officer and director of the Company (including, without limitation, under paragraph 14(c) of the Employment Agreement); (ii) my rights under any tax-qualified pension or tax deferred annuity plan or claims for accrued vested benefits under any other employee benefit plan, program, policy or arrangement maintained by the Company or under COBRA; (iii) my rights under the provisions of the Employment Agreement which are intended to survive termination of employment (including claims to payments, benefits or entitlements specifically payable or provided under the Employment Agreement); or (iv) my rights as a stockholder or as a director of the Company.

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**4. Governing Law; Enforceability.** The interpretation of this General Release will be construed and enforced in accordance with the laws of the State of New York without regard to that state's principles of conflicts of law. If, at any time after the execution of this General Release, any provision of this General Release will be held to be illegal or unenforceable by a court of competent jurisdiction, solely such provision will be of no force or effect.

**5. Acknowledgement.** I acknowledge that I have been advised by the Company in writing to consult, and I have consulted, independent legal counsel of my choice before signing this General Release. I further acknowledge that I have had the opportunity to consult independent legal counsel and to consider the terms of this General Release for a period of at least 21 days. I further acknowledge that I have carefully read this General Release in its entirety; that I have had an adequate opportunity to consider it and to consult with any advisors of my choice about it; that I have consulted with independent legal counsel of my choice who has answered to my satisfaction all questions I had regarding this General Release; that I understand all the terms of this General Release and their significance; that I am legally competent to execute this Agreement; that I have not relied on any statements or explanations made by the Company, any agent of the Company or its counsel; that I knowingly and voluntarily assent to all the terms and conditions contained herein; and that I am signing this General Release voluntarily and of my own free will.

**6. Effective Date.** I further acknowledge that this General Release will not become effective until the eighth day following my execution of this General Release (the "Effective Date"), and that I may at any time prior to the Effective Date revoke this General Release by delivering written notice of revocation to the Company, at 777 Old Saw Mill River Road, Tarrytown, New York 10591-6707, to the attention of the [General Counsel]. In the event that I revoke this General Release prior to the eighth day after its execution, this General Release will automatically be null and void.

**7. Survival.** The provisions in the Employment Agreement which are intended to survive termination of employment shall survive and continue in full force and effect.

Acknowledged and Agreed:  
REGENERON PHARMACEUTICALS, INC.

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**EXHIBIT C**

**GOLDEN PARACHUTE PROVISION**

(a) (i) In the event that you shall become entitled to payments and/or benefits provided by this Agreement or any other amounts in the "nature of compensation" (whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement with the Company, any person whose actions result in a change of ownership or effective control covered by Section 280G(b)(2) of the Code or any person affiliated with the Company or such person) as a result of such change in ownership or effective control (collectively the "Company Payments"), and such Company Payments will be subject to the tax (the "Excise Tax") imposed by Section 4999 of the Code (and any similar tax that may hereafter be imposed by any taxing authority) the Company shall pay to you at the time specified in subsection (d) below (x) an additional amount (the "Gross-up Payment") such that the net amount retained by you, after deduction of any Excise Tax on the Company Payments and any U.S. federal, state, and for local income or payroll tax upon the Gross-up Payment provided for by this paragraph (a), but before deduction for any U.S. federal, state, and local income or payroll tax on the Company Payments, shall be equal to the Company Payments and (y) an amount equal to the product of any deductions disallowed for federal, state or local income tax purposes because of the inclusion of the Gross-Up Payment in your adjusted gross income multiplied by your actual applicable marginal rate of federal, state or local income taxation, respectively, for the calendar year in which the Gross-Up Payment is to be made.

(ii) Notwithstanding the foregoing, if it shall be determined that you are entitled to a Gross-Up Payment, but that if the Company Payments (other than that portion valued under Q&A 24(c) of the proposed regulations under Section 280G of the Code(the "Stock Vesting Value")) (the "Cash Payments") are reduced by

the amount necessary such that the receipt of the Company Payments would not give rise to any Excise Tax (the "Reduced Payment") and the Reduced Payment (other than the Stock Vesting Value) would not be less than 90% of the Cash Payment, then no Gross-Up Payment shall be made to you and the Cash Payments, in the aggregate, shall be reduced to the Reduced Payments (other than the Stock Vesting Value). If the Reduced Payments is to be effective, payments shall be reduced as mutually agreed between the Company and you or, in the event the parties cannot agree, in the following order (1) any lump sum severance based on a multiple of Base Salary or annual bonus, (2) any other cash amounts payable to you and (3) any benefits valued as parachute payments.

(iii) In the event that the Internal Revenue Service or court ultimately makes a determination that the excess parachute payments plus the base amount is an amount other than as determined initially, an appropriate adjustment shall be made with regard to the Gross-Up Payment or Reduced Payment, as applicable to reflect the final determination and the resulting impact on whether (ii) applies.

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(b) For purposes of determining whether any of the Company Payments and Gross-up Payments (collectively the "Total Payments") will be subject to the Excise Tax and the amount of such Excise Tax, (x) the Total Payments shall be treated as "parachute payments" within the meaning of Section 280G(b)(2) of the Code, and all "parachute payments" in excess of the "base amount" (as defined under Section 280G(b)(3) of the Code) shall be treated as subject to the Excise Tax, unless and except to the extent that, in the opinion, delivered to the Company and you at a level of more likely than not, of the Company's independent certified public accountants appointed prior to any change in ownership (as defined under Section 280G(b)(2) of the Code) or tax counsel selected by such accountants (the "Accountants") such Total Payments (in whole or in part) either do not constitute "parachute payments," represent reasonable compensation for services actually rendered within the meaning of Section 280G(b)(4) of the Code in excess of the "base amount" or are otherwise not subject to the Excise Tax, and (y) the value of any non-cash benefits or any deferred payment or benefit shall be determined by the Accountants in accordance with the principles of Section 280G of the Code. In the event that the Accountants are serving (or decline to serve) as accountant or auditor for the individual, entity or group effecting the Change of Control, you may appoint another nationally recognized accounting firm or law firm to make the determinations hereunder (which accounting firm or law firm shall then be referred to as the "Accountants" hereunder). All determinations hereunder shall be made by the Accountants which shall provide detailed supporting calculations both to the Company and you at such time as it is requested by the Company or you. If the Accountants determine that payments under this Agreement must be reduced pursuant to this paragraph, they shall furnish you with a written opinion to such effect. The determination of the Accountants shall be final and binding upon the Company and you, subject to the other provisions herein.

(c) For purposes of determining the amount of the Gross-up Payment, you shall be deemed to pay U.S. federal income taxes at actual rate of U.S. federal income taxation in the calendar year in which the Gross-up Payment is to be made and state and local income taxes at the rate of taxation in the state and locality of your residence for the calendar year in which the Company Payment is to be made, net of the reduction in U.S. federal income taxes which could be obtained from deduction of such state and local taxes if paid in such year. In the event that the Excise Tax is subsequently determined by the Accountants to be less than the amount taken into account hereunder at the time the Gross-up Payment is made, you shall repay to the Company, at the time that the amount of such reduction in Excise Tax is finally determined, the portion of the prior Gross-up Payment attributable to such reduction (plus the portion of the Gross-up Payment attributable to the Excise Tax and U.S. federal, state and local income tax imposed on the portion of the Gross-up Payment being repaid by you if such repayment results in a reduction in Excise Tax or a U.S. federal, state and local income tax deduction), plus interest on the amount of such repayment at the rate provided in Section 1274(b)(2)(B) of the Code. Notwithstanding the foregoing, in the event any portion of the Gross-up Payment to be refunded to the Company has been paid to any U.S. federal, state and local tax authority, repayment thereof (and related amounts) shall not be required until actual refund or credit of such portion has been made to you, and interest payable to the Company shall not exceed the interest received or credited to you by such tax authority for the period it held such portion. Furthermore, to the extent the foregoing provision shall be deemed to create a loan of a personal nature in violation of Section 402 of the Sarbanes-Oxley Act of 2002, the provision for repayment shall be null and void. You and the Company shall mutually agree upon the course of action to be pursued (and the method of allocating the expense thereof) if your claim for refund or credit is denied.

In the event that the Excise Tax is later determined by the Accountant or the Internal Revenue Service to exceed the amount taken into account hereunder at the time the Gross-up Payment is made (including by reason of any payment the existence or amount of which cannot be determined at the time of the Gross-up Payment), the Company shall make an additional Gross-up Payment in respect of such excess (plus any interest or penalties payable with respect to such excess) at the time that the amount of such excess is finally determined.

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(d) The Gross-up Payment or portion thereof provided for in subsection (c) above shall be paid not later than the thirtieth (30th) day following an event occurring which subjects you to the Excise Tax; provided, however, that if the amount of such Gross-up Payment or portion thereof cannot be finally determined on or before such day, the Company shall pay to you on such day an estimate, as determined in good faith by the Accountant, of the minimum amount of such payments and shall pay the remainder of such payments (together with interest at the rate provided in Section 1274(b)(2)(B) of the Code), subject to further payments pursuant to subsection (c) hereof, as soon as the amount thereof can reasonably be determined, but in no event later than the ninetieth day after the occurrence of the event subjecting you to the Excise Tax. In the event that the amount of the estimated payments exceeds the amount subsequently determined to have been due, such excess shall constitute a loan by the Company to you, payable on the fifth day after demand by the Company (together with interest at the rate provided in Section 1274(b)(2)(B) of the Code), provided that, to the extent the foregoing provision shall be deemed to create a loan of a personal nature in violation of Section 402 of the Sarbanes-Oxley Act of 2002, the provision for repayment shall be null and void.

(e) In the event of any controversy with the Internal Revenue Service (or other taxing authority) with regard to the Excise Tax, you shall permit the Company to control issues related to the Excise Tax (at its expense), provided that such issues do not potentially materially adversely affect you, but you shall control any other issues. In the event the issues are interrelated, you and the Company shall in good faith cooperate so as not to jeopardize resolution of either issue, but if the parties cannot agree you shall make the final determination with regard to the issues. In the event of any conference with any taxing authority as to the Excise Tax or associated income taxes, you shall permit the representative of the Company to accompany you, and you and your representative shall cooperate with the Company and its representative.

(f) The Company shall be responsible for all charges of the Accountant.

(g) The Company and you shall promptly deliver to each other copies of any written communications, and summaries of any verbal communications, with any taxing authority regarding the Excise Tax covered by this Exhibit C.

(h) Any Gross-Up Payments hereunder shall be paid in the time and manner set forth in Section 14(o)(i) and (ii) of the Agreement.

**REGENERON PHARMACEUTICALS, INC.**

**CHANGE IN CONTROL SEVERANCE PLAN**

**As amended and restated, effective November 14, 2008**

**INTRODUCTION**

The purposes of this Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan (this “Plan”) are (i) to help the Company (as defined below) retain key employees of the Company, (ii) to help maintain the focus of such employees on the business of the Company and to mitigate the distractions caused by the possibility that the Company may be the target of an acquisition; and (iii) to provide certain benefits to such employees in the event their employment is terminated (or constructively terminated) after, or in contemplation of, a change in control. The possibility of such terminations and the uncertainty it creates may result in the loss or distraction of key employees of the Company to the detriment of the Company and its shareholders.

The Company’s Board of Directors (the “Board”) considers the retention of key employees and the avoidance of such loss and distraction to be essential to protecting and enhancing the best interests of the Company and its shareholders. The Board also believes that when a change in control is perceived as imminent, or is occurring, the Board should be able to receive and rely on disinterested service from employees regarding the best interests of the Company and its shareholders without concern that employees might be distracted or concerned by the personal uncertainties and risks created by a change in control.

Accordingly, in order to accomplish the above purposes, the Board has caused the Company to adopt this Plan, as amended and restated effective November 14, 2008 (the “Effective Date”).

1. Definitions. For the purpose of this Plan the foregoing terms shall have the following meanings:

(a) “Anticipatory Termination” means a termination of an Eligible Executive’s employment by the Company without Cause or by an Eligible Executive for Good Reason that occurs after a tender offer is announced for the Company or after material discussions have occurred with a possible acquirer with regard to a Transaction (as defined in the definition of “Change in Control” below), provided, that such offer or discussions have not terminated.

(b) “Average Bonus” shall mean the average amount in each of the Company’s last three (3) completed fiscal years prior to the termination of employment (or if higher the last three (3) completed fiscal years prior to the Change in Control) awarded to an Eligible Executive as an annual bonus for such years (or if not employed on the last day of three prior completed fiscal years, the average over those fiscal years when employed on the last day of a fiscal year or, if no such dates, the average of the Average Bonus of all Eligible Executives in the Eligible Executive’s Group; provided, that any bonus awarded to an Eligible Executive for a fiscal year during which he or she was employed for only a portion of the year shall be annualized to reflect a full year’s bonus for such year).

(c) “Bonus” shall mean the product of (i) the Eligible Executive’s annual base salary rate for the year in which the Date of Termination occurs (which is calculated immediately prior to any reduction in base salary (if any) if such termination is by the Eligible Executive for Good Reason) multiplied by (ii) the average of the percentages that bonuses represented of base salary for the fiscal years utilized to determine Average Bonus.

(d) “Cause” shall mean, as to each Eligible Executive, (i) the Eligible Executive’s willful misconduct involving the Company or its assets, business or employees or in the performance of his or her duties which is materially injurious to the Company (in a manner which would affect the Company economically or as to its reputation); (ii) the Eligible Executive’s indictment for, or conviction of, or pleading guilty or nolo contendere to, a felony (provided that for this purpose, a felony shall cover any action or inaction that is a felony or crime under federal, state or local law in the United States (collectively, “U.S. law”) and any action or inaction which takes place outside of the United States, if it would be a felony under U.S. law); (iii) the Eligible Executive’s continued and substantial failure to attempt in good faith to perform his or her duties with the Company (other than failure resulting from the Eligible Executive’s incapacity due to physical or mental illness or injury), which failure has continued for a period of at least ten (10) days after written notice thereof from the Company; (iv) the Eligible Executive’s breach of any material provisions of any written agreement with the Company, which breach, if curable, is not cured within ten (10) days after written notice thereof from the Company; or (v) the Eligible Executive’s failure to attempt in good faith to promptly follow a written direction of the Board or a more senior officer, provided that the failure shall not be considered “Cause” if the Eligible Executive, in good faith, believes that such direction, or implementation thereof, is illegal or inconsistent with the Company’s Code of Conduct and he or she promptly so notifies the Chairman of the Board in writing. No act or failure to act by an Eligible Executive shall be deemed to be “willful” if the Eligible Executive believed in good faith that such action or non-action was in, or not opposed to, the best interests of the Company.

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(e) A “Change in Control” shall mean the occurrence of any of the following events: (i) any “Person” (as defined in Section 3(a)(9) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as modified and used in Sections 13(d) and 14(d) thereof, except that such term shall not include (1) the Company, (2) a trustee or other fiduciary holding securities under an employee benefit plan of the Company, (3) an underwriter temporarily holding securities pursuant to an offering of such securities, or (4) a corporation owned, directly or indirectly, by the shareholders of the Company in substantially the same proportions as their ownership of stock of the Company) is or becomes the “Beneficial Owner” (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing thirty-five percent (35%) or more of the Company’s then outstanding securities, excluding any Person who is an officer or director of the Company or who becomes such a Beneficial Owner in connection with a transaction described in clause (A) of subsection (iii) below; (ii) the following individuals cease for any reason to constitute a majority of the number of directors then serving: individuals who, on the Effective Date, constitute the Board and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including but not limited to a consent solicitation, relating to the election of directors of the Company) whose appointment or election by the Board or nomination for election by the Company’s shareholders was approved or recommended by a vote of at least two-thirds (2/3) of the directors then still in office who either were directors on the Effective Date or whose appointment, election or nomination for election was previously so approved or recommended; (iii) there is consummated a merger or consolidation of the Company with any other corporation other than (A) a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) at least sixty percent (60%) of the combined voting power of the voting securities of the Company or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no Person is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company representing thirty-five percent (35%) or more of the combined voting power of the Company’s then outstanding securities; or (iv) the shareholders of the Company approve a plan of complete liquidation or dissolution of the Company or there is consummated an agreement for the sale or



disposition by the Company of all or substantially all of the Company's assets, other than a sale or disposition by the Company of all or substantially all of the Company's assets to an entity at least seventy-five percent (75%) of the combined voting power of the voting securities of which are owned by Persons in substantially the same proportions as their ownership of the Company immediately prior to such sale; subsections (iii) and (iv) above each a "Transaction". For the avoidance of doubt, the term "securities" shall refer solely to the Company's Common Stock, par value \$.001 per share and Class A Stock, par value \$.001 per share.

(f) "Code" shall mean the Internal Revenue Code of 1986, as amended.

(g) "Committee" shall mean the Compensation Committee of the Board.

(h) "Company" shall mean Regeneron Pharmaceuticals, Inc. and any successor thereto; provided, that for the purposes of this Plan, other than any obligation to make payments or provide benefits hereunder and as to the definition of Change in Control, "Company" shall also include all of the Company's subsidiaries (as defined in Code Section 424(f)).

(i) "Disability" shall mean, as to each Eligible Executive, the Eligible Executive's failure to have performed his or her material duties and responsibilities as a result of physical or mental illness or injury for more than one hundred eighty (180) days during a three hundred sixty-five (365) day period.

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(j) "Eligible Executives" shall mean Group 1 Executives and Group 2 Executives.

(k) "Equity Grant" shall mean any stock option, restricted stock award, or other equity grant under the Company's long-term incentive plans.

(l) "Good Reason" shall mean, as to each Eligible Executive, a termination (including, if applicable, by retirement in accordance with Company policy) by the Eligible Executive and effected by a written notice given within ninety (90) days after the occurrence of the Good Reason event. For purposes of this Agreement, "Good Reason" shall mean, as to each Eligible Executive, the occurrence of any of the following events without the Eligible Executive's express written consent which event is not cured within thirty (30) days after written notice thereof from the Eligible Executive to the Company: (i) any material diminution in the Eligible Executive's position, duties, responsibilities, title or authority, or the assignment to the Eligible Executive of duties and responsibilities materially inconsistent with his or her position, except in connection with the Eligible Executive's termination for Cause or as a result of death, or temporarily as a result of the Eligible Executive's incapacity or other absence for an extended period; (ii) any material breach by the Company of any material provision of any written agreement with the Eligible Executive or failure to timely pay any compensation obligation to the Eligible Executive; (iii) a reduction in the Eligible Executive's annual base salary or target bonus opportunity (if any); (iv) a relocation of the Eligible Executive's principal business location to an area outside of a fifty (50) mile radius of the Eligible Executive's current principal business location or (v) a failure by the Company to comply with this Plan.

(m) "Group 1 Executive" shall mean an officer or other executive who has been designated by the Committee as a Group 1 Executive in accordance with Section 2 below.

(n) "Group 2 Executive" shall mean an officer or other executive who has been designated by the Committee as a Group 2 Executive in accordance with Section 2 below.

(o) "Severance Multiplier" shall mean one for Group 1 Executives and two for Group 2 Executives.

(p) A termination "without Cause" shall mean a termination of an Eligible Executive's employment by the Company other than for a termination for Cause or due to Disability.

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2. Eligible Executives. Eligible Executives shall consist of those officers and other executives of the Company as the Committee in its sole discretion designates in writing to participate in the Plan. At the time the Committee designates an employee as an Eligible Executive, the Committee shall also designate whether such Eligible Executive is a Group 1 Executive or a Group 2 Executive. The Committee may, in its sole discretion, terminate an employee's participation in the Plan as an Eligible Executive by providing not less than one (1) year's prior written notice to the employee (a "Plan Participation Termination Notice") at any time following the two (2) year anniversary of the Effective Date; provided, that no Plan Participation Termination Notice shall be effective after a Change in Control (whether sent before or after). The Committee may designate additional Eligible Executives or change the designation of any Group 1 Executive to a Group 2 Executive at any time in its sole discretion.

3. Termination of Employment in Connection with a Change in Control. Subject to the provisions of Section 24 hereof:

(a) If (i) a Change in Control occurs and an Eligible Executive's employment with the Company is terminated by the Company without Cause or by the Eligible Executive for Good Reason at any time within two (2) years after the Change in Control or (ii) there was an Anticipatory Termination and the Change in Control has taken place within one hundred eighty (180) days thereafter, such Eligible Executive shall be entitled to the amounts provided in Section 4 upon such termination or, if an Anticipatory Termination, upon the Change in Control (less any severance benefits previously paid or provided by the Company).

(b) In the event of an Anticipatory Termination, if any Equity Grants in the name of the applicable Eligible Executive would vest as a result of the Anticipatory Termination had it occurred after the Change in Control (or the Equity Grant otherwise would have vested pursuant to its terms on or prior to the Change in Control if not for the Anticipatory Termination), any such Equity Grant that otherwise would be forfeited shall not be forfeited pending a determination of whether or not a Change in Control occurs within one hundred eighty (180) days thereafter (the "Determination Period"), but during the Determination Period no unvested Equity Grant shall vest or be exercisable and no dividends shall be payable unless and until the Change in Control takes place during the Determination Period. If a Change in Control occurs during the Determination Period, then the Equity Grants that would have vested during the Determination Period absent the Anticipatory Termination and any Equity Grants that would vest on the Change in Control or, upon a without Cause or Good Reason termination within two (2) years thereafter, shall become vested upon the Change in Control and the exercise period of all Equity Grants that are subject to exercise conditions shall be extended, to the extent applicable, to the later of (i) the permitted exercise dates after the Anticipatory Termination provided in the plan or grant assuming the Change in Control had happened immediately prior to the Anticipatory Termination and (ii) the date which is thirty (30) days

following the first date after such Change in Control in which shares of the Company could be traded by the Eligible Executive on the applicable market under the Company's or its subsidiary's trading window policies but, (x) not beyond the last day of extension permitted under Code Section 409A without such Equity Grant being deemed subject to the additional tax under Code Section 409A, and (y) in no event beyond the initial expiration date of the grant. In the event an Equity Grant would expire after an Anticipatory Termination and prior to it becoming exercisable (including as a result of a Change in Control) as a result of either (x) or (y) of the forgoing sentence, it may be exercised during the thirty (30) day period prior to its expiration (or, if in connection with a Change in Control, such other period (whether shorter or longer) that applies to other similar Equity Grants) but the transaction shall be held in escrow pending a determination of whether a Change in Control has taken place during the one hundred eighty (180) day period after termination of the Eligible Executive's employment.

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4. Compensation on Change in Control Termination. (a) If, pursuant to Section 3, an Eligible Executive is entitled to amounts and benefits under this Section 4, such Eligible Executive shall receive the following payments and benefits from the Company:

(i) (A) any base salary, bonus, paid time off or other compensation accrued or earned under law or in accordance with the Company's policies and practices applicable to the Eligible Executive but not yet paid; (B) subject to submission of appropriate documentation, any incurred but unreimbursed business expenses for the period prior to the Eligible Executive's termination payable in accordance with the Company's policies and practices; and (C) any other amounts or vested benefits due under the then applicable employee benefit (including without limitation any Supplemental Executive Retirement Plan), equity or incentive plans of the Company then in effect, applicable to the Eligible Executive (including, without limitation, the Company's 401(k) Savings Plan) as shall be determined and paid in accordance with such plans;

(ii) subject to Section 4(b) and Section 8 hereof, within ten (10) days after the satisfaction of the requirements of Section 8 hereof (or, if such termination occurred prior to a Change in Control, within ten (10) days after the latter of the aforesaid date or the Change in Control), a lump sum payment equal to the product of (A) the Severance Multiplier times (B) the sum of (x) the Eligible Executive's annual base salary rate (which is calculated immediately prior to any reduction in base salary (if any) if such termination is by the Eligible Executive for Good Reason) and (y) the Eligible Executive's Average Bonus;

(iii) subject to Section 4(b) and Section 8 hereof, within ten (10) days after the satisfaction of the requirements of Section 8 hereof (or, if such termination occurred prior to a Change in Control, within ten (10) days after the latter of the aforesaid date or the Change in Control), a pro rata Bonus payment for the year in which the Eligible Executive is terminated based on the portion of the year the Eligible Executive was employed;

(iv) to the extent not paid pursuant to Section 4(a)(i)(A) above, any earned but unpaid bonus for a previously completed fiscal year of the Company; provided that such bonus shall be paid to the Eligible Executive in the year following the completed fiscal year of the Company when other executives of the Company receive their bonuses (but not later than 2 ½ months following the completion of such fiscal year);

(v) subject to Section 4(b) and Section 8 hereof, continued coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), or otherwise, under the Company health plans in which the Eligible Executive and his/her dependents participated immediately prior to the Eligible Executive's Date of Termination, or materially equivalent plans thereto (the "Health Plans"), for the Eligible Executive and the Eligible Executive's dependents until the earlier of (A) (x) one (1) year following the Date of Termination applicable to the Eligible Executive if the Eligible Executive is a Group 1 Executive, or (y) eighteen (18) months following the Date of Termination applicable to the Eligible Executive if the Eligible Executive is a Group 2 Executive, and (B) the Eligible Executive's becoming eligible to participate in the health plan of another employer; provided, that the Eligible Executive timely elects such coverage and pays the same premium amount for such coverage as the Eligible Executive would pay if an active employee immediately prior to the Change in Control (the "Existing Premium Amount"); and further provided that such coverage shall cease to the extent that the providing of such coverage would violate applicable law. Furthermore, to the extent that the applicable coverage period in this Section 4(a)(v) can not be provided under the Company's policies or, if the providing of such coverage would result in taxation of the benefits under Code Section 105(h) (or a successor provision), the Company shall make payments to the Eligible Executive of the premiums it had been paying for such coverage for the Eligible Executive (but on a fully taxed grossed-up basis). In addition, if a Group 2 Executive has not become eligible to participate in the health plan of another employer by the date immediately following the expiration of the eighteen (18) month period referred to in the preceding sentence, the Company shall make a monthly payment to the Eligible Executive of the monthly premium it had been paying for such coverage for the Eligible Executive (but on a fully taxed grossed-up basis) for up to a maximum of six (6) months following the expiration of such eighteen (18) month period (or, if earlier, until the Eligible Executive becomes eligible to participate in the health plan of another employer).

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(vi) subject to Section 4(b) and Section 8 hereof, continued coverage (at Company expense to the same extent as payments were made by the Company while the Eligible Executive was an active employee) in all welfare benefit plans (other than those covered by (v) above) and financial/tax advisory and preparatory services that the Eligible Executive participated in prior to his/her Date of Termination for (x) one (1) year following the Date of Termination applicable to the Eligible Executive if the Eligible Executive is a Group 1 Executive, or (y) two (2) years following the Date of Termination applicable to the Eligible Executive if the Eligible Executive is a Group 2 Executive. All such coverage shall be provided in a manner such that it either (i) does not provide for a "deferral of compensation" within the meaning of Code Section 409A or (ii) complies with the requirements of Code Section 409A. Payment to an Eligible Executive of a lump sum amount equal to the premium payable for such coverage shall only be permitted if such payment may be made without violating the requirements of Code Section 409A.

(b) Severance payments and benefits pursuant to Section 4(a)(ii), (iii) or (iv) hereof are intended to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b)(4). Nevertheless, if the Company determines in good faith that any payment provided under such sections or otherwise under Section 4(a) would cause a violation of Code Section 409A if paid within the first six (6) months after termination of an Eligible Executive's employment, such amount(s) shall not be paid to such Eligible Executive during such six (6) month period but shall instead be paid or provided to such Eligible Executive immediately after the end of such six (6) month period, in a lump sum (without interest). Thereafter, payments to such Eligible Executive shall be made in accordance with the Company's normal payroll practices. In the event that continuation of any benefit would in the good faith judgment of the Company cause a violation of Code Section 409A if provided at Company cost during the first six (6) months after the Date of Termination of an Eligible Executive, if the Eligible Executive wants such benefit continuation, he/she shall pay to the Company the full cost therefor during such six (6) month period and the Company shall reimburse him/her for such cost in a lump sum payment immediately after the end of such six (6) month period.

5. Excise Tax. In the event that an Eligible Executive shall become entitled to payments and/or benefits provided by this Plan or any other amounts in the "nature of compensation" (whether pursuant to the terms of this Plan or any other plan, arrangement or agreement with the Company, including, without

limitation, an award agreement under an equity compensation plan, any Person whose actions result in a change of ownership or effective control covered by Section 280G(b)(2) of the Code or any person affiliated with the Company or such person) as a result of a Change in Control (collectively the “Company Payments”), and if such Company Payments will be subject to the tax (the “Excise Tax”) imposed by Section 4999 of the Code (and any similar tax that may hereafter be imposed by any taxing authority) the amounts of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Eligible Executive to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Eligible Executive (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Eligible Executive minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. The Eligible Executive may elect which payments and benefits shall be reduced to accomplish the foregoing, but, if the Eligible Executive does not make such an election, the first benefit to be reduced is acceleration of vesting of any stock option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur, and the second benefit to be reduced shall be any cash payments under this Plan.

(a) For purposes of determining whether any of the Company Payments will be subject to the Excise Tax and the amount of such Excise Tax, (x) the Company Payments shall be treated as “parachute payments” within the meaning of Section 280G(b)(2) of the Code, and all “parachute payments” in excess of the “base amount” (as defined under Code Section 280G(b)(3) of the Code) shall be treated as subject to the Excise Tax, unless and except to the extent that, in the opinion of the Company’s independent certified public accountants appointed prior to any change in ownership (as defined under Code Section 280G(b)(2)) or tax counsel selected by such accountants (the “Accountants”) such Company Payments (in whole or in part) either do not constitute “parachute payments,” including giving effect to the recalculation of stock options in accordance with Treasury Regulation Section 1.280G-1 Q/A33, represent reasonable compensation for services actually rendered within the meaning of Section 280G(b)(4) of the Code in excess of the “base amount” or are otherwise not subject to the Excise Tax, and (y) the value of any non-cash benefits or any deferred payment or benefit shall be determined by the Accountants in accordance with the principles of Section 280G of the Code. To the extent permitted under Revenue Procedure 2003-68, the value determination shall be recalculated to the extent it would be beneficial to the Eligible Executive, at the request of the Eligible Executive.

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(b) For purposes of making the calculation hereunder, the Eligible Executive shall be deemed to pay U.S. federal income taxes at the highest marginal rate of U.S. federal income taxation in effect in the calendar year in which the Company Payments are to be made and state and local income taxes at the highest marginal rate of taxation in the state and locality of the Eligible Executive’s residence in effect for the calendar year in which the Company Payments are to be made, net of the maximum reduction in U.S. federal income taxes which could be obtained from deduction of such state and local taxes if paid in such year.

(c) In the event of any controversy with the Internal Revenue Service (or other taxing authority) with regard to the Excise Tax, the Eligible Executive shall permit the Company to control issues related to the Excise Tax (at its expense), provided that such issues do not potentially materially adversely affect the Eligible Executive, but the Eligible Executive shall control any other issues. In the event the issues are interrelated, the Eligible Executive and the Company shall in good faith cooperate so as not to jeopardize resolution of either issue, but if the parties cannot agree the Eligible Executive shall make the final determination with regard to the issues. In the event of any conference with any taxing authority as to the Excise Tax or associated income taxes, the Eligible Executive shall permit the representative of the Company to accompany the Eligible Executive, and the Eligible Executive and the Eligible Executive’s representative shall cooperate with the Company and its representative.

(d) The Company shall be responsible for all charges of the Accountants.

(e) The Company and the Eligible Executive shall promptly deliver to each other copies of any written communications, and summaries of any verbal communications, with any taxing authority regarding the Excise Tax.

6. Notice of Termination. After a Change in Control, any purported termination of an Eligible Executive’s employment (other than by reason of death) shall be communicated by written Notice of Termination from the Company to the Eligible Executive or from the Eligible Executive to the Company, as the case may be, in accordance with Section 19. For purposes of this Plan, a “Notice of Termination” shall mean a notice which shall set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of an Eligible Executive’s employment. Further, a Notice of Termination for Cause after a Change in Control is required to include a copy of a resolution duly adopted by the affirmative vote of not less than two-thirds (2/3) of the entire membership of the Board (at a meeting of the Board which was called and held for the purpose of considering such termination and at which the Eligible Executive had the right to attend and speak) finding that, in the good faith opinion of the Board, the Eligible Executive has engaged in conduct set forth in the definition of Cause herein, and specifying the particulars thereof in detail.

7. Date of Termination. “Date of Termination,” with respect to any purported termination of an Eligible Executive’s employment after a Change in Control, shall mean the date specified in the Notice of Termination (or, in the case of a termination by the Company, if no date is specified, the date which is ten (10) days from the date of such Notice of Termination) and, in the case of a termination by an Eligible Executive for Good Reason, shall be thirty (30) days from the date such Notice of Termination is given.

8. Acceptance and Release. Any and all amounts payable and benefits or additional rights provided pursuant to Sections 4(a)(ii), (iii), (v) and (vi) above shall only be payable if the Eligible Executive executes and delivers to the Company within forty five (45) days following the Date of Termination an Acceptance Form and Release in the form attached hereto as Appendix B discharging all claims of the Eligible Executive which may have occurred up to the Date of Termination applicable to the Eligible Executive (with such changes therein as may be necessary to make it valid and encompassing under applicable law). Notwithstanding anything herein to the contrary, if an Eligible Executive materially breaches any of the provisions of Section 10 of this Plan, the Company may cease all payments and benefits due to such Eligible Executive thereafter under Sections 4(a)(ii), (iii), (v) and (vi) above (other than as required by law).

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9. No Duty to Mitigate/Set-off. The Company agrees that the Eligible Executive shall not be required to seek other employment or to attempt in any way to reduce any amounts payable to the Eligible Executive by the Company pursuant to this Plan. Further, other than as set forth in Section 4(a)(v)(B), the amount of any payment or benefit provided for in this Plan shall not be reduced by any compensation earned by an Eligible Executive or benefit provided to an Eligible Executive as the result of employment by another employer, unemployment insurance payments or otherwise. Except as otherwise provided herein and apart from any disagreement between an Eligible Executive and the Company concerning interpretation of this Plan or any term or provision hereof, the Company’s obligations to make the payments provided for in this Plan and otherwise to perform its obligations hereunder shall not be affected by any circumstances, including without limitation, any set-off, counterclaim, recoupment, defense or other right which the Company may have against an Eligible Executive. The

amounts due under Section 4 are inclusive, and in lieu of, any amounts payable under any other salary continuation or cash severance arrangement of the Company and to the extent paid or provided under any other such arrangement shall be offset against the amount due hereunder.

10. Confidentiality, Non-Solicitation and Cooperation.

(a) In consideration of participating in this Plan, by the execution and delivery to the Committee of an Acknowledgement and Agreement to Restrictive Covenants set forth on Appendix A attached hereto, if the Eligible Executive is employed by the Company at the time of a Change in Control or has been terminated in an Anticipatory Termination within one hundred eighty (180) days prior thereto, each Eligible Executive agrees to the following agreements:

(i) during the Eligible Executive's employment with the Company and thereafter, the Eligible Executive agrees not to, directly or indirectly, for any reason whatsoever, communicate or disclose to any unauthorized person, firm or corporation, or use for the Eligible Executive's own account, without the prior written consent of the Board or the Chief Executive Officer of the Company (the "CEO"), any proprietary processes, trade secrets or other confidential data or information of the Company and its related and affiliated companies concerning their businesses or affairs, accounts, products, services or customers, it being understood, however, that the obligations of this Section 10(a) shall not apply to the extent that the aforesaid matters (i) are disclosed in circumstances in which the Eligible Executive is legally required to do so, provided that the Eligible Executive gives the Company prompt written notice of receipt of notice of any legal proceedings so as the Company has the opportunity to obtain a protective order, or (ii) become known to and available for use by the public other than by the Eligible Executive's wrongful act or omission;

(ii) during the Eligible Executive's employment with the Company and thereafter, the Eligible Executive agrees to fully cooperate with the Company or its counsel in connection with any matter, investigation, proceeding or litigation regarding any matter in which the Eligible Executive was involved during the Eligible Executive's employment with the Company or to which the Eligible Executive has knowledge based on the Eligible Executive's employment with the Company; and

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(iii) during the Eligible Executive's employment with the Company and for the one (1) year period thereafter, if the Eligible Executive is receiving the amounts and benefits provided under Section 4, the Eligible Executive agrees that he or she will not individually or on behalf of any other person, firm, corporation or other entity (actions of such other person, firm, corporation or other entity not being attributable to the Eligible Executive unless he or she is personally involved therewith), solicit, induce, hire or retain any employee of the Company (or any person who had been such an employee in the prior three (3) months) to leave the employ of the Company and to accept employment or retention as an independent contractor with, or render services to or with any other person, firm, corporation or other entity unaffiliated with the Company or take any action to assist or aid any other person, firm, corporation or other entity in identifying, soliciting, hiring or retaining any such employee; provided, the Eligible Executive may serve as a reference after the Eligible Executive is no longer employed by the Company, but not with regard to any entity with which the Eligible Executive is affiliated or from which the Eligible Executive is receiving compensation and this provision shall not be violated by general advertising not specifically targeted at employees of the Company.

(b) Because the Company's remedies at law for a breach or threatened breach of any of the provisions of this Section 10 would be inadequate, in the event of such a breach or threatened breach by an Eligible Executive, in addition to any remedies at law, the Company shall be entitled to seek equitable relief in the form of specific performance, a temporary restraining order, a temporary or permanent injunction or any other equitable remedy which may then be available.

(c) If it is determined by a court of competent jurisdiction that any restriction in this Section 10 is excessive in duration or scope or is unreasonable or unenforceable, such restriction may be modified or amended by the court to render it enforceable to the maximum extent permitted.

(d) The agreements set forth in this Section 10 are in addition to any other activity limitations an Eligible Executive is subject to under any other agreement between the Eligible Executive and the Company or any other plan or arrangement of the Company applicable to the Eligible Executive.

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11. Service with Subsidiaries. For purposes of this Plan, employment by a subsidiary or a parent of the Company shall be deemed to be employment by the Company and references to the Company shall include all such entities, except that the payment obligation hereunder shall be solely that of the Company. A Change in Control, however, as used in this Plan, shall refer only to a Change in Control of the Company.

12. Liability Insurance; Indemnification.

If an Eligible Executive is receiving the payments and benefits under Section 4, then:

(a) the Company shall continue to cover such Eligible Executive, or cause the Eligible Executive to be covered, under any director and officer insurance maintained after the Change in Control for directors and officers of the Company (whether by the Company or another entity) at the highest level so maintained for any other past or active director or officer with regard to any action or omission of the Eligible Executive while an officer or director of the Company. Such coverage shall continue for any period during which the Eligible Executive may have any liability for the aforesaid actions or omissions; and

(b) following a Change in Control, the Company shall, with regard to matters related to such Eligible Executive's period of employment with the Company, indemnify the Eligible Executive to the fullest extent permitted or authorized by the Company's bylaws against any claims, suits, judgments, expenses (including reasonable attorney fees), with advancement of legal fees and disbursements to the fullest extent permitted by law, arising from, out of, or in connection with the Eligible Executive's services as an officer or director of the Company, as an officer or director of any affiliate for which the Eligible Executive was required to serve as such by the Company or as a fiduciary of any benefit plan of the Company or any affiliate.

13. Funding. This Plan shall be funded out of the general assets of the Company as and when benefits are payable under this Plan. To the extent that any Eligible Executive acquires a right to receive payments under this Plan, such right shall not be secured by any assets of the Company or any of its affiliated companies. The Eligible Executives shall be general creditors of the Company. Any assignment, lien or other encumbrance by an Eligible Executive of the amounts and benefits provided under this Plan shall be null and void. If the Company decides in its sole discretion to establish any advance accrued reserve on its books against the future expense of benefits payable hereunder, or if the Company decides in its sole discretion to fund a trust under this Plan, such reserve or trust shall not under any circumstances be deemed to be an asset of this Plan.

#### 14. Administration of this Plan.

(a) The general administration of this Plan on behalf of the Company (as “Plan Administrator” under Section 3(16)(A) of the Employee Retirement Income Security Act of 1974, as amended (“ERISA”)) shall be placed with the Committee.

(b) The Company may, in its sole discretion, pay or reimburse the members of the Committee for all reasonable expenses incurred in connection with their duties hereunder.

(c) Decisions of the Committee shall be made by a majority of its members attending a meeting at which a quorum is present (which meeting may be held telephonically), or by written action in accordance with applicable law. Subject to the terms of this Plan and provided that the Committee acts in good faith, the Committee shall have complete authority to determine an Eligible Executive’s participation and benefits under this Plan, to interpret and construe, in its sole discretion, the provisions of this Plan, and to make decisions in all disputes involving the rights of any person interested in this Plan. All decisions by the Committee shall be made in the Committee’s sole discretion and shall be final and binding on all persons having or claiming any interest in this Plan. Notwithstanding the foregoing, all decisions of the Committee after a Change in Control shall be reviewable on a *de novo* basis by an arbitrator or court, as applicable.

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(d) The Committee may delegate any and all of its powers and responsibilities hereunder to other persons by formal resolution filed with and accepted by the Board. Any such delegation shall not be effective until it is accepted by the Board and the persons designated and may be rescinded at any time by written notice from the Committee to the person to whom the delegation is made.

(e) The Committee may employ such legal counsel, accountants and other persons as may be required in carrying out its work in connection with this Plan.

(f) The Committee shall maintain such accounts and records regarding the fiscal and other transactions of this Plan and such other data as may be required to carry out its functions under this Plan and to comply with all applicable laws.

(g) The Company shall be the Plan Administrator for the purposes of any applicable law and shall be responsible for the preparation and filing of any required returns, reports, statements or other filings with appropriate governmental agencies. The Company shall also be responsible for the preparation and delivery of information to persons entitled to such information under any applicable law.

(h) The Company shall indemnify, to the full extent permitted by law and its Certificate of Incorporation and By-laws (but only to the extent not directly covered by insurance) its officers and directors, (and any employee involved in carrying out the functions of the Company under this Plan), each member of the Committee, and any person designated pursuant to Section 14(d) above, against any expenses, including amounts paid in settlement of a liability, which are reasonably incurred in connection with any legal action to which such person is a party by reason of his or her duties or responsibilities with respect to this Plan, except with regard to matters as to which he or she shall be adjudged in such action to be liable for gross negligence, willful misconduct or fraud in the performance of his or her duties.

15. ERISA Provisions (Including Claims Procedures). This Plan is intended to be a “top hat” welfare benefit plan within the meaning of U.S. Department of Labor Regulation Section 2520.104-24. Administrative provisions about this Plan are contained in Appendix C hereto. This Plan document, including the Appendices hereto, shall constitute the Plan document and shall be distributed to Eligible Executives in this form.

16. Employee Benefit Plans. The amounts and benefits specified in Section 4 hereof shall not be paid to any Eligible Executive as an employee and no Eligible Executive shall be eligible to participate in employee benefit plans maintained by the Company following the Date of Termination applicable to such Eligible Executive except as specifically provided herein or in such benefit plan(s). Amounts paid pursuant to Section 4 shall not be taken into account for purposes of determining contributions to or calculating accrued benefits under the employee benefit plans maintained by the Company, except for accrued amounts that would be so taken into account pursuant to the terms of the applicable plan.

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17. Successors; Binding Agreement. In addition to any obligations imposed by law upon any successor to the Company, the Company will require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company to expressly assume and agree in writing to be obligated to make the payments and provide the benefits under this Plan in the same manner and to the same extent that the Company would have been obligated under this Plan if no such succession had taken place. This Plan shall inure to the benefit of and be enforceable by each Eligible Executive’s personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. If an Eligible Executive shall die while any amount would still be payable to such Eligible Executive hereunder, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Plan to the executors, personal representatives or administrators of such Eligible Executive’s estate as if the Eligible Executive had continued to live. No rights or obligations hereunder may be assigned by an Eligible Executive.

18. Amendment and Termination. This Plan shall continue until terminated by the Company in accordance with this Section 18, but the Plan shall cover only the first Change in Control occurring hereafter. The Company reserves the right to amend or terminate, in whole or in part, any or all of the provisions of this Plan by action of the Board or the Committee at any time and for any reason prior to a Change in Control, provided that in no event shall any amendment which reduces an Eligible Executive’s right to payment and/or benefits under this Plan or any termination of this Plan be effective as to any Eligible Executive then participating in this Plan prior to the one (1) year anniversary such amendment or Plan termination is adopted by the Board or the Committee, and provided further that no such amendment or termination that is not effective prior to a Change in Control shall be effective after a Change in Control.

19. Notices. Any notice or other communication required or permitted under this Plan shall be in writing and shall be delivered personally, or sent by registered mail, postage prepaid. Any such notice shall be deemed given when so delivered personally, or, if mailed, five (5) days after the date of deposit in the United States mails,

(i) If to the Company, to:

- (ii) If to an Eligible Executive, to his or her last shown address on the books of the Company.

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20. Separability. If any provisions of this Plan (including the appendices hereto) shall be declared to be invalid or unenforceable, in whole or in part, (by a court of competent jurisdiction) such invalidity or unenforceability shall not affect the validity of the remaining provisions of this Plan (including the appendices hereto).

21. Legal Fees.

(a) In the event the Company does not make the payments due hereunder on a timely basis (as determined by an arbitrator) and the matter is arbitrated pursuant to Section 22 below, if the Eligible Executive prevails in such arbitration, the Company shall pay all costs of such arbitration, including reasonable legal fees and other reasonable fees and expenses which the Eligible Executive may incur (on a tax grossed up basis, to the extent such amounts are taxable to the Eligible Executive).

(b) The Company shall pay to the Eligible Executive interest at the prime lending rate (as reported from time to time by The Wall Street Journal) on all or any part of any amount to be paid to Eligible Executive hereunder that is not paid when due. The prime rate for each calendar quarter shall be the prime rate in effect on the first day of the calendar quarter.

22. Arbitration. Any dispute or controversy arising under or in connection with this Plan shall be settled exclusively by arbitration conducted in the City of New York in the State of New York under the Commercial Arbitration Rules then prevailing of the American Arbitration Association and such submission shall request the American Arbitration Association to: (i) appoint an arbitrator experienced and knowledgeable concerning the matter then in dispute; (ii) require the testimony to be transcribed; (iii) require the award to be accompanied by findings of fact and the statement for reasons for the decision; and (iv) request the matter to be handled by and in accordance with the expedited procedures provided for in the Commercial Arbitration Rules. The determination of the arbitrators, which shall be based upon a de novo interpretation of this Plan, shall be final and binding and judgment may be entered on the arbitrators' award in any court having jurisdiction. The Company shall pay all costs of the American Arbitration Association and the arbitrator.

23. Withholding. The Company shall have the right to make such provisions as it deems necessary or appropriate to satisfy any obligations it reasonably believes it may have to withhold federal, state or local income or other taxes incurred by reason of payments pursuant to this Plan. In lieu thereof, the Company shall have the right to withhold the amounts of such taxes from any other sums due or to become due from the Company to an Eligible Executive upon such terms and conditions as the Committee may prescribe.

24. Code Section 409A. This Plan is intended to comply with the applicable requirements of Code Section 409A and shall be limited, construed, interpreted and administered in accordance with such intent. The Company reserves the right to amend the provisions of this Plan at any time in order to avoid the imposition of the additional tax under Code Section 409A on any payments to be made hereunder. The Company shall indemnify the Eligible Executives for any taxes, interest or penalties incurred under Code Section 409A as a result of any payments or benefits hereunder in such a manner that the Eligible Executive will have no after tax cost as a result thereof. Without limiting the generality of the foregoing:

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(a) For purposes of this Plan, the employment of Eligible Executives with the Company will not be treated as terminated unless and until such termination of employment constitutes a "separation from service" for purposes of Section 409A of the Code.

(b) The Acceptance Form and Release described in Section 8 hereof shall be provided to the Eligible Executive and shall be required to be executed by the Eligible Executive in a time period which will not result in severance payments made to the Eligible Executive hereunder failing to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b)(4). Severance payments pursuant to Section 4(a) hereof are intended to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b)(4).

(c) If the provisions of Section 3(b) are applicable to an equity or equity-based award subject to the provisions of Section 409A of the Code, payment of such awards shall be made, if provided for in Section 3(b), in a time period which will not result in such payments failing to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b)(4).

(d) To the extent necessary to comply with the provisions of Section 409A of the Code and the guidance issued thereunder (A) reimbursements or tax gross-up payments to an Eligible Executive pursuant to Section 4, Section 12, Section 21, this Section 24 or otherwise hereunder shall be made not later than the end of the calendar year following the year in which the reimbursable expense is incurred or tax subject to a gross-up provision is paid by the Eligible Executive, as applicable, and shall otherwise be made in a manner that complies with the requirements of Treasury Regulation Section 1.409A-3(i)(l)(iv).

25. Non-Exclusivity of Rights. Nothing in this Plan shall prevent or limit an Eligible Executive's continuing or future participation in any benefit, bonus, incentive, equity or other plan or program provided by the Company for which the Eligible Executive may qualify, nor shall anything herein (except Section 8) limit or otherwise prejudice such rights as the Eligible Executive may have under any other currently existing plan, agreement as to employment, or termination from employment with the Company or any other contractual or statutory entitlements. Amounts that are vested benefits or those which an Eligible Executive is otherwise entitled to receive under any other plan or program of the Company, at or subsequent to the Termination Date applicable to such Eligible Executive, shall be payable in accordance with such other plan or program, except as otherwise specifically provided herein. With the exception of the provisions in this Agreement regarding vesting and exercisability of Equity Grants following an Anticipatory Termination, nothing in this Plan will affect any term or provision of any stock option award between an Eligible Executive and the Company and the rights set forth in this Plan are in addition to, and not in lieu of, the terms of any such award agreements. Notwithstanding the foregoing, an Eligible Executive shall not be entitled to received duplicative severance payments and benefits and,

to the extent that an Eligible Executive is entitled to severance payments and benefits under any other plan or agreement, such Eligible Executive shall be entitled to the greater of the payments and benefits thereunder or hereunder but not under both plans or agreements.

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26. At Will Employment. This Plan does not constitute a contract of employment and, subject to any other agreement between an Eligible Executive and the Company, the Company reserves the right to terminate an Eligible Executive's employment at any time with or without reason or notice (unless otherwise prohibited by law), subject to the payment and other provisions hereof.

27. Governing Law. The construction, interpretation and administration of this Plan shall be governed by ERISA. To the extent not so governed, it shall be construed, interpreted, and governed in accordance with the laws of the State of New York without reference to rules relating to conflicts of law.

**IN WITNESS WHEREOF**, this amended and restated Plan has been adopted effective as of November 14, 2008, and Regeneron Pharmaceuticals, Inc. has caused this instrument to be signed by its officer or representative duly authorized on this 14<sup>th</sup> day of November 2008.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski

Name: Stuart Kolinski

Title: Senior Vice President & General Counsel

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### Appendix A

#### FORM OF

#### ACKNOWLEDGEMENT AND AGREEMENT TO RESTRICTIVE COVENANTS

The Compensation Committee  
Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591

Reference is hereby made to the Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, as amended and restated effective November 14, 2008 (the "Plan"). Any capitalized term used but not defined herein shall have the meaning ascribed to such term in the Plan.

In consideration of participation in the Plan as an Eligible Executive, the undersigned hereby acknowledges and agrees that if the undersigned is employed by the Company at the time of a Change in Control or has been terminated in an Anticipatory Termination within one hundred eighty (180) days prior thereto, the undersigned shall be bound by the restrictive covenants and agreements set forth in Section 10 of the Plan.

\_\_\_\_\_  
[Name of Eligible Executive]

Effective Date:

### Appendix B

#### ACCEPTANCE FORM AND RELEASE

#### Release

1. I agree and acknowledge that the payments and other benefits provided pursuant to the Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan ("Plan"), as amended and restated effective November 14, 2008 and my rights under any equity grant (i) are in full discharge of any and all liabilities and obligations of the Company to me, monetarily or with respect to employee benefits or otherwise, including but not limited to any and all obligations arising under any alleged written or oral employment agreement, policy, plan or procedure of the Company and/or any alleged understanding or arrangement between me and the Company; and (ii) exceed any payment, benefit, or other thing of value to which I might otherwise be entitled under any policy, plan or procedure of the Company and/or any agreement between me and the Company.

2. In consideration for the payments and benefits to be provided to me pursuant to the Plan, I forever release and discharge the Company from any and all claims. This includes claims that are not specified in this Acceptance Form and Release (this "Release"), claims of which I am not currently aware, claims under: (i) the Age Discrimination in Employment Act, as amended; (ii) Title VII of the Civil Rights Act of 1964, as amended; (iii) the Americans with Disabilities Act, as amended; (iv) the Employee Retirement Income Security Act of 1974, as amended (excluding claims for accrued, vested benefits under any employee benefit pension plan of the Company in accordance with the terms and conditions of such plan and applicable law); (v) the Workers' Adjustment and Retraining Notification Act; (vi) the Family and Medical Leave Act; (vii) any claim under the New York State Human Rights Law and the New York City Administrative Code; (viii) any other claim (whether based on federal, state, or local law, statutory or decisional) relating to or arising out of my employment, the terms and conditions of such employment, the separation of such employment, and/or any of the events relating directly or indirectly to or surrounding the separation of that employment, including, but not limited to, breach of contract (express or implied), wrongful discharge, detrimental reliance, defamation, emotional distress or compensatory or punitive damages; and (ix) any claim for attorneys' fees, costs, disbursements and/or the like. Notwithstanding anything herein to the contrary,

the sole matters to which this Release does not apply are (i) the rights of indemnification and directors and officers liability insurance coverage to which I was entitled immediately prior to my termination; (ii) my rights under any tax-qualified pension plan or claims for accrued vested benefits under any other employee benefit plan, policy or arrangement maintained by the Company or under the Consolidated Omnibus Budget Reconciliation Act of 1985; and (iii) my rights under the specific terms of any equity grant.

3. This Release applies to me and to anyone who succeeds to my rights, such as my heirs, executors, administrators of my estate, trustees, and assigns. This Release is for the benefit of (i) the Company, (ii) any related corporation or entity, (iii) any director, officer, employee, or agent of the Company or of any such related corporation or entity, or (iv) any person, corporation or entity who or that succeeds to the rights of the Company or of any such person, corporation or entity.

4. I acknowledge that I: (a) have carefully read in their entirety the Plan, this Release [and the information attached as Appendix I provided pursuant to the Older Workers Benefit Protection Act]; (b) have had an opportunity to consider fully for at least [twenty-one (21)] [forty-five (45)] days the terms of the Plan, this Release [and information attached as Appendix I]; (c) have been advised by the Company in writing to consult with an attorney of my choosing in connection with the Plan, this Release [and the information attached as Appendix I]; (d) fully understand the significance of all of the terms and conditions of the Plan, Release [and the information attached as Appendix I], and have discussed them with my independent legal counsel, or have had a reasonable opportunity to do so; (e) have had answered to my satisfaction any questions I have asked with regard to the meaning and significance of any of the provisions of the Plan, this Release [and the information attached as Appendix I]; and (f) am signing this Release voluntarily and of my own free will and assent to all the terms and conditions contained herein and contained in the Plan and the Release.

5. I understand that I will have [twenty-one (21)] [forty-five (45)] days from the date of receipt of this Release [and information attached as Appendix I] to consider the terms and conditions of those documents. I may execute and thereby accept this Release by signing and sending it to \_\_\_\_\_. After executing this Release and returning it to \_\_\_\_\_, I shall have seven (7) days (the "Revocation Period") to revoke this Release by indicating my desire to do so in writing delivered by no later than 5:00 p.m. on the seventh (7th) day following the date I sign and return this Release. The effective date of this Release shall be the eighth (8th) day following my signing and return of this Release. If the last day of the Revocation Period falls on a Saturday, Sunday or holiday, the last day of the Revocation Period will be deemed to be the next business day. In the event I do not accept this Release, or in the event I revoke this Release during the Revocation Period, my rights under the Plan, this Release, including but not limited to my rights to receive payments and other benefits from the Company, shall be deemed automatically null and void.

Print Name: \_\_\_\_\_  
Employee

Date: \_\_\_\_\_

Signature: \_\_\_\_\_  
Employee

STATE OF NEW YORK )  
 ) ss:  
COUNTY OF \_\_\_\_\_ )

On this \_\_\_ day of \_\_\_\_\_, before me personally came \_\_\_\_\_ to be known and known to me to be the person described and who executed the foregoing Release, and (s)he duly acknowledged to me that (s)he executed the same.

\_\_\_\_\_  
Notary Public

**ACCEPTANCE FORM AND RELEASE**

**Acceptance Form:**

I have read the Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, as amended and restated effective November 14, 2008 ("Plan") and the accompanying Release [and the information attached as Appendix I] and hereby accept the benefits provided under the Plan, subject to the terms and conditions set forth in the Plan and the Release.

Print Name: \_\_\_\_\_  
Employee

Date: \_\_\_\_\_

Signature: \_\_\_\_\_  
Employee

STATE OF NEW YORK )  
 ) ss:  
COUNTY OF \_\_\_\_\_ )



On this \_\_\_ day of \_\_\_\_\_, before me personally came \_\_\_\_\_ to be known and known to me to be the person described and who executed the foregoing Release, and (s)he duly acknowledged to me that (s)he executed the same.

\_\_\_\_\_  
Notary Public

## APPENDIX C

### PROVISIONS RELATING TO ERISA

#### A. Claims Procedure

1. Any claim by an Eligible Executive with respect to eligibility, participation, contributions, benefits or other aspects of the operation of the Plan shall be made in writing to a person designated by the Committee from time to time for such purpose. If the designated person receiving a claim believes, following consultation with the Chairman of the Committee, that the claim should be denied, he or she shall notify the Eligible Executive in writing of the denial of the claim within ninety (90) days after his or her receipt thereof. This period may be extended an additional ninety (90) days in special circumstances and, in such event, the Eligible Executive shall be notified in writing of the extension, the special circumstances requiring the extension of time and the date by which the Committee expects to make a determination with respect to the claim. If the extension is required due to the Eligible Executive's failure to submit information necessary to decide the claim, the period for making the determination will be tolled from the date on which the extension notice is sent until the date on which the Eligible Executive responds to the Plan's request for information.

2. If a claim is denied in whole or in part, or any adverse benefit determination is made with respect to the claim, the Eligible Executive will be provided with a written notice setting forth (a) the specific reason or reasons for the denial making reference to the pertinent provisions of the Plan or of Plan documents on which the denial is based, (b) a description of any additional material or information necessary to perfect or evaluate the claim, and explain why such material or information, if any, is necessary, and (c) inform the Eligible Executive of his or her right, pursuant to Paragraph A(1) of this Appendix, to request review of the decision. The notice shall also provide an explanation of the Plan's claims review procedure and the time limits applicable to such procedure, as well as a statement of the Eligible Executive's right to bring a civil action under Section 502(a) of ERISA following an adverse benefit determination on review. If an Eligible Executive is not notified (of the denial or an extension) within ninety (90) days from the date the Eligible Executive notifies the Plan Administrator, the Eligible Executive may request a review of the application as if the claim had been denied.

3. An Eligible Executive may appeal the denial of a claim by submitting a written request for review to the Committee, within sixty (60) days after written notification of denial is received. Such period may be extended by the Committee for good cause shown. The claim will then be reviewed by the Committee. In connection with this appeal, the Eligible Executive (or his or her duly authorized representative) may (a) be provided, upon written request and free of charge, with reasonable access to (and copies of) all documents, records, and other information relevant to the claim; and (b) submit to the Committee written comments, documents, records, and other information related to the claim. If the Committee deems it appropriate, it may hold a hearing as to a claim. If a hearing is held, the Eligible Executive shall be entitled to be represented by counsel.

4. The review by the Committee will take into account all comments, documents, records, and other information the Eligible Executive submits relating to the claim. The Committee will make a final written decision on a claim review, in most cases within sixty (60) days after receipt of a request for a review. In some cases, the claim may take more time to review, and an additional processing period of up to sixty (60) days may be required. If that happens, the Eligible Executive will receive a written notice of that fact, which will also indicate the special circumstances requiring the extension of time and the date by which the Committee expects to make a determination with respect to the claim. If the extension is required due to the Eligible Executive's failure to submit information necessary to decide the claim, the period for making the determination will be tolled from the date on which the extension notice is sent to the Eligible Executive until the date on which the Eligible Executive responds to the Plan's request for information.

5. The Committee decision on the claim for review will be communicated to the Eligible Executive in writing. If an adverse benefit determination is made with respect to the claim, the notice will include (a) the specific reason(s) for any adverse benefit determination, with references to the specific Plan provisions on which the determination is based; (b) a statement that the Eligible Executive is entitled to receive, upon request and free of charge, reasonable access to (and copies of) all documents, records and other information relevant to the claim; and (c) a statement of the Eligible Executive's right to bring a civil action under Section 502(a) of ERISA. An Eligible Executive may not start a lawsuit to obtain benefits until after he or she has requested a review and a final decision has been reached on review, or until the appropriate time frame described above has elapsed since the Eligible Executive filed a request for review and you have not received a final decision or notice that an extension will be necessary to reach a final decision. The law also permits the Eligible Executive to pursue his or her remedies under section 502(a) of ERISA without exhausting these appeal procedures if the Plan has failed to follow them.

#### B. Plan Interpretation and Benefit Determination

1. The Committee (or, where applicable, any duly authorized delegee of the Committee) shall have the exclusive right, power, and authority, in its sole and absolute discretion, to administer, apply and interpret the Plan and any other documents, and to decide all factual and legal matters arising in connection with the operation or administration of the Plan.

2. Without limiting the generality of the foregoing paragraph, the Committee (or, where applicable, any duly authorized delegee of the Committee) shall have the sole and absolute discretionary authority to:

(a) take all actions and make all decisions (including factual decisions) with respect to the eligibility for, and the amount of, benefits payable under the Plan;

(b) formulate, interpret and apply rules, regulations and policies necessary to administer the Plan;

(c) decide questions, including legal or factual questions, relating to the calculation and payment of benefits, and all other determinations made, under the Plan;

(d) resolve and/or clarify any factual or other ambiguities, inconsistencies and omissions arising under this Plan or other Plan documents; and

(e) process, and approve or deny, benefit claims and rule on any benefit exclusions.

All determinations made by the Committee (or, where applicable, any duly authorized delegee of the Committee) with respect to any matter arising under the Plan shall be final and binding on the Company, Eligible Executive, beneficiary, and all other parties affected thereby. Notwithstanding the foregoing, all decisions of the Committee after a Change in Control shall be reviewable on a *de novo* basis by an arbitrator or court, as applicable.

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**Regeneron Pharmaceuticals, Inc.**  
**Computation of Ratio of Earnings to Combined Fixed Charges**  
*(Dollars in thousands)*

	2004	2005	2006	2007	2008 (B)
<b>Earnings:</b>					
Income (loss) from continuing operations					
before income (loss) from equity investee	\$ 41,565	\$ (95,456)	\$ (103,150)	\$ (105,600)	\$ (82,710)
Fixed charges	14,060	13,687	13,643	13,708	\$ 11,261
Amortization of capitalized interest	78	78	73	23	20
Interest capitalized	-	-	-	-	-
<b>Adjusted earnings</b>	<b>\$ 55,703</b>	<b>\$ (81,691)</b>	<b>\$ (89,434)</b>	<b>\$ (91,869)</b>	<b>\$ (71,429)</b>
<b>Fixed charges:</b>					
Interest expense	\$ 12,175	\$ 12,046	\$ 12,043	\$ 12,043	\$ 7,752
Interest capitalized	-	-	-	-	-
Assumed interest component of rental charges	1,885	1,641	1,600	1,665	3,509
<b>Total fixed charges</b>	<b>\$ 14,060</b>	<b>\$ 13,687</b>	<b>\$ 13,643</b>	<b>\$ 13,708</b>	<b>\$ 11,261</b>
<b>Ratio of earnings to fixed charges</b>	<b>3.96</b>	<b>(A)</b>	<b>(A)</b>	<b>(A)</b>	<b>(A)</b>

(A) Due to the registrant's losses for the years ended December 31, 2005, 2006, 2007, and 2008 the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

(B) During the year ended December 31, 2008, the registrant repurchased \$82.5 million and repaid the remaining \$117.5 million of its convertible senior subordinate notes. As of December 31, 2008, the registrant therefore does not have any registered debt outstanding.

	2005	2006	2007	2008 (B)
Coverage deficiency	\$95,378	\$103,077	\$105,577	\$82,690

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-50480, 333-85330, 333-97176, 333-33891, 333-80663, 333-61132, 333-97375, 333-119257 and 333-151941) and on Form S-3 (No. 333-121225) of Regeneron Pharmaceuticals, Inc., of our report dated February 26, 2009 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers LLP

New York, New York  
February 26, 2009

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

I, Leonard S. Schleifer, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2009

By: /s/ LEONARD S. SCHLEIFER  
Leonard S. Schleifer, M.D., Ph.D.  
President and Chief Executive Officer

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

I, Murray A. Goldberg, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2009

By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg

Senior Vice President, Finance & Administration,

Chief Financial Officer, Treasurer, and Assistant

Secretary

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

In connection with the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ LEONARD S. SCHLEIFER

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Leonard S. Schleifer, M.D., Ph.D.

Chief Executive Officer

February 26, 2009

/s/ MURRAY A. GOLDBERG

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Murray A. Goldberg

Chief Financial Officer

February 26, 2009

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