



# **FORM 10-K**

## **REGENERON PHARMACEUTICALS INC - REGN**

**Filed: February 27, 2008 (period: December 31, 2007)**

Annual report which provides a comprehensive overview of the company for the past year

## PART I

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- [Item 1.](#) [Business](#)
- [Item 1A.](#) [Risk Factors](#)
- [Item 1B.](#) [Unresolved Staff Comments](#)
- [Item 2.](#) [Properties](#)
- [Item 3.](#) [Legal Proceedings](#)
- [Item 4.](#) [Submission of Matters to a Vote of Security Holders](#)

## PART II

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- [Item 5.](#) [Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of](#)
- [Item 6.](#) [Selected Financial Data](#)
- [Item 7.](#) [Management's Discussion and Analysis of Financial Condition and Results of Operations](#)
- [Item 7A.](#) [Quantitative and Qualitative Disclosure About Market Risk](#)
- [Item 8.](#) [Financial Statements and Supplementary Data](#)
- [Item 9.](#) [Changes in and Disagreements with Accountants on Accounting and Financial Disclosure](#)
- [Item 9A.](#) [Controls and Procedures](#)
- [Item 9B.](#) [Other Information](#)

## PART III

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- [Item 10.](#) [Directors and Executive Officers and Corporate Governance](#)
- [Item 11.](#) [Executive Compensation](#)
- [Item 12.](#) [Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters](#)
- [Item 13.](#) [Certain Relationships and Related Transactions, and Director Independence](#)
- [Item 14.](#) [Principal Accountant Fees and Services](#)

## PART IV

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- [Item 15.](#) [Exhibits and Financial Statement Schedules](#)

[SIGNATURE](#)

[INDEX TO FINANCIAL STATEMENTS](#)

[EXHIBIT INDEX](#)

[EX-3.1 \(EX-3.1: RESTATED CERTIFICATE OF INCORPORATION\)](#)

[EX-10.18 \(EX-10.18: DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT\)](#)

[EX-10.19 \(EX-10.19: LICENSE AND COLLABORATION AGREEMENT\)](#)

[EX-10.20 \(EX:10.20: STOCK PURCHASE AGREEMENT\)](#)

[EX-10.21 \(EX-10.21: INVESTOR AGREEMENT\)](#)

[EX-12.1 \(EX-12.1: STATEMENT RE: COMPUTATION OF RATIO OF EARNINGS TO  
COMBINED FIXED CHARGES\)](#)

[EX-23.1 \(EX-23.1: CONSENT OF PRICEWATERHOUSECOOPERS LLP\)](#)

[EX-31.1 \(EX-31.1: CERTIFICATION\)](#)

[EX-31.2 \(EX-31.2: CERTIFICATION\)](#)

[EX-32 \(EX-32: CERTIFICATION\)](#)

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
**Form 10-K**

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the fiscal year ended December 31, 2007
- OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

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: None**

**Securities registered pursuant to Section 12(g) 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 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. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$1,112,577,000 computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2007, 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 15, 2008:

<u>Class of Common Stock</u>	<u>Number of Shares</u>
Class A Stock, \$.001 par value	2,257,698
Common Stock, \$.001 par value	76,727,047

**DOCUMENTS INCORPORATED BY REFERENCE:**

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2007 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 59 to 61 of this filing.

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## PART I

### Item 1. *Business*

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

### **General**

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We currently have four clinical development programs, including three late-stage clinical programs: ARCALYST™(rilonacept; also known as IL-1Trap) in various inflammatory indications, aflibercept (VEGF Trap) in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. Aflibercept is being developed in oncology in collaboration with the sanofi-aventis Group. The VEGF Trap-Eye is being developed in collaboration with Bayer HealthCare LLC. Our fourth clinical development program is REGN88, an antibody to the Interleukin-6 receptor (IL-6R) that is being developed with sanofi-aventis. REGN88 entered clinical development in patients with rheumatoid arthritis in the fourth quarter of 2007. 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 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. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to 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. We believe that our ability to develop product candidates is enhanced by the application of our 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*®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the *VelocImmune* platform which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we moved our first antibody product candidate (REGN88) into clinical trials in the fourth quarter of 2007. We plan to advance two new antibody product candidates into clinical development in 2008 and an additional two to three antibody product candidates each year thereafter beginning in 2009. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

### **Late-Stage Clinical Programs:**

#### **1. ARCALYST™ — Inflammatory Diseases**

ARCALYST™(rilonacept; also known as IL-1Trap) is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. We are evaluating ARCALYST™ in a number of diseases and disorders where IL-1 may play an important role, including a group of

rare diseases called Cryopyrin-Associated Periodic Syndromes (CAPS) and other diseases associated with inflammation.

In November 2007, we announced that we received notification from the U.S. Food and Drug Administration (FDA) that the action date for the FDA's priority review of the Biologics License Application (BLA) for ARCALYST™ in CAPS had been extended three months to February 29, 2008. In August 2007, the FDA granted priority review status to the BLA for ARCALYST™ for the long-term treatment of CAPS. The FDA previously granted Orphan Drug status and Fast Track designation to ARCALYST™ for the treatment of CAPS. In July 2007, ARCALYST™ also received Orphan Drug designation in the European Union for the treatment of CAPS.

CAPS represents a group of rare inherited auto-inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). CAPS also includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). ARCALYST™ has not been studied, and is not expected to be indicated, for the treatment of NOMID. The syndromes included in CAPS are characterized by spontaneous, systemic inflammation and are termed auto-inflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours. CAPS is caused by a range of mutations in the gene NLRP3 (formerly known as *CIAS1*) which encodes a protein named cryopyrin. Currently, there are no medicines approved for the treatment of CAPS.

We have initiated a Phase 2 safety and efficacy trial of ARCALYST™ in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy used to control the disease. We previously reported positive results from an exploratory proof of concept study of ARCALYST™ in ten patients with chronic active gout. In those patients, treatment with ARCALYST™ demonstrated a statistically significant reduction in patient pain scores in the single-blind, placebo-controlled study. Mean patients' pain scores, the key symptom measure in persistent gout, were reduced 41% ( $p=0.025$ ) during the first two weeks of active treatment and reduced 56% ( $p<0.004$ ) after six weeks of active treatment. In this study, in which safety was the primary endpoint measure, treatment with ARCALYST™ was generally well-tolerated. We are also evaluating the potential use of ARCALYST™ in other indications in which IL-1 may play a role.

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 our ARCALYST™ product candidate currently in clinical development.

## **2. 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 that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis began the first four trials of our global Phase 3 development program in the second half of 2007. One trial is evaluating aflibercept in combination with docetaxel/prednisone in patients with first line metastatic androgen

independent prostate cancer. A second trial is evaluating aflibercept in combination with docetaxel in patients with second line metastatic non-small cell lung cancer. The third Phase 3 trial is evaluating aflibercept in first-line metastatic pancreatic cancer in combination with gemcitabine. The fourth Phase 3 trial is evaluating aflibercept in second-line metastatic colorectal cancer in combination with FOLFIRI (Folinic Acid (leucovorin), 5-fluorouracil, and irinotecan). In all of these trials, aflibercept is being combined with the current standard of chemotherapy care for the stated development stage of the cancer type.

The collaboration is conducting a number of other trials in the global development program for aflibercept. Five safety and tolerability studies of aflibercept in combination with standard chemotherapy regimens are continuing in a variety of cancer types to support the Phase 3 clinical program. Sanofi-aventis has also expanded the development program to Japan, where they are conducting a Phase 1 safety and tolerability study in combination with another investigational agent in patients with advanced solid malignancies.

The collaboration is also conducting Phase 2 single-agent studies of aflibercept in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). The AOC and NSCLA trials are fully enrolled and ongoing. The SMA trial is approximately 50% enrolled and continues to enroll patients. In 2004, the FDA granted Fast Track designation to aflibercept for the treatment of SMA.

In addition, more than 10 studies are currently underway or scheduled to begin that 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.

The first registration submission to a regulatory agency for aflibercept is possible as early as 2008, potentially as third line treatment as a single agent in advanced ovarian cancer (AOC) or in AOC patients with SMA. However, in order for our ongoing Phase 2 study in AOC to be sufficient to support such a submission, we believe that the final unblinded results of the study would have to demonstrate a more robust response rate than that reported in the interim analysis of blinded data from the study presented in June 2007 at the annual meeting of the American Society of Clinical Oncology (ASCO).

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). Vascular Endothelial Growth Factor (VEGF) is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth, and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin® (a trademark of Genentech, Inc.) is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

#### **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 \$400.0 million in milestone

payments upon receipt of specified marketing approvals. This total includes up to \$360.0 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. Another \$40.0 million of milestone payments relate 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.

### 3. *VEGF Trap — Eye Diseases*

The VEGF Trap-Eye is a form of the VEGF Trap that has been purified and formulated with excipients and at concentrations suitable for direct injection into the eye. The VEGF Trap-Eye currently is being tested in a Phase 3 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and has completed a small pilot study in patients with diabetic macular edema (DME).

In the clinical development program for the VEGF Trap-Eye, we and Bayer HealthCare have initiated a Phase 3 study of the VEGF Trap-Eye in wet AMD. This first trial, known as VIEW 1 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), is comparing the VEGF Trap-Eye and Genentech, Inc.'s Lucentis® (ranibizumab), an anti-angiogenic agent approved for use in wet AMD. This Phase 3 trial is evaluating dosing intervals of four and eight weeks for the VEGF Trap-Eye compared with ranibizumab dosed according to its label every four weeks. We and Bayer HealthCare plan to initiate a second Phase 3 trial in wet AMD in 2008. This second trial will be conducted primarily in the European Union and other parts of the world outside the U.S.

In October 2007, we and Bayer HealthCare announced positive results from the full analysis of the primary 12-week endpoint of a Phase 2 study evaluating the VEGF Trap-Eye in wet AMD. The VEGF Trap-Eye met the primary study endpoint of a statistically significant reduction in retinal thickness, a measure of disease activity, after 12 weeks of treatment compared with baseline (all five dose groups combined, mean decrease of 119 microns,  $p < 0.0001$ ). The mean change from baseline in visual acuity, a key secondary endpoint of the study, also demonstrated statistically significant improvement (all groups combined, increase of 5.7 letters,  $p < 0.0001$ ). Preliminary analyses at 16 weeks showed that the VEGF Trap-Eye, dosed monthly, achieved a mean gain in visual acuity of 9.3 to 10 letters (for the 0.5 and 2 mg dose groups, respectively). In additional exploratory analyses, the VEGF Trap-Eye, dosed monthly, reduced the proportion of patients with vision of 20/200 or worse (a generally accepted definition for legal blindness) from 14.3% at baseline to 1.6% at week 16; 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.) was likewise increased from 19.0% at baseline to 49.2% at 16 weeks. These findings were presented at the Retina Society Conference in September 2007.

We and Bayer HealthCare are also developing the VEGF Trap-Eye in DME. In May 2007, at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO), the companies reported results from a small pilot study of the VEGF Trap-Eye in patients with DME. In the study, the VEGF Trap-Eye was well tolerated and demonstrated activity in five patients, with decreases in retinal thickness and improvement in visual acuity.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) and Lucentis® (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is

characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

### **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 the VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of the VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, diabetic eye diseases, and other diseases and disorders. Bayer HealthCare will market the VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of the VEGF Trap-Eye. If the 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 the 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 the VEGF Trap-Eye in wet AMD, and can earn up to \$90.0 million in additional development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135.0 million in sales milestones if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

### **Antibody Research Technologies and Development Program:**

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 current clinical pipeline, including aflibercept, the VEGF Trap-Eye, and ARCALYST™. 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.

Regeneron scientists also have discovered and developed a new technology for designing protein therapeutics that facilitates the discovery and production of fully human monoclonal antibodies. We call our technology *VelocImmune*® and, as described below, we believe that it is an improved way of generating a wide variety of high affinity, therapeutic, fully human monoclonal antibodies.

#### ***VelocImmune*® (Human Monoclonal Antibodies)**

We have developed a novel mouse technology platform, called *VelocImmune*, for producing fully human monoclonal antibodies. The *VelocImmune* mouse platform was generated by exploiting our *VelociGene* technology platform (see below), in a process in which six megabases of mouse immune gene loci were replaced, or “humanized,” with corresponding human immune gene loci. The *VelocImmune* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune* and our related technologies 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 development and are exploring possible additional licensing or collaborative arrangements with third parties related to *VelocImmune* and related technologies.

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

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The first therapeutic antibody to enter clinical development under the collaboration, REGN88, is an antibody to the Interleukin-6 receptor (IL-6R), which has started clinical trials in rheumatoid arthritis. The second is expected to be an antibody to Delta-like ligand-4 (Dll4) which is currently scheduled to commence clinical development in mid-2008. 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 will fund up to \$475.0 million of our research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against these targets through December 31, 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.

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 funding drug candidate development costs up front. We are responsible for reimbursing sanofi-aventis for half of the total development costs it paid 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 \$250.0 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.

### **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 a \$20.0 million non-refundable, up-front payment to us. AstraZeneca is required to make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three 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 a \$20.0 million non-refundable, up-front payment to us. Astellas is required to make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three 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.

### ***VelociGene*® and *VelociMouse*<sup>tm</sup> (Target Validation)**

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 knock-out 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 also 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.

### **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 use 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 will be made widely 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, we are entitled to receive a minimum of \$17.9 million over a five-year period. We will receive another \$1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which will be 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.

### ***Cell Line Expression Technologies***

Many proteins that are of potential pharmaceutical value are proteins which are "secreted" from the cells into the bloodstream. Examples of secreted proteins include growth factors (such as insulin and growth hormone) and antibodies. Current technologies for the isolation of cells engineered to produce high levels of secreted proteins are both laborious and time consuming. We have developed enabling platforms for the high-throughput, rapid generation of high-producing cell lines for our Traps and our *VelocImmune* human monoclonal antibodies.

### **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 plan in mid-2008 to commence Phase 1 clinical development of a fully human monoclonal antibody to Dll4 that was discovered using our *VelocImmune* 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.

### **Manufacturing**

In 1993, we purchased our 104,000 square foot Rensselaer, New York manufacturing facility, and in 2003 completed a 19,500 square foot expansion of this facility. This facility is used to manufacture therapeutic candidates for our own preclinical and clinical studies. We also used the facility to manufacture a product for Merck & Co., Inc. under a contract that expired in October 2006. In July 2002, we leased 75,000 square feet in a building near our Rensselaer facility which we have used primarily for the manufacture of Traps and for warehouse space. In June 2007, we exercised a purchase option on this building, which totals 272,000 square feet (including the 75,000 square feet we already leased), and completed the purchase of this property in October 2007. At December 31, 2007, we employed 207 people at our Rensselaer facilities. There were no impairment losses associated with long-lived assets at these facilities as of December 31, 2007.

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 the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.*”). Our competitors include Genentech, Novartis, Pfizer Inc., Bayer HealthCare, Onyx Pharmaceuticals, Inc., Abbott Laboratories, sanofi-aventis, Merck, 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 if we achieve product commercialization, one or more of our competitors may achieve product commercialization earlier than we do or obtain patent protection that dominates or adversely affects our activities. Our ability to compete will depend on how fast we can develop safe and effective product candidates, complete clinical testing and approval processes, and supply commercial quantities of the product to the market. Competition among product candidates approved for sale will also be based on efficacy, safety, reliability, availability, price, patent position, and other factors.

*ARCALYST™.* The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex Corporation), Remicade® (Centocor, Inc.), and Humira® (Abbott) and the IL-1 receptor antagonist Kineret (Amgen), and other marketed therapies, makes it difficult to successfully develop and commercialize ARCALYST™. Even if ARCALYST™ is ever approved for sale, it will be difficult for our drug to compete against these FDA approved drugs because doctors and patients will have significant experience using these effective medicines. Moreover, 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. 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. Many of these molecules are further along in development than aflibercept and may offer competitive advantages over our molecule. Novartis has an ongoing Phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Each of Pfizer and Onyx Pharmaceuticals (together with its partner Bayer) 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 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 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 that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) 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 National Eye Institute plans to initiate a Phase 3 trial to compare Lucentis to Avastin in the treatment of wet AMD. Avastin 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), Remicade® (Centocor), 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 an antibody against the interleukin-6 (IL-6) receptor. Roche's antibody has completed Phase 3 clinical trials 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.

*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.

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 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 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**

Through 2006, our operations were managed in two business segments: research and development, and contract manufacturing. The research and development segment 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. It 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, and (ii) the supply of specified, ordered research materials using Regeneron-developed proprietary technology. The contract manufacturing segment included all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2006 and 2005, the Company manufactured a product for Merck under a contract that expired in October 2006. For financial information about these segments, see Note 20, "Segment Information", beginning on page F-36 in our Financial Statements. Due to the expiration of our manufacturing agreement with Merck, beginning in 2007, we only have a research and development business segment.

### **Employees**

As of December 31, 2007, we had 682 full-time employees, of whom 107 held a Ph.D. or M.D. degree or both. We believe that we have been successful in attracting skilled and experienced personnel in a highly competitive environment; however, competition for these personnel is intense. None of our personnel are covered by collective bargaining agreements and our management considers its relations with our employees to be good.

### **Available Information**

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission, or SEC, under the Securities Exchange Act of 1934, or the Exchange Act. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including Regeneron, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at <http://www.sec.gov>.

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

### **Item 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, 2007, we had a cumulative loss of \$793.2 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

***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.

***We have a significant amount of debt that is scheduled to mature in 2008.***

We have \$200.0 million of convertible debt that, unless converted to shares of our Common Stock, will mature in October 2008. Our debt obligations could require us to use a significant portion of our cash to pay principal and interest on our debt.

### **Risks Related to Development of Our Product Candidates**

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

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party 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 our lead product candidates, aflibercept, VEGF Trap-Eye, and ARCALYST™, in a wide variety of indications. We are studying aflibercept in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and ARCALYST™ in a variety of systemic inflammatory disorders.

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 achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.***

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many 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. For example, we are studying higher doses of ARCALYST™ in different diseases after a Phase 2 trial using lower doses of ARCALYST™ in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

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 the product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

***The data from the Phase 3 clinical program for ARCALYST™ in CAPS (Cryopyrin-Associated Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of ARCALYST™.***

We submitted a completed BLA to the FDA for ARCALYST™ in CAPS in the second quarter of 2007. However, the efficacy and safety data from the Phase 3 clinical program included in the BLA may be inadequate to support approval for commercialization of ARCALYST™. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance.

Further, before a product candidate is approved for marketing, our manufacturing facilities must be inspected by the FDA and the FDA will not approve the product for marketing if we or our third party manufacturers are not in compliance with current good manufacturing practices. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for ARCALYST™, they may pose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. These restrictions and requirements would likely result in increased expenditures and lower revenues and may restrict our ability to commercialize ARCALYST™ profitably.

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, marketing and approval for drugs, and commercial sales 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™ in those countries.

***Serious complications or side effects have occurred, and may continue to occur, in clinical trials of some of our product candidates which could lead to delay or discontinuation of development and 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 trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some 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. These serious and potentially life-threatening risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, intestinal perforation, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the 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 include side effects that we have not yet seen in our trials such as heart attack and stroke. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

It is possible that safety or tolerability concerns may arise as we continue to test ARCALYST™ in patients with inflammatory diseases and disorders. Like cytokine antagonists such as Kineret® (Amgen), Enbrel® (Immunex), and Remicade® (Centocor), 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 infections have been reported in patients taking ARCALYST™. One subject with adult Still's disease in a study of ARCALYST™ developed an infection in his elbow with mycobacterium intracellulare. The patient was on chronic glucocorticoid treatment for Still's disease. The infection occurred after an intraarticular glucocorticoid injection into the elbow and subsequent local exposure to a suspected source of mycobacteria. One patient with polymyalgia rheumatica in another study developed bronchitis/sinusitis, which resulted in hospitalization. One patient in an open-label study of ARCALYST™ in CAPS developed sinusitis and streptococcus pneumoniae meningitis and subsequently died. In addition, patients given infusions of ARCALYST™ have developed hypersensitivity reactions or infusion reactions. These or other complications or side effects could impede or result in us abandoning the development of ARCALYST™.

***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. Of the clinical study subjects who

received ARCALYST™ for rheumatoid arthritis and other indications, fewer than 5% of patients developed antibodies and no side effects related to antibodies were observed. Using a very sensitive test, approximately 40% of the patients in the CAPS pivotal study tested positive at least once for low levels of antibodies to ARCALYST™. Again, no side effects related to antibodies were observed and there were no observed effects on drug efficacy or drug levels. However, 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. For example, we are currently testing a new formulation of the VEGF Trap-Eye. 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, ARCALYST™, and REGN88, 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.

### **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* 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 the 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 the 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 the VEGF Trap-Eye, which

represents a potential competitive threat 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 the 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.

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.

In December 2003, we entered into a non-exclusive license agreement with Cellectis Inc. that granted us certain rights in a family of patents relating to homologous recombination. Cellectis now claims that agreements we entered into relating to our *VelocImmune* mice with AstraZeneca, Astellas, and sanofi-aventis are outside of the scope of our license from Cellectis. We disagree with Cellectis' position and are in discussions with Cellectis regarding this matter. If we are not able to resolve this dispute, Cellectis may commence a lawsuit against us and our *VelocImmune* licensees alleging infringement of Cellectis' patents.

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

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

## **Regulatory and Litigation Risks**

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

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the 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. 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.

***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. 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.

***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 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, 2007, which report is included in this Annual Report on Form 10-K. 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.

## 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 \$475.0 million between 2008 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, 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. Sanofi-aventis may terminate the collaboration for our material breach or, in the case of the discovery agreement, if certain minimal criteria for the discovery program are not achieved by December 31, 2010. 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.

***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 would create substantial new and additional risks to the successful development and commercialization of aflibercept.

***If our collaboration with Bayer HealthCare for the 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 the 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 the 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 the 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 the 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 the 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 the 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 the VEGF Trap-Eye.

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

We depend upon third-party collaborators, including 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.

#### **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 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.

***Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.***

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture 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.

#### **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 have no sales or distribution personnel or capabilities and have only a small staff with commercial capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. 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 the VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

***Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.***

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<sup>®</sup> (Genentech), 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, and Pfizer. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Novartis has an ongoing Phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. 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<sup>®</sup> (Genentech), and their extensive, ongoing clinical development plan for Avastin<sup>®</sup> (Genentech) 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<sup>®</sup> (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.

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<sup>®</sup>) 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 that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformatted version of Genentech's approved VEGF antagonist, Avastin<sup>®</sup>, with success for the treatment of wet AMD. The National Eye Institute recently has received funding for a Phase 3 trial to compare Lucentis<sup>®</sup> (Genentech) to Avastin<sup>®</sup> (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis<sup>®</sup> (Genentech) and the potential off-label use of Avastin<sup>®</sup> (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the 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<sup>®</sup> (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin<sup>®</sup> (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<sup>®</sup> (Immunex), Remicade<sup>®</sup> (Centocor), and Humira<sup>®</sup> (Abbott), and the IL-1 receptor antagonist Kineret<sup>®</sup> (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST<sup>™</sup>. This is one of the reasons we discontinued the development of ARCALYST<sup>™</sup> in adult rheumatoid arthritis. In addition, even if ARCALYST<sup>™</sup> is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful 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<sup>™</sup>, 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 and Company, Xoma Ltd., and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis has commenced advanced clinical testing of its IL-1 antibody in Muckle-Wells Syndrome, which is part of the group of rare genetic diseases called CAPS. Novartis' IL-1 antibody and these other 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™. For example, we may find it difficult to enroll patients in clinical trials for ARCALYST™ if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

We are developing ARCALYST™ for the treatment of a group of rare diseases associated with mutations in the NLRP3 gene. These rare genetic disorders affect a small group of people, estimated to be in the hundreds. There may be too few patients with these genetic disorders to profitably commercialize ARCALYST™ in this indication.

We are developing REGN88 for the treatment of rheumatoid arthritis. The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott), and other marketed therapies makes it more difficult to successfully develop and commercialize REGN88. REGN88 is a human monoclonal antibody targeting the interleukin-6 receptor. Roche is developing an antibody against the interleukin-6 (IL-6) receptor. Roche's antibody has completed Phase 3 clinical trials and is the subject of a filed Biologics License Application with the FDA. Roche's IL-6 receptor antibody, other clinical candidates in development, and drugs now or in the future 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.

***The successful commercialization of 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 products, if commercialized, may be significantly more expensive than traditional drug treatments. 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.

We are seeking approval to market ARCALYST™ 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 our products, including ARCALYST™, 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.

### **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:

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

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

***Future sales of our common stock by our significant shareholders or us may depress our stock price 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, 2007, our seven largest shareholders beneficially owned 54.0% of our outstanding shares of Common

Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of December 31, 2007. As of December 31, 2007, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 19.3% of 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 rights 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, 2007, holders of Class A Stock held 22.8% of the combined voting power of all of Common Stock and Class A Stock then outstanding. 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 our company 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, 2007:

- our current executive officers and directors beneficially owned 12.6% 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, 2007, and 27.7% 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, 2007; and
- our seven largest shareholders beneficially owned 54.0% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of December 31, 2007. In addition, these seven shareholders held 58.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of December 31, 2007.

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 the Company’s 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 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. We currently lease approximately 232,000 square feet of laboratory and office facilities in Tarrytown, New York under operating lease agreements. In December 2006, we entered into a new operating lease agreement for approximately 221,000 square feet of laboratory and office space at the Company’s current Tarrytown location. The new lease includes approximately 27,000 square feet that we currently occupy (the “retained facilities”) and approximately 194,000 square feet to be located in new facilities that are under construction and expected to be completed in mid-2009. In October 2007, we amended the December 2006 operating lease agreement to increase the amount of new space we will lease from approximately 194,000 square feet to approximately 230,000 square feet, for an amended total under the new lease of approximately 257,000 square feet. The term of the lease is expected to commence in mid-2008 and will expire approximately 16 years later. 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.

We own a facility in Rensselaer, New York, consisting of two buildings totaling approximately 123,500 square feet of research, manufacturing, office, and warehouse space. In June 2007, we exercised a purchase option on a 272,000 square foot building in Rensselaer, New York. Prior to the purchase, which was completed in October 2007, the Company leased approximately 75,000 square feet of manufacturing, office, and warehouse space in that building.

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

<u>Location</u>	<u>Square Footage</u>	<u>Expiration</u>	<u>Current Monthly Base Rental Charges (1)</u>	<u>Renewal Option Available</u>
Tarrytown (2)	205,000	June, 2009 (3)	\$ 311,000	None
Tarrytown (2)	230,000	June, 2024 (3)		Three 5-year terms
Tarrytown	27,000	June, 2024 (3)	\$ 54,000	Three 5-year terms
Tarrytown (4)	10,000	September, 2009	\$ 22,000	Two 3-month terms

(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 release the 205,000 square feet of space in our current facility and take over 230,000 square feet in the newly constructed buildings.

(3) Estimated based upon expected completion of our new facilities, as described above.

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

### **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, 2007.

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

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

	<u>High</u>	<u>Low</u>
<b>2006</b>		
First Quarter	\$ 18.00	\$ 14.35
Second Quarter	16.69	10.97
Third Quarter	17.00	10.88
Fourth Quarter	24.85	15.27
<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

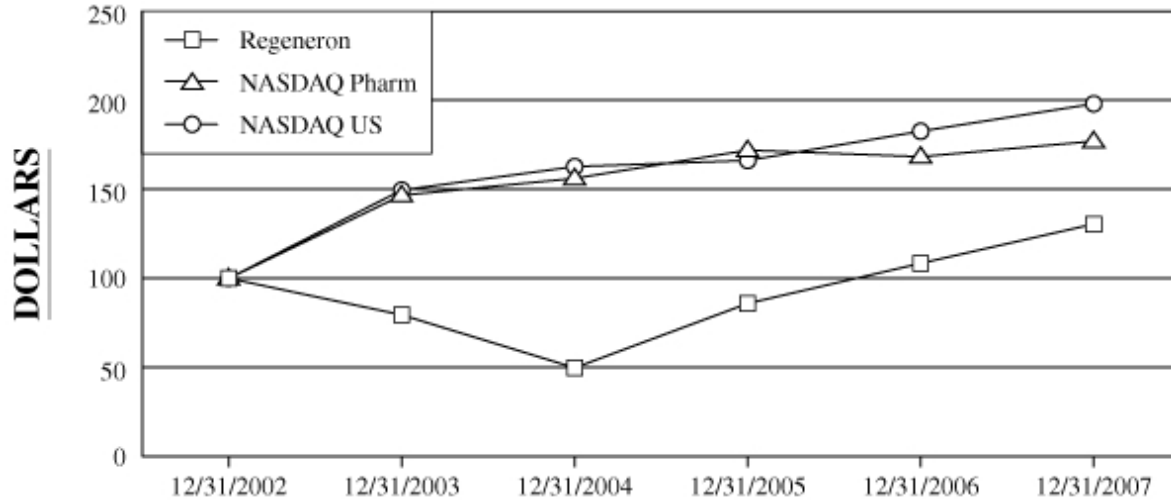
As of February 15, 2008, there were 515 shareholders of record of our Common Stock and 42 shareholders of record of our Class A Stock.

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 2008 Annual Meeting of Shareholders to be filed with the SEC is incorporated by reference into Item 12 of this Report on Form 10-K.

### 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, 2002 through December 31, 2007. The comparison assumes that \$100 was invested on December 31, 2002 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.



	12/31/2002	12/31/2003	12/31/2004	12/31/2005	12/31/2006	12/31/2007
Regeneron	\$ 100.00	\$ 79.47	\$ 49.76	\$ 85.90	\$ 108.43	\$ 130.47
Nasdaq Pharm	100.00	146.59	156.13	171.93	168.29	176.97
Nasdaq US	100.00	149.52	162.72	166.18	182.57	197.98



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

### **Overview**

We are a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We currently have four clinical development programs, including three late-stage clinical programs: ARCALYST™ (rilonacept; also known as IL-1 Trap) in various inflammatory indications, aflibercept (VEGF Trap) in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. Aflibercept is being developed in oncology in collaboration with sanofi-aventis. The VEGF Trap-Eye is being developed in collaboration with Bayer HealthCare LLC. Our fourth clinical development program is REGN88, an antibody to the Interleukin-6 receptor (IL-6R) that entered clinical development in patients with rheumatoid arthritis in the fourth quarter of 2007. 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 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.

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

From inception on January 8, 1988 through December 31, 2007, we had a cumulative loss of \$793.2 million. In the absence of revenues from the commercialization of our 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 the VEGF Trap-Eye and ARCALYST™; advance new product candidates into clinical development from our existing research programs utilizing our technology for designing fully human monoclonal antibodies; continue our research and development programs; and commercialize 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 sales of common equity and convertible debt and from funding from our collaborators in the form of up-front payments, research progress payments, and payments for our research and development activities.

In 2007, our research and development expenses totaled \$201.6 million. In 2008, we expect these expenses to increase substantially as we (i) expand our research and preclinical and clinical development activities in connection with our new antibody collaboration with sanofi-aventis, (ii) expand our Phase 3 VEGF Trap-Eye clinical program and our ARCALYST™ and aflibercept clinical programs, and (iii) increase our research and development headcount. Due to our new antibody collaboration with sanofi-aventis, we expect a greater proportion of our research and development expenses to be funded by our collaborators in 2008 than in 2007.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2007 was 627 compared with 573 in 2006 and 696 in 2005. In 2007 our average headcount increased primarily to support our expanded development programs for the VEGF Trap-Eye and ARCALYST™ and our plans to move our first antibody candidate into clinical trials. In 2006, our average headcount decreased primarily as a result of reductions

made in the fourth quarter of 2005 and mid-year in 2006. These workforce reductions were associated with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of our collaboration with Procter & Gamble, and the completion of contract manufacturing for Merck in October 2006. In 2008, we expect our average headcount to increase to approximately 825-875 primarily to support the expansion of our research and development activities as described above, especially in connection with our new 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 2007 and plans for 2008 are as follows:

<b>Product Candidate</b>	<b>2007 Events</b>	<b>2008 Events/Plans</b>
ARCALYST™ (rilonacept; also known as IL-1 Trap)	<ul style="list-style-type: none"> <li>Completed the 24-week open-label safety extension phase of the Phase 3 trial in CAPS</li> <li>FDA accepted BLA submission for CAPS</li> <li>Granted Orphan Drug designation in CAPS in European Union</li> <li>Reported positive results in exploratory proof-of-concept study in patients with chronic active gout</li> <li>Initiated Phase 2 trial evaluating safety and efficacy of ARCALYST™ in preventing gout-induced flares in patients initiating allopurinol therapy</li> </ul>	<ul style="list-style-type: none"> <li>Receive FDA review decision on BLA submission for CAPS (expected at the end of February 2008)</li> <li>If marketing approval is obtained, launch ARCALYST™ commercially in CAPS</li> <li>Evaluate ARCALYST™ in certain other disease indications in which IL-1 may play an important role</li> </ul>
Aflibercept (VEGF Trap — Oncology)	<ul style="list-style-type: none"> <li>Sanofi-aventis initiated four Phase 3 trials of aflibercept in combination with standard chemotherapy regimens</li> <li>NCI/CTEP initiated 10 studies of aflibercept</li> <li>Reported interim results from Phase 2 single-agent trials in advanced ovarian cancer and in non-small cell lung adenocarcinoma</li> <li>Initiated Japanese Phase 1 trial of aflibercept in combination with another investigational agent in patients with solid malignancies</li> </ul>	<ul style="list-style-type: none"> <li>Sanofi-aventis to initiate a fifth Phase 3 study of aflibercept in combination with standard chemotherapy regimen</li> <li>Report final data from Phase 2 single-agent trials in advanced ovarian cancer and in non-small cell lung adenocarcinoma</li> <li>Complete enrollment of Phase 2 single-agent study in symptomatic malignant ascites (SMA)</li> <li>Report interim data from the SMA Phase 2 trial</li> <li>NCI/CTEP to begin to report data from trials</li> <li>NCI/CTEP to initiate additional exploratory safety and efficacy studies</li> </ul>
VEGF Trap-Eye (intravitreal injection)	<ul style="list-style-type: none"> <li>Initiated first Phase 3 trial in wet AMD in patients in the U.S. and Canada</li> <li>Reported positive primary endpoint results and preliminary extended treatment results of Phase 2 trial in wet AMD</li> <li>Reported positive results in Phase 1 trial in DME</li> </ul>	<ul style="list-style-type: none"> <li>Initiate second Phase 3 trial in wet AMD in the European Union and certain other countries around the world</li> <li>Explore additional eye disease indications</li> </ul>

<b>Product Candidate</b>	<b>2007 Events</b>	<b>2008 Events/Plans</b>
Antibodies	<ul style="list-style-type: none"> <li>Entered global, strategic collaboration agreement with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies</li> <li>Initiated Phase 1 trial for REGN88 in rheumatoid arthritis</li> </ul>	<ul style="list-style-type: none"> <li>Initiate Phase 1 trial for the D114 antibody in oncology</li> <li>Report data for Phase 1 trial of REGN88 in rheumatoid arthritis</li> <li>Advance a third antibody candidate into clinical development</li> </ul>

## **Collaborations**

Our current collaboration agreements with sanofi-aventis and Bayer HealthCare, and our expired agreement with The Procter & Gamble Company, are summarized below.

### ***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 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 \$400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to \$360.0 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. Another \$40.0 million of milestone payments relate 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 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, 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. Since inception of the collaboration through December 31, 2007, we and sanofi-aventis have incurred \$306.8 million in agreed upon development expenses related to the aflibercept program. 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.

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.

#### *Antibodies*

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The first therapeutic antibody to enter clinical development under the collaboration, REGN88, is an antibody to the Interleukin-6 receptor (IL-6R), which has started clinical trials in rheumatoid arthritis. The second is expected to be an antibody to Delta-like ligand-4 (Dl14), which is currently slated to enter clinical development in mid-2008.

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 will fund up to \$475.0 million of our 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 \$75.0 million for the period from the collaboration's inception through December 31, 2008, and \$100.0 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. 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. 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 development expenses that were fully funded by sanofi-aventis (or half of \$0.7 million as of December 31, 2007) 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.

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 \$250.0 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.

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 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 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. Under the investor agreement, sanofi-aventis has three demand rights to require us to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the 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 and the existing collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept, 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 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 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 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 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 more of the outstanding shares of Common Stock and (iii) into an issuer tender offer, or a tender offer by a third party that is recommended or not opposed by our Board of Directors. Sanofi-aventis has agreed to vote, and cause its affiliates to vote, all shares of our voting securities they are entitled to vote, 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 Shares, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events.

### ***Bayer HealthCare LLC***

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, the 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 the VEGF Trap-Eye in wet AMD, and are eligible to receive up to \$90.0 million in additional development and regulatory milestones related to the VEGF Trap-Eye program. We are also eligible to receive up to an additional \$135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

We will share equally with Bayer HealthCare in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. If the 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 \$25.4 million at December 31, 2007) 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 the VEGF Trap-Eye and retain exclusive rights to any future profits from commercialization.

Agreed upon development expenses incurred by both companies in 2007 under a global development plan were shared as follows: The first \$50.0 million was shared equally and we were solely responsible for up to the next \$40.0 million. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

In 2008, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first \$70.0 million will be shared equally, we are solely responsible for up to the next \$30.0 million, and over \$100.0 million will be shared equally. In 2009 and thereafter, all development expenses will be shared equally. We are also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

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 the 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, we and Bayer HealthCare approved a global development plan for the VEGF Trap-Eye in wet AMD. The plan includes 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 the VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, we determined the appropriate accounting policy for payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's VEGF Trap-Eye development expenses, and the financial statement classifications and periods in which past and future payments from Bayer HealthCare (including the \$75.0 million up-front payment and development and regulatory milestone payments) and cost-sharing of VEGF Trap-Eye development expenses will be recognized in our Statement of Operations.

#### ***The Procter & Gamble Company***

In May 1997, we entered into a long-term collaboration with Procter & Gamble to discover, develop, and commercialize pharmaceutical products, and Procter & Gamble agreed to provide funding in support of our research efforts related to the collaboration. In accordance with the companies' collaboration agreement, Procter & Gamble was obligated to fund our research on therapeutic areas that were of particular interest to Procter & Gamble through December 2005, with no further research obligations by either party thereafter. Under the collaboration agreement, research support from Procter & Gamble was \$2.5 million per quarter, plus annual adjustments for inflation, through December 2005.

In June 2005, we and Procter & Gamble amended our collaboration agreement. Under the terms of the modified agreement, the two companies agreed that the research activities being pursued under the collaboration agreement were completed on June 30, 2005, six months prior to the December 31, 2005 expiration date in the collaboration agreement. Procter & Gamble agreed to make a one-time \$5.6 million payment to Regeneron, which was received in July 2005, and to fund our research under the agreement through the second quarter of 2005. We agreed to pay Procter & Gamble approximately \$1.0 million to acquire certain capital equipment owned by Procter & Gamble and located at our facilities. We and Procter & Gamble divided rights to research programs and preclinical product candidates that were developed during the research term of the collaboration. Neither party has the right to participate in the development or commercialization of the other party's product candidates. We are entitled to receive royalties based on any future product sales of a Procter & Gamble preclinical candidate arising from the collaboration, and Procter & Gamble is entitled to receive a small royalty on any sales of a single Regeneron candidate that is not currently being developed. Neither party is entitled to receive either royalties or other payments based on any other products arising from the collaboration.

## Other Agreements

### *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 a \$20.0 million non-refundable, up-front payment to us. AstraZeneca is required to make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three 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.

### *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 a \$20.0 million non-refundable, up-front payment to us. Astellas is required to make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three 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.

### *National Institutes of Health*

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 use 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 embryonic stem cells (ES cells) which can be used to produce knockout mice. These materials will be made widely 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, we are entitled to receive a minimum of \$17.9 million over a five-year period. We will receive another \$1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which will be 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.

## Accounting for Stock-based Employee Compensation

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. (SFAS) 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date. Prior to the adoption of the fair value method, we accounted for stock-based compensation to employees under the intrinsic value method of accounting set forth in Accounting Principles Board Opinion No. (APB) 25, *Accounting for Stock Issued to Employees*, and related interpretations. Therefore, compensation expense related to employee stock options was not reflected in operating expenses in any period prior to the first quarter of 2005 and prior period operating results were not restated.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. 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 the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Effective January 1, 2005, and prior to our adoption of SFAS 123R, we 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, we were 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 our loss by \$0.8 million and is included in our operating results for the year ended December 31, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on our loss from operations, net loss, and net loss per share for the year ended December 31, 2006 was not significant, and there was no impact to our cash flows for the year ended December 31, 2006.

Non-cash stock-based employee compensation expense related to stock option awards (Stock Option Expense) recognized in operating expenses totaled \$28.0 million, \$18.4 million, and \$19.9 million for the years ended December 31, 2007, 2006, and 2005, respectively. In addition, for the year ended December 31, 2005, \$0.1 million of Stock Option Expense was capitalized into inventory. As of December 31, 2007, there was \$60.6 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. We expect to recognize this compensation cost over a weighted-average period of 1.8 years. In addition, there are 723,092 options which are unvested as of December 31, 2007 and would become vested upon our products achieving certain sales targets and the optionee satisfying certain service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2.7 million and will begin to be recognized only if, and when, these options' performance condition is considered to be probable of attainment.

#### ***Assumptions***

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. 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 option grants with similar exercise prices. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. The following table summarizes the weighted average values of the assumptions we used in computing the fair value of option grants during 2007, 2006, and 2005:

	<u>2007</u>	<u>2006</u>	<u>2005</u>
Expected volatility	53%	67%	71%
Expected lives from grant date	5.6 years	6.5 years	5.9 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	3.60%	4.51%	4.16%

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 any period.

## Results of Operations

### 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:

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

We recognize revenue from sanofi-aventis, in connection with our aflibercept and antibody collaborations, in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and FASB Emerging Issue Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21) (see “Critical Accounting Policies and Significant Judgments and Estimates”). 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. Non-refundable, up-front payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance periods based on the specific terms of the collaboration agreements, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

	<u>December 31,</u>	
Sanofi-aventis Contract Research & Development Revenue	<u>2007</u>	<u>2006</u>
	(In millions)	
Aflibercept:		
Regeneron expense reimbursement	\$ 38.3	\$ 36.4
Recognition of deferred revenue related to up-front payments	<u>8.8</u>	<u>11.4</u>
Total aflibercept	<u>47.1</u>	<u>47.8</u>
Antibody:		
Regeneron expense reimbursement	3.7	
Recognition of deferred revenue related to up-front payments	<u>0.9</u>	
Total antibody	<u>4.6</u>	
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, 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 accordance with SAB 104 and EITF 00-21. 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, when we commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, we recognized, as a cumulative catch-up, 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, 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 is being 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 is being 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.



depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$3.0 million and \$1.8 million of Stock Option Expense for the years ended December 31, 2007 and 2006, 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 their VEGF Trap-Eye development expenses that we are obligated to reimburse. 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 Stock Option Expense, as described above. Clinical trial expenses increased due primarily to higher costs related to our Phase 3 study of the VEGF Trap-Eye in wet AMD, which we initiated in the third quarter of 2007, and our ongoing Phase 1 and 2 studies of the VEGF Trap-Eye in wet AMD. Clinical manufacturing costs increased due primarily to higher costs related to manufacturing ARCALYST<sup>™</sup> and preclinical and clinical supplies of REGN88, which were partly offset by lower costs related to manufacturing aflibercept and the 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 primarily increased in connection with higher Company headcount and to support 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, Stock Option 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:

<u>Project Costs</u>	<u>Year Ended December 31,</u>		
	<u>2007</u>	<u>2006</u>	<u>Increase</u>
		<u>(In millions)</u>	<u>(Decrease)</u>
ARCALYST <sup>™</sup>	\$ 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>

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 the 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 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 product revenues and material net cash inflows. In the second quarter of 2007, we submitted a BLA for ARCALYST™ for the treatment of CAPS, a group of rare genetic disorders. We cannot predict whether or when the commercialization of ARCALYST™ in CAPS will result in a material net cash inflow 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.

*General and Administrative Expenses:*

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 Stock Option 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 is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in October 2008 and bear interest at 5.5% per annum.

***Years Ended December 31, 2006 and 2005***

*Net Loss:*

Regeneron reported a net loss of \$102.3 million, or \$1.77 per share (basic and diluted), for the year ended December 31, 2006, compared to a net loss of \$95.4 million, or \$1.71 per (basic and diluted) for 2005.

Revenues:

Revenues for the years ended December 31, 2006 and 2005 consist of the following:

	<u>2006</u>	<u>2005</u>
	(In millions)	
Contract research & development revenue		
Sanofi-aventis	\$ 47.8	\$ 43.4
Procter & Gamble		6.0
Other	<u>3.3</u>	<u>3.1</u>
Total contract research & development revenue	51.1	52.5
Contract manufacturing revenue	<u>12.3</u>	<u>13.7</u>
Total revenue	<u>\$ 63.4</u>	<u>\$ 66.2</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 a total of \$105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. 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.

	<u>December 31,</u>	
	<u>2006</u>	<u>2005</u>
	(In millions)	
Sanofi-aventis Contract Research & Development Revenue		
Regeneron expense reimbursement	\$ 36.4	\$ 33.9
Recognition of deferred revenue related to up-front payments	<u>11.4</u>	<u>9.5</u>
Total	<u>\$ 47.8</u>	<u>\$ 43.4</u>

Sanofi-aventis' reimbursement of Regeneron aflibercept expenses increased in 2006 compared to 2005, primarily due to higher costs related to our manufacture of aflibercept clinical supplies during the first half of 2006. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in 2006 from the same period in 2005, due to our receipt in January 2006 of a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' aflibercept collaboration to include Japan. As of December 31, 2006, \$70.0 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Contract research and development revenue earned from Procter & Gamble decreased in 2006 compared to 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005, as described above under "Collaborations — The Procter & Gamble Company." Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

In October 2006 we entered into our VEGF Trap-Eye collaboration with Bayer HealthCare. In the fourth quarter of 2007, we determined the appropriate accounting policy for payments from Bayer HealthCare and, in 2007, commenced recognizing previously deferred payments in our Statement of Operations through a cumulative catch-up, as described above. Accordingly, there was no contract research and development revenue earned from Bayer HealthCare in 2006. As of December 31, 2006, the \$75.0 million up-front payment received from Bayer HealthCare in October 2006 was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes \$0.5 million recognized in connection with our NIH Grant, as described above.

Contract manufacturing revenue relates to our long-term agreement with Merck, which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer facility. Contract manufacturing revenue decreased in 2006 compared to 2005 due to a decrease in product shipments to Merck in 2006. Revenue and the related

manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in 2006 and 2005 were \$1.2 million and \$1.4 million, respectively, 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 and there was no Merck deferred revenue as of the end of 2006.

*Expenses:*

Total operating expenses decreased to \$171.1 million in 2006 from \$190.6 million in 2005 due, in part, to our lower headcount, as described above. (Also see “Severance Costs” below.)

Operating expenses in 2006 and 2005 include a total of \$18.4 million and \$19.9 million of Stock Option Expense, respectively, as detailed below:

<u>Expenses</u>	<u>For the Year Ended December 31, 2006</u>		
	<u>Expenses Before Inclusion of Stock Option Expense</u>	<u>Stock Option Expense</u>	<u>Expenses as Reported</u>
Research and development	\$ 126.9	\$ 10.2	\$ 137.1
Contract manufacturing	7.8	0.3	8.1
General and administrative	18.0	7.9	25.9
Total operating expenses	<u>\$ 152.7</u>	<u>\$ 18.4</u>	<u>\$ 171.1</u>

<u>Expenses</u>	<u>For the Year Ended December 31, 2005</u>		
	<u>Expenses Before Inclusion of Stock Option Expense</u>	<u>Stock Option Expense</u>	<u>Expenses as Reported</u>
Research and development	\$ 143.7	\$ 11.9	\$ 155.6
Contract manufacturing	9.2	0.4	9.6
General and administrative	17.8	7.6	25.4
Total operating expenses	<u>\$ 170.7</u>	<u>\$ 19.9</u>	<u>\$ 190.6</u>

*Research and Development Expenses:*

Research and development expenses decreased to \$137.1 million for the year ended December 31, 2006 from \$155.6 million for 2005. The following table summarizes the major categories of our research and development expenses for the years ended December 31, 2006 and 2005:

<u>Research and Development Expenses</u>	<u>Year Ended December 31,</u>		
	<u>2006</u>	<u>2005</u>	<u>Increase (Decrease)</u>
Payroll and benefits (1)	\$ 44.8	\$ 53.6	\$ (8.8)
Clinical trial expenses	14.9	18.2	(3.3)
Clinical manufacturing costs (2)	39.2	41.6	(2.4)
Research and preclinical development costs	17.5	19.2	(1.7)
Occupancy and other operating costs	20.7	23.0	(2.3)
Total research and development	<u>\$ 137.1</u>	<u>\$ 155.6</u>	<u>\$ (18.5)</u>

- (1) Includes \$8.4 million and \$10.5 million of Stock Option Expense for the years ended December 31, 2006 and 2005, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$1.8 million and \$1.4 million of Stock Option Expense for the years ended December 31, 2006 and 2005, respectively.

Payroll and benefits decreased principally due to our lower headcount in 2006. In addition, payroll and benefits in 2006 and 2005 included \$0.4 million and \$2.2 million, respectively, of severance costs associated with our workforce reduction plan that we initiated in October 2005. Clinical trial expenses decreased primarily due to lower ARCALYST™ costs in 2006 as we discontinued clinical development of ARCALYST™ in adult rheumatoid arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs related to Phase 1 and Phase 2 clinical trials that we are conducting in wet AMD. Clinical manufacturing costs decreased because of lower costs in 2006 related to manufacturing ARCALYST™ clinical supplies, which were partially offset by higher costs related to manufacturing aflibercept clinical supplies. Research and preclinical development costs decreased principally because of lower costs for general research supplies in 2006 as we narrowed the focus of our research and development efforts due, in part, to the expiration of our collaboration with Procter & Gamble in June 2005, as described above. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount and lower costs for utilities associated with our leased research facilities in Tarrytown, New York.

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 stock-based employee compensation expense related to stock option awards, and manufacturing and other costs related to activities that benefit multiple projects. Our estimates of research and development costs for clinical development programs are shown below:

<u>Project Costs</u>	<u>Year Ended December 31,</u>		<u>Increase (Decrease)</u>
	<u>2006</u>	<u>2005</u> (In millions)	
ARCALYST™	\$ 29.6	\$ 57.2	\$ (27.6)
Aflibercept	30.7	27.8	2.9
VEGF Trap-Eye	21.9	9.3	12.6
Other research programs & unallocated costs	54.9	61.3	(6.4)
Total research and development expenses	<u>\$ 137.1</u>	<u>\$ 155.6</u>	<u>\$ (18.5)</u>

For the reasons described above under “Research and Development Expenses” for the years ended December 31, 2007 and 2006, 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 product revenues and material net cash inflows.

*Contract Manufacturing Expenses:*

Contract manufacturing expenses decreased to \$8.1 million in 2006, compared to \$9.6 million in 2005, primarily because we shipped less product to Merck in 2006.

*General and Administrative Expenses:*

General and administrative expenses increased to \$25.9 million in 2006 from \$25.4 million in the same period of 2005 as higher legal expenses related to general corporate matters and higher patent-and trademark-related costs were partly offset by lower professional fees for internal audit and other administrative advisory services and lower administrative facility costs.

*Other Income and Expense:*

In June 2005, we and Procter & Gamble amended our collaboration agreement and agreed that the research activities of both companies under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble made a one-time \$5.6 million payment to us, which we recognized as other contract income in 2005. In January 2005, we and sanofi-aventis amended our collaboration agreement to exclude rights to

develop and commercialize aflibercept for intraocular delivery to the eye. In connection with the amendment, sanofi-aventis made a one-time \$25.0 million payment to us, which we recognized as other contract income in 2005.

Investment income increased to \$16.5 million in 2006 from \$10.4 million in 2005, due primarily to 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), as well as higher effective interest rates on investment securities in 2006. Interest expense was \$12.0 million in 2006 and 2005. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

### **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, payments earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis, Bayer HealthCare, and Merck, and investment income.

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

At December 31, 2007, we had \$846.3 million in cash, cash equivalents, restricted cash and marketable securities compared with \$522.9 million at December 31, 2006. In connection with our non-exclusive license agreements with AstraZeneca and Astellas, as described above, AstraZeneca and Astellas each made an up-front payment to us of \$20.0 million in February and April 2007, respectively. 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 the VEGF Trap-Eye in wet AMD. In December 2007, we received an \$85.0 million upfront payment in connection with our new collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. 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.

#### ***Cash Provided by Operations:***

Net cash provided by operations was \$27.4 million in 2007 and \$23.1 million in 2006, and net cash used in operations was \$30.3 million in 2005. Our net losses of \$105.6 million in 2007, \$102.3 million in 2006, and \$95.4 million in 2005 included \$28.1 million, \$18.7 million, and \$21.9 million, respectively, of non-cash stock-based employee compensation costs, consisting primarily of Stock Option Expense. Our net losses also included depreciation and amortization of \$11.5 million, \$14.6 million, and \$15.5 million in 2007, 2006, and 2005, respectively, and a \$5.9 million non-cash charge in 2007 related to marketable securities which we considered to be other than temporarily impaired in value.

In 2007, end-of-year accounts receivable increased by \$10.8 million compared to 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. At December 31, 2007, our deferred revenue balances 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 these deferred payments and prior year deferred payments from sanofi-aventis and Bayer HealthCare, in our Statement of Operations. 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.

In 2006, end-of-year accounts receivable balances decreased by \$29.0 million compared to 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. In 2005, our deferred revenue balances increased by \$14.5 million compared to 2004, due primarily to the January 2006 \$25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, partly offset by 2005 revenue recognition from deferred sanofi-aventis up-front payments.

The majority of our cash expenditures in 2007, 2006, and 2005 were to fund research and development, primarily related to our clinical programs and, in 2007, our preclinical human monoclonal antibody programs. In 2007, 2006, and 2005, we made two semi-annual interest payments totaling \$11.0 million per year on our convertible senior subordinated notes.

*Cash Provided by Investing Activities:*

Net cash used in investing activities was \$85.7 million in 2007 and \$155.1 million in 2006, and net cash provided by investing activities was \$115.5 million in 2005. In 2007 and 2006, purchases of marketable securities exceeded sales or maturities by \$67.3 million and \$150.7 million, respectively, whereas in 2005, sales or maturities of marketable securities exceeded purchases by \$120.5 million. In addition, capital expenditures in 2007 included the purchase of land and a building in Rensselaer, NY for \$9.0 million.

*Cash Provided by Financing Activities:*

Cash provided by financing activities was \$319.4 million in 2007, \$185.4 million in 2006, and \$4.1 million in 2005. 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 \$7.6 million in 2007, \$10.4 million in 2006, and \$4.1 million in 2005.

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

*Aflibercept*

Under our aflibercept collaboration agreement with sanofi-aventis, as described under "Collaborations" above, 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, 2007, we and sanofi-aventis have incurred \$306.8 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 2008.

Sanofi-aventis funded \$38.3 million, \$36.4 million, and \$33.9 million, respectively, of our aflibercept development costs in 2007, 2006, and 2005, of which \$10.5 million, \$6.8 million, and \$10.5 million, respectively, were included in accounts receivable as of December 31, 2007, 2006, and 2005. In addition, we received up-front payments of \$80.0 million in September 2003 and \$25.0 million in January 2006 from sanofi-aventis in connection with our collaboration. Both up-front payments 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 2007, 2006, and 2005, we recognized \$8.8 million, \$11.4 million, and \$9.5 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.

#### *Antibodies*

As part of the discovery agreement under our collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies, as described under “Collaborations” above, sanofi-aventis will fund up to \$475.0 million of our research through December 31, 2012, subject to specified funding limits of \$75.0 million for the period from the collaboration’s inception through December 31, 2008, and \$100.0 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.

As part of the license agreement under the collaboration, 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 (called Shared Phase 3 Trial Costs) for that drug candidate 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 development expenses that were fully funded by sanofi-aventis (or half of \$0.7 million as of December 31, 2007) 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. The first therapeutic antibody to enter clinical development under the collaboration is REGN88, which has started clinical trials in rheumatoid arthritis. The second is expected to be a Dll4 antibody, which is currently slated to enter clinical development in mid-2008.

In 2007, sanofi-aventis funded \$3.0 million of our expenses under the collaboration’s discovery agreement and \$0.7 million of our REGN88 development costs under the license agreement. These amounts were included in accounts receivable as of December 31, 2007. 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 2007, we recognized \$0.9 million related to this up-front payment.

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 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 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.

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

Under our collaboration agreement with Bayer HealthCare, as described under “Collaborations” above, agreed upon VEGF Trap-Eye development expenses incurred by both companies in 2007 under a global development plan, were shared as follows: The first \$50.0 million was shared equally and we were solely responsible for up to the next \$40.0 million. In 2007, cost-sharing between Bayer HealthCare and us of VEGF Trap-Eye development expenses resulted in (i) reimbursement of \$14.3 million of our VEGF Trap-Eye development expenses by Bayer HealthCare,

of which \$2.8 million was included in accounts receivable at December 31, 2007, and (ii) payment of \$4.9 million of Bayer HealthCare VEGF Trap-Eye development expenses by us, which was included in accrued expenses at December 31, 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

In 2008, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first \$70.0 million will be shared equally, we are solely responsible for up to the next \$30.0 million, and over \$100.0 million will be shared equally. In 2009 and thereafter, all development expenses will be shared equally.

If the 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 \$25.4 million as of December 31, 2007) 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. In 2007, we and Bayer HealthCare initiated a Phase 3 study of the VEGF Trap-Eye in wet AMD. A second Phase 3 study of the VEGF Trap-Eye in wet AMD is planned for 2008.

We received a \$75.0 million up-front payment in October 2006 and a \$20.0 non-substantive milestone payment in August 2007 from Bayer HealthCare in connection with our collaboration. Both payments 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 2007, we recognized \$15.9 million of revenue related to these deferred payments. We did not recognize revenue in connection with our collaboration with Bayer HealthCare in 2006.

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 the VEGF Trap-Eye.

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

Under our five-year grant from the NIH, as described under "Other Agreements" above, we are entitled to receive a minimum of \$17.9 million over a five-year period, subject to compliance with the grant's terms and annual funding approvals, and another \$1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium. In 2007 and 2006, we recognized \$5.5 million and \$0.5 million, respectively, of revenue related to the NIH Grant, of which \$1.0 million and \$0.5 million, respectively, was receivable at the end of 2007 and 2006. In 2008, we expect to receive funding of approximately \$5 million for reimbursement of Regeneron expenses related to the NIH Grant.

#### ***License Agreement with AstraZeneca and Astellas:***

Under these non-exclusive license agreements, AstraZeneca and Astellas each made a \$20.0 million non-refundable, up-front payment to us in February and April 2007, respectively. AstraZeneca and Astellas are each required to make up to five additional annual payments of \$20.0 million, subject to each licensee's ability to terminate its license agreement with us after making the first three additional payments or earlier if the technology does not meet minimum performance criteria.

#### ***Severance Costs:***

In September 2005, we announced plans to reduce our workforce by approximately 165 employees in connection with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the September 2005 expiration of our collaboration with Procter & Gamble, and the completion of contract manufacturing for Merck in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions occurred in 2006 as we completed activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction were comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included \$0.2 million of non-cash expenses. Estimated

termination costs associated with the workforce reduction in 2006 were measured in October 2005 and expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Total costs associated with the 2005 and 2006 workforce reductions were \$2.6 million, of which \$2.2 million was charged to expense in the fourth quarter of 2005 and \$0.4 million was charged to expense in 2006.

***Convertible Debt:***

In 2001, we issued \$200.0 million aggregate principal amount of convertible senior subordinated notes in a private placement and received proceeds, after deducting the initial purchasers' discount and out-of pocket expenses, of \$192.7 million. The notes bear interest at 5.5% per annum, payable semi-annually, and mature in 2008. The notes are convertible into shares of our Common Stock at a conversion price of approximately \$30.25 per share, subject to adjustment in certain circumstances. If the price per share of our Common Stock is above \$30.25 at maturity, we would expect the notes would be converted into shares of Common Stock. Otherwise, we will be required to repay the \$200.0 million aggregate principal amount of the notes or refinance the notes prior to maturity; however, we can provide no assurance that we will be able to successfully arrange such refinancing.

***New Operating Lease — Tarrytown, New York Facilities:***

We currently lease approximately 232,000 square feet of laboratory and office facilities in Tarrytown, New York under operating lease agreements. In December 2006, we entered into a new operating lease agreement for approximately 221,000 square feet of laboratory and office space at our current Tarrytown location. The new lease includes approximately 27,000 square feet that we currently occupy (our retained facilities) and approximately 194,000 square feet to be located in new facilities that are under construction and expected to be completed in mid-2009. In 2007, we amended the December 2006 operating lease agreement to increase the amount of new space we will lease from approximately 194,000 square feet to approximately 230,000 square feet, for an amended total under the new lease of approximately 257,000 square feet. The term of the lease is now expected to commence in mid-2008 and will expire approximately 16 years later. 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 \$19.6 million in 2007, \$3.3 million in 2006, and \$4.7 million in 2005. In 2008, we expect to incur approximately \$55 to \$65 million in capital expenditures primarily in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our new Tarrytown operating lease, as described above. We expect that approximately \$30 million of projected 2008 Tarrytown tenant improvement costs will be reimbursed by our landlord in connection with our new operating lease.

***Funding Requirements:***

Our total expenses for research and development from inception through December 31, 2007 have been approximately \$1,352 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* technology platform. We incurred expenses associated with these agreements, which include an allocable portion of general and administrative costs, of \$108.2 million, \$43.4 million, and \$42.2 million in 2007, 2006, and 2005, 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 55-65% of our expenditures for 2008 will be directed toward the preclinical and clinical development of product candidates, including ARCALYST™, aflibercept, VEGF Trap-Eye, and monoclonal antibodies (including REGN88 and the Dll4 antibody); approximately 15-20% of our expenditures for 2008 will be applied to our basic research and early preclinical activities and the remainder of our expenditures for 2008 will be used for the continued development of our novel technology platforms, capital expenditures, and general corporate purposes.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2007. These obligations and commitments assume non-termination of agreements and represent expected payments based on current operating forecasts, which are subject to change:

	<u>Total</u>	<u>Payments Due by Period</u>			
		<u>Less than one year</u>	<u>1 to 3 years</u>	<u>3 to 5 years</u>	<u>Greater than 5 years</u>
			(In millions)		
Convertible senior subordinated notes payable (1)	\$ 211.0	\$ 211.0			
Operating leases (2)	253.0	5.1	\$ 24.6	\$ 29.7	\$ 193.6
Purchase obligations (3)	125.9	60.4	65.5		
Total contractual obligations	<u>\$ 589.9</u>	<u>\$ 276.5</u>	<u>\$ 90.1</u>	<u>\$ 29.7</u>	<u>\$ 193.6</u>

- (1) Includes amounts representing interest.
- (2) 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 2007, these costs were \$8.8 million.
- (3) 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 the VEGF Trap-Eye in collaboration with Bayer HealthCare) such 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. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

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

We believe that our existing capital resources, 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 the \$1.6 million letter of credit issued to our landlord in connection with our new 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, 2007, 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.

### **Critical Accounting Policies and Significant Judgments and Estimates**

#### *Revenue Recognition:*

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 possible, and could result in material changes to the amount of revenue recognized each year in the future. In addition, performance periods may be extended if development programs encounter delays or we and our collaborators decide to expand our clinical plans for a drug candidate into additional disease indications. 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. For the year ended December 31, 2006, changes in estimates of our performance periods, including an extension of our estimated performance period for our aflibercept collaboration with sanofi-aventis, did not have a material impact on contract research and development revenue that we recognized. 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 \$105.0 million of 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.

#### *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 15% 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, 2007 or 2006.

*Depreciation of Property, Plant, and Equipment:*

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

Building and improvements	7-30 years
Laboratory and computer equipment	3-5 years
Furniture and fixtures	5 years

Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

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.

*Stock-based Employee Compensation:*

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of SFAS 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date. Prior to the adoption of the fair value method, we accounted for stock-based compensation to employees under the intrinsic value method of accounting set forth in APB 25, *Accounting for Stock Issued to Employees*, and related interpretations. Therefore, compensation expense related to employee stock options was not reflected in operating expenses in any period prior to the first quarter of 2005 and prior period operating results have not been restated.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. 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 the number of awards that are expected to be forfeited at the

time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Effective January 1, 2005, and prior to our adoption of SFAS 123R, we 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, we were 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 our loss by \$0.8 million and is included in our operating results for the year ended December 31, 2006 as a cumulative-effect adjustment of a change in accounting principle.

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. 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 option grants with similar exercise prices. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future.

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

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, however on December 14, 2007, the FASB issued a proposed staff position (FSP FAS 157-b) which would delay the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. We are required to adopt SFAS 157 as it relates to our financial assets and financial liabilities effective for the fiscal year beginning January 1, 2008, and as it relates to our nonfinancial assets and nonfinancial liabilities for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of SFAS 157 will have a material impact on our financial statements.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Our management does not anticipate that the adoption of SFAS 159 will have a material impact on our financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, *Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We are required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Our management does not anticipate that the adoption of EITF 07-3 will have a material impact on our financial statements.

### **Item 7A. Quantitative and Qualitative Disclosure 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 investment grade corporate, asset-backed, and U.S. government securities.

We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in approximately a \$1.9 million and \$1.7 million decrease in the fair value of our investment portfolio at December 31, 2007 and 2006, respectively. The increase in the potential impact of an interest rate change at December 31, 2007, compared to December 31, 2006, is due primarily to slight increases in our investment portfolio's duration to maturity at the end of 2007 versus the end of 2006.

*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 2007, we recognized a \$5.9 million charge related to marketable securities 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-38 of this report. The supplementary financial information required by this Item is included at pages F-37 and F-38 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 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, 2007. The effectiveness of our internal control over financial reporting as of December 31, 2007 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, 2007 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.

**PART III**

**Item 10. Directors and 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 under the captions “Election of Directors,” “Board Committees and Meetings,” “Executive Officers of the Company,” and “Section 16(a) Beneficial Ownership Reporting Compliance,” in our definitive proxy statement with respect to our 2008 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.regn.com>) under the Investor Relations heading.

**Item 11. Executive Compensation**

The information called for by this item will be included under the captions “Compensation Committee Report,” “Compensation Committee Interlocks and Insider Participation,” “Executive Compensation” and “Compensation of Directors” in our definitive proxy statement with respect to our 2008 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 under the captions “Equity Compensation Plan Information,” “Security Ownership of Management” and “Stock Ownership of Certain Beneficial Owners” in our definitive proxy statement with respect to our 2008 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 under the captions “Elections of Directors” and “Review of Transactions with Related Persons” in our definitive proxy statement with respect to our 2008 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 under the caption “Information about Fees Paid to Independent Registered Public Accounting Firm” in our definitive proxy statement with respect to our 2008 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 financial statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

## 2. Financial Statement Schedules

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

## 3. Exhibits

Exhibit Number	Description
3.1	— 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	(c) — 2000 Long-Term Incentive Plan.
10.3.1	(d) — Amendment No. 1 to 2000 Long-Term Incentive Plan, effective as of June 14, 2002.
10.3.2	(d) — Amendment No. 2 to 2000 Long-Term Incentive Plan, effective as of December 20, 2002.
10.3.3	(e) — Amendment No. 3 to 2000 Long-term Incentive Plan, effective as of June 14, 2004.
10.3.4	(f) — Amendment No. 4 to 2000 Long-term Incentive Plan, effective as of November 15, 2004.
10.3.5	(g) — 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.
10.3.6	(g) — 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.
10.3.7	(h) — 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.
10.4	(d) — Employment Agreement, dated as of December 20, 2002, between the Company and Leonard S. Schleifer, M.D., Ph.D.
10.5*	(i) — Employment Agreement, dated as of December 31, 1998, between the Company and P. Roy Vagelos, M.D.
10.6	(j) — Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, effective as of February 1, 2006.
10.7	(k) — Indenture, dated as of October 17, 2001, between Regeneron Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, as trustee.
10.8	(k) — Registration Rights Agreement, dated as of October 17, 2001, among Regeneron Pharmaceuticals, Inc., Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, and Robertson Stephens, Inc.
10.9*	(l) — IL-1 License Agreement, dated June 26, 2002, by and among the Company, Immunex Corporation, and Amgen Inc.
10.10*	(m) — Collaboration, License and Option Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and the Company.
10.11*	(n) — Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.11.1*	(i) — Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 31, 2004.
10.11.2	(o) — Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of January 7, 2005.
10.11.3*	(p) — Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 21, 2005.
10.11.4*	(p) — 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.



Exhibit Number	Description
10.12	(n) — Stock Purchase Agreement, dates as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.13*	(q) — License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
10.14*	(r) — Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007 by and between AstraZeneca UK Limited and Regeneron Pharmaceuticals, Inc.
10.15	(s) — Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc.
10.16*	(t) — Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and Regeneron Pharmaceuticals, Inc.
10.17*	(u) — First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of October 24, 2007.
10.18*	— Discovery and Preclinical Development Agreement, dated as of November 28, 2007, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.19*	— 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.
10.20	— 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.
10.21	— 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.
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 and Exchange Act of 1934.
31.2	— Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	— Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

**Description:**

- (a) Incorporated by reference from the Form 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 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2001, filed March 22, 2002.
- (d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2002, filed March 31, 2003.
- (e) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2004, filed August 5, 2004.
- (f) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 17, 2004.
- (g) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.
- (h) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.
- (i) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2004, filed March 11, 2005.
- (j) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 25, 2006.
- (k)



- (l) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2002, filed August 13, 2002.
- (m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended March 31, 2003, filed May 15, 2003.
- (n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2003, filed November 11, 2003.
- (o) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.
- (p) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2005, filed February 28, 2006.
- (q) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed October 18, 2006.
- (r) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2006, filed March 12, 2007.
- (s) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.
- (t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended March 31, 2007, filed May 4, 2007.
- (u) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended September 31, 2007, filed November 7, 2007.

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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.

## SIGNATURE

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 27, 2008

## 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 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.	President, Chief Executive Officer, and Director (Principal Executive Officer)
<u>                  /s/ Murray A. Goldberg                  </u> Murray A. Goldberg	Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer)
<u>                  /s/ Douglas S. McCorkle                  </u> Douglas S. McCorkle	Vice President, Controller and Assistant Treasurer (Principal Accounting Officer)
<u>                  /s/ George D. Yancopoulos                  </u> George D. Yancopoulos, M.D., Ph.D	Executive Vice President, Chief Scientific Officer, President, Regeneron Research Laboratories, and Director
<u>                  /s/ P. Roy Vagelos                  </u> P. Roy Vagelos, M.D.	Chairman of the Board
<u>                  /s/ Charles A. Baker                  </u> Charles A. Baker	Director

<b>Signature</b>	<b>Title</b>
<hr/> <i>/s/ Michael S. Brown</i> <hr/> Michael S. Brown, M.D.	Director
<hr/> <i>/s/ Alfred G. Gilman</i> <hr/> Alfred G. Gilman, M.D., Ph.D.	Director
<hr/> <i>/s/ Joseph L. Goldstein</i> <hr/> Joseph L. Goldstein, M.D.	Director
<hr/> <i>/s/ Arthur F. Ryan</i> <hr/> Arthur F. Ryan	Director
<hr/> <i>/s/ George L. Sing</i> <hr/> George L. Sing	Director

**REGENERON PHARMACEUTICALS, INC.**  
**INDEX TO FINANCIAL STATEMENTS**

	<u>Page Numbers</u>
<b><u>REGENERON PHARMACEUTICALS, INC.</u></b>	
<a href="#"><u>Report of Independent Registered Public Accounting Firm</u></a>	F-2
<a href="#"><u>Balance Sheets at December 31, 2007 and 2006</u></a>	F-3
<a href="#"><u>Statements of Operations for the years ended December 31, 2007, 2006, and 2005</u></a>	F-4
<a href="#"><u>Statements of Stockholders' Equity for the years ended December 31, 2007, 2006, and 2005</u></a>	F-5 to F-6
<a href="#"><u>Statements of Cash Flows for the years ended December 31, 2007, 2006, and 2005</u></a>	F-7
	F-8 to
<a href="#"><u>Notes to Financial Statements</u></a>	F-38

## 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, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007 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, 2007, 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 27, 2008

**REGENERON PHARMACEUTICALS, INC.**

**BALANCE SHEETS**  
**December 31, 2007 and 2006**

	<u>2007</u>	<u>2006</u>
	<u>(In thousands, except share data)</u>	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 498,925	\$ 237,876
Marketable securities	267,532	221,400
Accounts receivable from the sanofi-aventis Group	14,244	6,900
Accounts receivable — other	4,076	593
Prepaid expenses and other current assets	<u>13,052</u>	<u>3,215</u>
Total current assets	797,829	469,984
Restricted cash	1,600	1,600
Marketable securities	78,222	61,983
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	58,304	49,353
Other assets	<u>303</u>	<u>2,170</u>
Total assets	<u>\$ 936,258</u>	<u>\$ 585,090</u>
<b>LIABILITIES and STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 39,232	\$ 21,471
Deferred revenue from sanofi-aventis, current portion	18,855	8,937
Deferred revenue — other, current portion	25,577	14,606
Notes payable	<u>200,000</u>	
Total current liabilities	283,664	45,014
Deferred revenue from sanofi-aventis	126,431	61,013
Deferred revenue — other	65,896	62,439
Notes payable		<u>200,000</u>
Total liabilities	<u>475,991</u>	<u>368,466</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 — 2,260,266 in 2007 and 2,270,353 in 2006	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized; shares issued and outstanding — 76,592,218 in 2007 and 63,130,962 in 2006	77	63
Additional paid-in capital	1,253,235	904,407
Accumulated deficit	(793,217)	(687,617)
Accumulated other comprehensive income (loss)	<u>170</u>	<u>(231)</u>
Total stockholders' equity	460,267	216,624
Total liabilities and stockholders' equity	<u>\$ 936,258</u>	<u>\$ 585,090</u>

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

**REGENERON PHARMACEUTICALS, INC.**

**STATEMENTS OF OPERATIONS**

**For the Years Ended December 31, 2007, 2006, and 2005**

	<u>2007</u>	<u>2006</u>	<u>2005</u>
	(In thousands, except per share data)		
<b>Revenues</b>			
Contract research and development from sanofi-aventis	\$ 51,687	\$ 47,763	\$ 43,445
Other contract research and development	44,916	3,373	9,002
Contract manufacturing		12,311	13,746
Technology licensing	<u>28,421</u>		
	<u>125,024</u>	<u>63,447</u>	<u>66,193</u>
<b>Expenses</b>			
Research and development	201,613	137,064	155,581
Contract manufacturing		8,146	9,557
General and administrative	<u>37,865</u>	<u>25,892</u>	<u>25,476</u>
	<u>239,478</u>	<u>171,102</u>	<u>190,614</u>
Loss from operations	<u>(114,454)</u>	<u>(107,655)</u>	<u>(124,421)</u>
<b>Other income (expense)</b>			
Other contract income (includes \$25.0 million from sanofi-aventis)			30,640
Investment income	20,897	16,548	10,381
Interest expense	<u>(12,043)</u>	<u>(12,043)</u>	<u>(12,046)</u>
	<u>8,854</u>	<u>4,505</u>	<u>28,975</u>
Net loss before cumulative effect of a change in accounting principle	(105,600)	(103,150)	(95,446)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")		<u>813</u>	
Net loss	<u>\$ (105,600)</u>	<u>\$ (102,337)</u>	<u>\$ (95,446)</u>
<b>Net loss per share, basic and diluted:</b>			
Net loss before cumulative effect of a change in accounting principle	\$ (1.59)	\$ (1.78)	\$ (1.71)
Cumulative effect of adopting SFAS 123R		<u>0.01</u>	
Net loss	<u>\$ (1.59)</u>	<u>\$ (1.77)</u>	<u>\$ (1.71)</u>
Weighted average shares outstanding, basic and diluted	66,334	57,970	55,950

**REGENERON PHARMACEUTICALS, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
**For the Years Ended December 31, 2007, 2006, and 2005**

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation (In thousands)	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	Comprehensive Income (Loss)
	Shares	Amount	Shares	Amount						
<b>Balance, December 31, 2004</b>	2,358	\$ 2	53,502	\$ 54	\$ 675,389	\$ (2,299)	\$ (489,834)	\$ (769)	\$ 182,543	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			494		4,081				4,081	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			90		632				632	
Conversion of Class A Stock to Common Stock	(11)		11							
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(5)		(54)	54				
Stock-based compensation expense					19,963	1,930			21,893	
Net loss, 2005							(95,446)		(95,446)	\$ (95,446)
Change in net unrealized gain (loss) on marketable securities								299	299	299
<b>Balance, December 31, 2005</b>	2,347	2	54,092	54	700,011	(315)	(585,280)	(470)	114,002	<u>\$ (95,147)</u>
Issuance of Common Stock in a public offering at \$23.03 per share			7,600	8	175,020				175,028	
Cost associated with issuance of equity securities					(412)				(412)	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			1,243	1	10,391				10,392	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			121		1,884				1,884	
Conversion of Class A Stock to Common Stock	(77)		77							
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(2)							
Stock-based compensation expense					18,641				18,641	
Adjustment to reduce unearned compensation upon adoption					(315)	315				

of SFAS 123R											
Cumulative effect of adopting SFAS 123R					(813)				(813)		
Net loss, 2006							(102,337)		(102,337)	\$	(102,337)
Change in net unrealized gain (loss) on marketable securities								239	239		239
<b>Balance, December 31, 2006</b>	2,270	2	63,131	63	904,407	—	(687,617)	(231)	216,624	\$	<u>(102,098)</u>

(Continued)

**REGENERON PHARMACEUTICALS, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY — (Continued)**  
**For the Years Ended December 31, 2007, 2006, and 2005**

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation (In thousands)	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	Comprehensive Income (Loss)
	Shares	Amount	Shares	Amount						
Issuance of Common Stock in 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>	<u>2,260</u>	<u>\$ 2</u>	<u>76,592</u>	<u>\$ 77</u>	<u>\$ 1,253,235</u>	<u>—</u>	<u>\$ (793,217)</u>	<u>\$ 170</u>	<u>\$ 460,267</u>	<u>\$ (105,199)</u>

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

**REGENERON PHARMACEUTICALS, INC.**  
**STATEMENTS OF CASH FLOWS**  
**For the Years Ended December 31, 2007, 2006, and 2005**

	<u>2007</u>	<u>2006</u> (In thousands)	<u>2005</u>
<b>Cash flows from operating activities</b>			
Net loss	\$ (105,600)	\$ (102,337)	\$ (95,446)
Adjustments to reconcile net loss to net cash provided			
by (used in) operating activities			
Depreciation and amortization	11,487	14,592	15,504
Non-cash compensation expense	28,075	18,675	21,859
Impairment charge on marketable securities	5,943		
Cumulative effect of a change in accounting principle		(813)	
Changes in assets and liabilities			
(Increase) decrease in accounts receivable	(10,827)	29,028	6,581
(Increase) decrease in prepaid expenses and other assets	(9,649)	155	74
Decrease in inventory		3,594	1,250
Increase in deferred revenue	89,764	60,833	14,469
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	18,179	(652)	5,413
Total adjustments	<u>132,972</u>	<u>125,412</u>	<u>65,150</u>
Net cash provided by (used in) operating activities	<u>27,372</u>	<u>23,075</u>	<u>(30,296)</u>
<b>Cash flows from investing activities</b>			
Purchases of marketable securities	(594,446)	(456,893)	(102,990)
Sales or maturities of marketable securities	527,169	306,199	223,448
Capital expenditures	(18,446)	(2,811)	(4,964)
Increase in restricted cash		(1,600)	
Net cash (used in) provided by investing activities	<u>(85,723)</u>	<u>(155,105)</u>	<u>115,494</u>
<b>Cash flows from financing activities</b>			
Net proceeds from the issuance of Common Stock	319,400	185,008	4,081
Other		390	
Net cash provided by financing activities	<u>319,400</u>	<u>185,398</u>	<u>4,081</u>
Net increase in cash and cash equivalents	261,049	53,368	89,279
Cash and cash equivalents at beginning of period	<u>237,876</u>	<u>184,508</u>	<u>95,229</u>
Cash and cash equivalents at end of period	<u>\$ 498,925</u>	<u>\$ 237,876</u>	<u>\$ 184,508</u>
<b>Supplemental disclosure of cash flow information</b>			
Cash paid for interest	\$ 11,000	\$ 11,000	\$ 11,002

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

# REGENERON PHARMACEUTICALS, INC.

## NOTES TO FINANCIAL STATEMENTS

For the years ended December 31, 2007, 2006, and 2005

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

### 1. Organization and Business

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

### 2. Summary of Significant Accounting Policies

#### *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.

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

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

Building and improvements	7-30 years
Laboratory and computer equipment	3-5 years
Furniture and fixtures	5 years

Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets. 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 Statement of Financial Accounting Standards No. ("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.

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

***Revenue Recognition***

a. Contract Research and Development and Research Progress Payments

The Company recognizes 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”). 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 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 and 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 sanofi-aventis. 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 possible, and could result in material changes to the amount of revenue recognized each year in the future. In addition, performance periods may be extended if the Company and its collaborators decide to expand the clinical plans for a drug candidate into

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

additional disease indications. 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 (see Note 13).

c. Technology Licensing

The Company enters into non-exclusive license agreements with third parties that allow the third party to utilize the Company's *VelocImmune*<sup>®</sup> technology in its internal research programs. The terms of these agreements include annual, non-refundable, up-front 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 (see Note 12). Annual, non-refundable, up-front payments under these agreements, where continuing involvement is required of the Company, are deferred and recognized ratably over their respective annual license periods.

***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 (see Note 10), 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 (see Note 11), expenses related to the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. All costs associated with research and development are expensed as incurred.

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 start-up costs are typically 10% to 15% of the total contract value. On an actual basis, this percentage range can be 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

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)  
(Unless otherwise noted, dollars in thousands, except per share data)

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.

**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 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, 2007, 2006, and 2005 does not include common stock equivalents, since such inclusion would be antidilutive. Disclosures required by SFAS 128, *Earnings per Share*, have been included in Note 19.

**Income Taxes**

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which realization is uncertain. See Note 17.

**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, 2007, 2006, and 2005 have been included in the Statements of Stockholders' Equity.

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

***Concentrations of Credit Risk***

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities, and receivables from sanofi-aventis and Bayer HealthCare. 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 has 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 the Company to the risk of not being able to recover the full principal value of the security. The Company recognizes a charge to earnings in a period when the Company considers a marketable security to be other than temporarily impaired in value.

***Risks and Uncertainties***

Regeneron has had no sales of its products and there is no assurance that the Company's research and development efforts will be successful, that the Company will ever have commercially approved products, or that the Company will achieve significant sales of any such products. The Company has generally incurred net losses and negative cash flows from operations since its inception. Revenues to date have principally been limited to (i) payments from the Company's collaborators and other entities for the Company's development activities with respect to product candidates and to utilize the Company's technology platforms, (ii) payments for past contract manufacturing activities, and (iii) investment income. The Company operates in an environment of rapid change in technology and is dependent upon the services of its employees, consultants, collaborators, and certain third-party suppliers, 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.

Contract research and development revenue in 2007 was primarily earned from sanofi-aventis and Bayer HealthCare under collaboration agreements (see Note 11 for the terms of these agreements). The Company recognizes revenue from its collaborations with sanofi-aventis and Bayer HealthCare in accordance with SAB 104 and EITF 00-21, as described above. These collaboration agreements contain early termination provisions, as defined, 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. Significant estimates include (i) useful lives of property, plant, and equipment, (ii) the periods over which certain revenues and expenses will be recognized, including contract research and development revenue recognized from non-refundable licensing payments and expense recognition of certain clinical trial costs which are included in research and development expenses, (iii) the extent to which deferred tax assets and liabilities are offset by a valuation allowance, and (iv) 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 our Common Stock price, (b) 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), (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 compensation expense in accordance with the provisions of SFAS 123R, *Share-*

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

*Based Payment*, as described below, the Company is required to estimate, at the time of grant, the number of stock option awards that are expected to be forfeited.

***Stock-based Employee Compensation***

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of SFAS 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*. As a result, in 2005, the Company recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005 (including replacement options granted under the Company's stock option exchange program which concluded on January 5, 2005 (see Note 14)) and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. 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.

For the years ended December 31, 2007, 2006, and 2005, \$28.0 million, \$18.4 million, and \$19.9 million, respectively, of non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") was recognized in operating expenses. In addition, for the year ended December 31, 2005, \$0.1 million of Stock Option Expense was capitalized in inventory.

Other disclosures required by SFAS 123 and SFAS 123R have been included in Note 14.

***Statement of Cash Flows***

Supplemental disclosure of noncash investing and financing activities:

In 2007, 2006, and 2005, the Company recognized \$0.1 million, \$0.3 million, and \$1.9 million, respectively, of compensation expense related to Restricted Stock awards, the fair value of which is expensed, on a pro rata basis, over the period that the restrictions on the shares lapse (see Note 14).

Included in accounts payable and accrued expenses at December 31, 2007, 2006, and 2005 were \$1.7 million, \$0.8 million, and \$0.2 million of capital expenditures, respectively.

Included in accounts payable and accrued expenses at December 31, 2006, 2005, and 2004 were \$1.4 million, \$1.9 million, and \$0.6 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2007, 2006, and 2005, the Company contributed 64,532, 120,960, and 90,385 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

Included in marketable securities at December 31, 2007, 2006, and 2005 were \$2.2 million, \$1.5 million, and \$1.2 million of accrued interest income, respectively.

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

In September 2006, the Financial Accounting Standards Board (“FASB”) issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (“GAAP”), and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, however on December 14, 2007, the FASB issued a proposed staff position (“FSP FAS 157-b”) which would delay the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. The Company is required to adopt SFAS 157 as it relates to the Company’s financial assets and financial liabilities effective for the fiscal year beginning January 1, 2008, and as it relates to the Company’s nonfinancial assets and nonfinancial liabilities for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of SFAS 157 will have a material impact on the Company’s financial statements.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Management does not anticipate that the adoption of SFAS 159 will have a material impact on the Company’s financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, *Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (“EITF 07-3”). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company is required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Management does not anticipate that the adoption of EITF 07-3 will have a material impact on the Company’s financial statements.

**3. Severance Costs**

In September 2005, the Company announced plans to reduce its workforce by approximately 165 employees in connection with narrowing the focus of the Company’s research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of the Company’s collaboration with The Procter & Gamble Company, and the completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions occurred during 2006 as the Company completed activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction were comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included non-cash expenses due to the accelerated vesting of certain stock options and restricted stock held by affected employees. Estimated termination costs associated with the planned workforce reduction in 2006 were measured in October 2005 and were expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for*

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

*Costs Associated with Exit or Disposal Activities.* The total costs associated with the 2005 and 2006 workforce reductions were \$2.6 million, including \$0.2 million of non-cash expenses.

Severance costs associated with the workforce reduction plan that were charged to expense in 2005, 2006, and 2007 consist of the following:

	<u>Costs charged to expense in 2005</u>	<u>Costs paid or settled in 2005</u>	<u>Accrued liability at December 31, 2005</u>
Employee severance, payroll taxes, and benefits	\$ 1,786	\$ 879	\$ 907
Other severance costs	206	30	176
Non-cash expenses	221	221	
Total	<u>\$ 2,213</u>	<u>\$ 1,130</u>	<u>\$ 1,083</u>

	<u>Costs charged to expense 2006</u>	<u>Costs paid or settled in 2006</u>	<u>Accrued liability at December 31, 2006</u>
Employee severance, payroll taxes, and benefits	\$ 315	\$ (1,159)	\$ 63
Other severance costs	33	(209)	
Total	<u>\$ 348</u>	<u>\$ (1,368)</u>	<u>\$ 63</u>

	<u>Costs charged to expense in 2007</u>	<u>Costs paid or settled in 2007</u>	<u>Accrued liability at December 31, 2007</u>
Employee severance, payroll taxes, and benefits	\$ 43	\$ (106)	\$ —

These severance costs are included in the Company's Statement of Operations for the years ended December 31, 2007, 2006, and 2005 as follows:

	<u>2007 R&amp;D</u>	<u>2006 R&amp;D</u>	<u>G&amp;A</u>	<u>2005 R&amp;D</u>	<u>G&amp;A</u>
Employee severance, payroll taxes, and benefits	\$ 43	\$ 317	\$ (2)	\$ 1,734	\$ 52
Other severance costs		33		206	
Non-cash expenses				215	6
Total	<u>\$ 43</u>	<u>\$ 350</u>	<u>\$ (2)</u>	<u>\$ 2,155</u>	<u>\$ 58</u>

For segment reporting purposes (see Note 20), all severance-related expenses are included in the Research & Development segment.

#### 4. Marketable Securities

The Company considers its unrestricted marketable securities to be "available-for-sale," as defined by SFAS 115, *Accounting for Certain Investments in Debt and Equity Securities*. Gross unrealized holding gains and losses are reported as a net amount in a separate component of stockholders' equity entitled Accumulated Other Comprehensive Income (Loss). The net change in unrealized holding gains and losses is excluded from operations and included in stockholders' equity as a separate component of comprehensive loss.

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)  
(Unless otherwise noted, dollars in thousands, except per share data)

The following tables summarize the amortized cost basis of marketable securities, the aggregate fair value of marketable securities, and gross unrealized holding gains and losses at December 31, 2007 and 2006:

	Amortized Cost Basis	Fair Value	Unrealized Holding		
			Gains	(Losses)	Net
<b>At December 31, 2007</b>					
Maturities within one year					
Corporate and municipal bonds	\$ 69,213	\$ 69,263	\$ 74	\$ (24)	\$ 50
Asset-backed securities	73,939	73,706	99	(332)	(233)
Commercial paper	64,846	64,870	25	(1)	24
U.S. government obligations	50,386	50,475	89		89
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>
Maturities between one and two years					
Corporate and municipal bonds	49,724	49,947	289	(66)	223
Asset-backed securities	20,295	20,323	173	(145)	28
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>
<b>At December 31, 2006</b>					
Maturities within one year					
Corporate and municipal bonds	\$ 25,254	\$ 25,221		\$ (33)	\$ (33)
Asset-backed securities	94,159	94,075	\$ 6	(90)	(84)
Commercial paper	69,547	69,535	9	(21)	(12)
U.S. government obligations	22,267	22,243	1	(25)	(24)
Certificates of deposit	10,327	10,326	2	(3)	(1)
	<u>221,554</u>	<u>221,400</u>	<u>18</u>	<u>(172)</u>	<u>(154)</u>
Maturities between one and two years					
Corporate and municipal bonds	6,047	6,032		(15)	(15)
Asset-backed securities	32,835	32,762	3	(76)	(73)
U.S. government obligations	23,190	23,189	6	(7)	(1)
	<u>62,072</u>	<u>61,983</u>	<u>9</u>	<u>(98)</u>	<u>(89)</u>
	<u>\$ 283,626</u>	<u>\$ 283,383</u>	<u>\$ 27</u>	<u>\$ (270)</u>	<u>\$ (243)</u>

In addition, cash equivalents at December 31, 2007 and 2006 included an unrealized holding loss of \$9 thousand and an unrealized holding gain of \$12 thousand, respectively.

Realized gains and losses are included as a component of investment income. For the years ended December 31, 2007, 2006, and 2005, gross realized gains and losses on sales of marketable securities was not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the securities, adjusted for the amortization of any discount or premium. In 2007, deterioration in the credit quality of marketable securities from two issuers

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)  
 (Unless otherwise noted, dollars in thousands, except per share data)

has subjected the Company to the risk of not being able to recover the full principal value of these securities, which totals \$14.0 million. Since market activity for these securities is very limited, their fair values at December 31, 2007 were developed based on information provided by the Company's investment advisors, including but not limited to estimated value of the assets underlying each security and quoted bid prices, as applicable. 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. Excluding these other than temporarily impaired securities, fair value of marketable securities has been estimated based on inputs that are observable for each security, either directly or indirectly, through corroboration with observable market data.

The following table shows the unrealized losses and fair value of the Company's marketable securities with unrealized losses that are deemed to be only temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at December 31, 2007 and 2006. The securities listed at December 31, 2007 mature at various dates through December 2009.

	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, 2007</b>						
Corporate and municipal bonds	\$ 36,979	\$ (89)	\$ 3,056	\$ (1)	\$ 40,035	\$ (90)
Asset-backed securities	18,674	(360)	12,390	(116)	31,064	(476)
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>
<b>At December 31, 2006</b>						
Corporate and municipal bonds	\$ 12,113	\$ (31)	\$ 12,191	\$ (18)	\$ 24,304	\$ (49)
Asset-backed securities	92,544	(161)	891	(5)	93,435	(166)
Commercial paper	12,949	(20)			12,949	(20)
U.S. government obligations	23,273	(25)	2,023	(7)	25,296	(32)
Certificates of deposit	3,034	(3)			3,034	(3)
	<u>\$ 143,913</u>	<u>\$ (240)</u>	<u>\$ 15,105</u>	<u>\$ (30)</u>	<u>\$ 159,018</u>	<u>\$ (270)</u>

At December 31, 2007, the unrealized losses in the Company's marketable securities were primarily caused by general instability in the credit markets at the end of 2007. At December 31, 2006, the unrealized losses in the Company's marketable securities were primarily caused by interest rate increases, which generally resulted in a decrease in the market value of the Company's portfolio. Based upon the Company's currently projected sources and uses of cash, the Company intends to hold these securities until a recovery of fair value, which may be maturity. Therefore, the Company does not consider these marketable securities at December 31, 2007 and 2006 to be other than temporarily impaired. However, further deterioration in the credit markets may subject the Company to the risk of not being able to recover the full principal value of certain of its marketable securities, which could have a material impact on the Company's financial statements.

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

**5. Accounts Receivable**

Accounts receivable as of December 31, 2007 and 2006 consist of the following:

	<u>2007</u>	<u>2006</u>
Receivable from sanofi-aventis (see Note 11)	\$ 14,244	\$ 6,900
Receivable from Bayer HealthCare (see Note 11)	2,797	
Other	<u>1,279</u>	<u>593</u>
	<u>\$ 18,320</u>	<u>\$ 7,493</u>

**6. Property, Plant, and Equipment**

Property, plant, and equipment as of December 31, 2007 and 2006 consist of the following:

	<u>2007</u>	<u>2006</u>
Land	\$ 2,117	\$ 475
Building and improvements	66,208	57,045
Leasehold improvements	13,982	14,662
Construction-in-progress	4,677	203
Laboratory and other equipment	61,717	59,164
Furniture, fixtures, software and computer equipment	<u>6,080</u>	<u>5,413</u>
	154,781	136,962
Less, accumulated depreciation and amortization	<u>(96,477)</u>	<u>(87,609)</u>
	<u>\$ 58,304</u>	<u>\$ 49,353</u>

In October 2007, the Company purchased land and a building in Rensselaer, New York for \$9.0 million. The Company previously leased manufacturing, office, and warehouse space in a portion of the purchased building (see Note 10).

Depreciation and amortization expense on property, plant, and equipment amounted to \$10.4 million, \$14.3 million, and \$15.4 million for the years ended December 31, 2007, 2006, and 2005, respectively. Included in these amounts was \$0.7 million and \$0.9 million of depreciation and amortization expense related to contract manufacturing that was capitalized into inventory for the years ended December 31, 2006 and 2005, respectively.

**7. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses as of December 31, 2007 and 2006 consist of the following:

	<u>2007</u>	<u>2006</u>
Accounts payable	\$ 8,128	\$ 4,349
Payable due to Bayer HealthCare (see Note 11)	4,892	
Accrued payroll and related costs	14,514	9,932
Accrued clinical trial expense	5,609	2,606
Accrued expenses, other	3,797	2,292
Interest payable on convertible notes	<u>2,292</u>	<u>2,292</u>
	<u>\$ 39,232</u>	<u>\$ 21,471</u>

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

**8. Deferred Revenue**

Deferred revenue as of December 31, 2007 and 2006 consists of the following:

	<u>2007</u>	<u>2006</u>
<b>Current portion:</b>		
Received from sanofi-aventis (see Note 11)	\$ 18,855	\$ 8,937
Received from Bayer HealthCare (see Note 11)	13,179	12,561
Received for technology license agreements (see Note 12)	11,579	
Other	<u>819</u>	<u>2,045</u>
	<u>\$ 44,432</u>	<u>\$ 23,543</u>
<b>Long-term portion:</b>		
Received from sanofi-aventis	\$ 126,431	\$ 61,013
Received from Bayer HealthCare	<u>65,896</u>	<u>62,439</u>
	<u>\$ 192,327</u>	<u>\$ 123,452</u>

**9. 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 Class A Stockholders are entitled to ten votes per share, while Common Stockholders are entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. 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 October 2001, the Company completed a private placement of \$200.0 million aggregate principal amount of senior subordinated notes, which are convertible into shares of the Company's Common Stock. See Note 10.

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 11.

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 11) and the Company's collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept (see Note 11), 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

## REGENERON PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS — (Continued) (Unless otherwise noted, dollars in thousands, except per share data)

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 indertaken 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 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.

#### 10. 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, the Company amended the December 2006 operating lease agreement to increase the amount of new space to be leased. The term of the lease is expected to commence in mid-2008 and will expire approximately 16 years later. 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, 2007 and 2006 in the accompanying financial statements.

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.

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 (see Note 6).

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

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

Based, in part, upon budgeted construction and tenant improvement costs related to our new operating lease for facilities to be constructed in Tarrytown, New York, as described above, at December 31, 2007, 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>
2008	\$ 4,686	\$ 429	\$ 5,115
2009	9,573	339	9,912
2010	14,453	185	14,638
2011	14,713	13	14,726
2012	14,979		14,979
Thereafter	193,643		193,643
	<u>\$ 252,047</u>	<u>\$ 966</u>	<u>\$ 253,013</u>

Rent expense under operating leases was:

<u>Year Ending December 31,</u>	<u>Facilities</u>	<u>Equipment</u>	<u>Total</u>
2007	\$ 4,632	\$ 363	\$ 4,995
2006	4,492	307	4,799
2005	4,606	319	4,925

In addition to its rent expense for various facilities, the Company paid additional rental charges for utilities, real estate taxes, and operating expenses of \$8.8 million, \$8.7 million, and \$9.5 million for the years ended December 31, 2007, 2006, and 2005, 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 bear interest at 5.5% per annum, payable semi-annually, and mature on October 17, 2008. Deferred Financing Costs, which are included in other assets, are amortized as interest expense over the period from the Notes’ issuance to stated maturity. The Notes are convertible, at the option of the holder at any time, into shares of the Company’s Common Stock at a conversion price of approximately \$30.25 per share, subject to adjustment in certain circumstances. Regeneron may also redeem some or all of the Notes at any time if the closing price of the Company’s Common Stock has exceeded 140% of the conversion price then in effect for a specified period of time. The fair market value of the Notes fluctuates over time. The estimated fair value of the Notes at December 31, 2007 was approximately \$206.1 million.

**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

## REGENERON PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS — (Continued) (Unless otherwise noted, dollars in thousands, except per share data)

Company incurred expenses of \$1.0 million, \$1.1 million, and \$1.0 million for the years ended December 31, 2007, 2006, and 2005, respectively.

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

In December 2003, the Company entered into a non-exclusive license agreement with Collectis Inc. that granted the Company certain rights in a family of patents relating to homologous recombination. Collectis now claims that agreements the Company entered into relating to its *VelocImmune* mice with AstraZeneca UK Limited, Astellas Pharma Inc., and sanofi-aventis are outside of the scope of the Company's license from Collectis. The Company disagrees with Collectis' position and is in discussions with Collectis regarding this matter. If the Company is not able to resolve this dispute, Collectis may commence a lawsuit against the Company and its *VelocImmune* licensees alleging infringement of Collectis' patents. The Company is unable to estimate the losses or expenses, if any, that may result from the resolution of this matter; however, such losses or expenses could be material.

#### 11. 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 or other contract income, as applicable, totaled \$96.6 million, \$51.1 million, and \$83.1 million in 2007, 2006, and 2005, 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 \$108.2 million, \$43.4 million and \$42.2 million in 2007, 2006, and 2005, 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

## REGENERON PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS — (Continued) (Unless otherwise noted, dollars in thousands, except per share data)

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 \$400.0 million in additional milestone payments upon receipt of specified marketing approvals. This total includes up to \$360.0 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. Another \$40.0 million of milestone payments relate 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 \$306.8 million as of December 31, 2007, 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 \$47.1 million, \$47.8 million, and \$43.4 million of contract research and development revenue in 2007, 2006, and 2005, respectively, in connection with the Aventis Agreement, as amended. The Company also recognized the \$25.0 million Intraocular Termination Payment as other contract income in 2005. At December 31, 2007 and 2006, amounts receivable from sanofi-aventis totaled \$10.5 million and \$6.9 million, respectively, and deferred revenue was \$61.2 million and \$70.0 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 9).

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 \$475.0 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 \$75.0 million for the period from the collaboration's inception through December 31, 2008, and \$100.0 million annually in each of the next four years. The Discovery

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)  
(Unless otherwise noted, dollars in thousands, except per share data)

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. Upon inception of the Antibody Collaboration, the Company and sanofi-aventis began co-developing the first therapeutic antibody, REGN88, under the License Agreement.

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 \$0.7 million as of December 31, 2007) 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 \$250.0 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* technology for agreed upon consideration.

## REGENERON PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS — (Continued) (Unless otherwise noted, dollars in thousands, except per share data)

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 \$85.0 million up-front payment received in December 2007 and reimbursement of Regeneron-incurred expenses under the Discovery and License Agreements are being recognized as contract research and development revenue over the related performance period. In connection with the Antibody Collaboration, the Company recognized \$4.6 million of contract research and development revenue in 2007. In addition, at December 31, 2007, amounts receivable from sanofi-aventis totaled \$3.7 million and deferred revenue was \$84.1 million.

#### **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 \$110.0 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 the 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 \$135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

The Company will share equally with Bayer HealthCare in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. If the 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 \$25.4 million as of December 31, 2007) 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 the VEGF Trap-Eye and retains exclusive rights to any future profits from commercialization.

Agreed upon development expenses incurred by both companies in 2007 under a global development plan were shared as follows: The first \$50.0 million were shared equally and the Company was solely responsible for up to the next \$40.0 million. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

In 2008, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first \$70.0 million will be shared equally, the Company is solely responsible for up to the next \$30.0 million; and over \$100.0 million will be shared equally. In 2009 and thereafter, all development expenses will be shared equally. Regeneron 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 the 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 the VEGF Trap-Eye in wet AMD. The plan includes 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

## REGENERON PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS — (Continued) (Unless otherwise noted, dollars in thousands, except per share data)

HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for the 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, and the financial statement classifications and periods in which past and future payments from Bayer HealthCare (including the \$75.0 million up-front payment and development and regulatory milestone payments) and cost-sharing of VEGF Trap-Eye development expenses will be recognized in the Company's Statement of Operations.

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, 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, 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, as a cumulative catch-up, 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 the Company's 2007 VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In addition, in the fourth quarter of 2007, the Company recognized as additional research and development expense a cumulative catch-up of \$10.6 million of 2007 VEGF Trap-Eye development expenses that the Company was obligated to reimburse to Bayer HealthCare.

At December 31, 2007, in connection with cost-sharing of VEGF Trap-Eye development expenses under the collaboration, \$4.9 million was payable to Bayer HealthCare and \$2.8 million was receivable from Bayer HealthCare. In addition, at December 31, 2007 and 2006, deferred revenue from the Company's collaboration with Bayer HealthCare was \$79.1 million and \$75.0 million, respectively.

#### ***c. The Procter & Gamble Company***

In May 1997, the Company entered into a long-term collaboration with The Procter & Gamble Company to discover, develop, and commercialize pharmaceutical products, and Procter & Gamble agreed to provide funding for Regeneron's research efforts related to the collaboration. In accordance with the companies' collaboration agreement (the "P&G Agreement"), Procter & Gamble was obligated to fund Regeneron research on therapeutic areas that were of particular interest to Procter & Gamble through December 2005, with no further research obligations by either party thereafter. Under the P&G Agreement, research support from Procter & Gamble was \$2.5 million per quarter, plus adjustments for inflation, through December 2005.

In June 2005, the Company and Procter & Gamble amended the P&G Agreement. Pursuant to the terms of the modified agreement, the Company and Procter & Gamble agreed that the research activities of the parties under the P&G Agreement were completed on June 30, 2005, six months prior to the December 31, 2005 expiration date in the P&G Agreement. In connection with the amendment, Procter & Gamble made a one-time \$5.6 million payment to Regeneron and the Company paid approximately \$1.0 million to Procter & Gamble to acquire certain capital equipment owned by Procter & Gamble and located at the Company's facilities. Procter & Gamble and the Company divided rights to research programs and pre-clinical product candidates that were developed during the research term of the P&G Agreement. Neither party has the right to participate in the development or commercialization of the other party's product candidates. The Company is entitled to receive royalties based on any future

## REGENERON PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS — (Continued) (Unless otherwise noted, dollars in thousands, except per share data)

product sales of a Procter & Gamble pre-clinical candidate arising from the collaboration, and Procter & Gamble is entitled to receive a small royalty on any sales of a single Regeneron candidate that is currently not being developed. Neither party is entitled to receive royalties or other payments based on any other products arising from the collaboration.

Contract research and development revenue related to the Company's collaboration with Procter & Gamble was \$6.0 million in 2005. In addition, the one-time \$5.6 million payment made by Procter & Gamble to the Company in connection with the amendment to the P&G Agreement was recognized as other contract income in 2005.

#### *d. 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*® 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 2007, 2006, and 2005, the Company recognized \$2.4 million, \$1.8 million, and \$2.2 million, respectively, of contract research and development revenue in connection with the Serono Agreement.

#### *e. 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. The NIH grant provides a minimum of \$17.9 million in funding over a five-year period, 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. The Company will also receive another \$1.0 million in funding to optimize certain existing technology for use in the Knockout Mouse Project. In 2007 and 2006, the Company recognized contract research and development revenue of \$5.5 million and \$0.5 million, respectively, from the NIH Grant.

## 12. 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* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million non-refundable, up-front payment to the Company which was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. AstraZeneca is required to make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. 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 year ended December 31, 2007, the Company recognized \$17.1 million of revenue and, at December 31, 2007, deferred revenue was \$2.9 million.

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* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million non-refundable, up-front payment to the Company, which was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. Astellas is required to make up to five additional annual payments of

## REGENERON PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS — (Continued) (Unless otherwise noted, dollars in thousands, except per share data)

\$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. 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 year ended December 31, 2007, the Company recognized \$11.3 million of revenue and, at December 31, 2007, deferred revenue was \$8.7 million.

#### 13. 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 originally extended for six years. In February 2005, the Company and Merck amended the Merck Agreement to extend the Production Period 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 the cost of Company activities performed on behalf of Merck prior to the Production Period and for miscellaneous costs during the Production Period ("Internal Costs"). These payments 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 ("Manufacturing Payments") were recognized after the Intermediate was tested and approved by, and shipped (FOB Shipping Point) to, Merck.

In 2006 and 2005, Merck contract manufacturing revenue totaled \$12.3 million and \$13.7 million, respectively. Such amounts include \$1.2 million and \$1.4 million of previously deferred Capital Costs, respectively.

#### 14. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan") which, as amended, provides for the issuance of up to 18,500,000 shares of Common Stock in respect of awards. In addition, shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the 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.

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)  
(Unless otherwise noted, dollars in thousands, except per share data)

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, 2007, there were 744,879 shares available for future grants under the 2000 Incentive Plan.

**a. Stock Options**

Transactions involving stock option awards during 2005, 2006, and 2007 under the 1990 and 2000 Incentive Plans are summarized in the table below.

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

<u>Stock Options:</u>	<u>Number of Shares</u>	<u>Weighted- Average Exercise Price</u>	<u>Weighted- Average Remaining Contractual Term (in years)</u>	<u>Intrinsic Value (in thousands)</u>
Outstanding at December 31, 2004	15,140,568	\$ 18.68		
<b>2005:</b>				
Granted	4,551,360	\$ 10.08		
Forfeited	(1,975,108)	\$ 20.83		
Expired	(2,399,410)	\$ 30.18		
Exercised	<u>(597,918)</u>	\$ 9.50		
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	<u>17,672,356</u>	\$ 17.05	6.68	\$ 146,827
Vested and expected to vest at				
December 31, 2007	16,945,428	\$ 17.09	6.62	\$ 140,881
Exercisable at December 31, 2005	7,321,256	\$ 17.79		
Exercisable at December 31, 2006	7,890,856	\$ 17.41		
Exercisable at December 31, 2007	9,369,665	\$ 17.02	5.27	\$ 86,252

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 2007, 2006, and 2005 was \$12.6 million, \$13.2 million, and \$1.6 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, 2005, 2006, and 2007.

REGENERON PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS — (Continued)  
(Unless otherwise noted, dollars in thousands, except per share data)

	Number of Options Granted	Weighted- Average Exercise Price	Weighted- Average Fair Value
<b>2005:</b>			
Exercise price equal to market price	4,551,360	\$ 10.08	\$ 6.68
<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

The following table summarizes stock option information as of December 31, 2007:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted- Average Exercise Price	Number Exercisable	Weighted- Average Exercise Price
\$ 4.83 to \$ 8.50	2,075,472	3.35	\$ 8.19	840,272	\$ 7.80
\$ 8.52 to \$ 9.49	2,539,210	5.76	\$ 9.30	1,973,719	\$ 9.26
\$ 9.50 to \$11.64	2,122,728	7.79	\$ 11.61	1,028,792	\$ 11.59
\$11.70 to \$17.89	2,300,442	6.28	\$ 13.47	2,018,882	\$ 13.25
\$18.17 to \$20.32	3,481,247	7.91	\$ 19.96	1,496,971	\$ 19.73
\$20.79 to \$27.07	3,221,553	9.72	\$ 22.05	79,325	\$ 23.50
\$27.53 to \$37.94	1,871,704	3.45	\$ 32.85	1,871,704	\$ 32.85
\$51.56 to \$51.56	<u>60,000</u>	2.16	\$ 51.56	<u>60,000</u>	\$ 51.56
\$ 4.83 to \$51.56	<u>17,672,356</u>	6.68	\$ 17.05	<u>9,369,665</u>	\$ 17.02

Non-cash stock-based employee compensation expense recognized in operating expenses is provided in Note 2. As of December 31, 2007, there was \$60.6 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 1.8 years. In addition, there are 723,092 options which are unvested as of December 31, 2007 and would become vested upon the attainment of certain performance and service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2.7 million and will begin to be recognized only if, and when, these options' performance condition is considered to be probable of attainment.

**Fair value Assumptions:**

The fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Incentive Plan during 2007, 2006, and 2005 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this 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 option grants with similar exercise prices. 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

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

the weighted average values of the assumptions used in computing the fair value of option grants during 2007, 2006, and 2005.

	<u>2007</u>	<u>2006</u>	<u>2005</u>
Expected volatility	53%	67%	71%
Expected lives from grant date	5.6 years	6.5 years	5.9 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	3.60%	4.51%	4.16%

**2005 Stock Option Exchange:**

In December 2004, the Company's shareholders approved a stock option exchange program. Under the program, Company regular employees who work an average of 20 hours per week, other than the Company's chairman and the Company's president and chief executive officer, were provided the opportunity to make a one-time election to surrender options granted under the 1990 and 2000 Incentive Plans that had an exercise price of at least \$18.00 and exchange them for replacement options granted under the 2000 Incentive Plan in accordance with the following exchange ratios:

<u>Exercise Price of Eligible Options</u>	<u>Exchange Ratio (Number of Eligible Options to be Surrendered and Cancelled for Each Replacement Option)</u>
\$18.00 to \$28.00	1.50
\$28.01 to \$37.00	2.00
\$37.01 and up	3.00

Participation in the stock option exchange program was voluntary, and non-employee directors, consultants, former employees, and retirees were not eligible to participate. The participation deadline was January 5, 2005 and 329 eligible employees participated in the program. These employees elected to exchange options with a total of 3,665,819 underlying shares of Common Stock, and the Company issued 1,977,840 replacement options with an exercise price of \$8.50 per share on January 5, 2005.

Each replacement option was completely vested upon grant. Each replacement option granted to an employee other than our executive vice president and senior vice presidents will ordinarily become vested and exercisable with respect to one-fourth of the shares initially underlying such option on each of the first, second, third and fourth anniversaries of the grant date so that such replacement option will be fully vested and exercisable four years after it was granted. Each replacement option granted to the Company's executive vice president and senior vice presidents will ordinarily vest with respect to all shares underlying such option if both (i) the Company's products have achieved gross sales of at least \$100 million during any consecutive twelve month period (either directly by the Company or through its licenses) and (ii) the specific executive or senior vice president has remained employed by the Company for at least three years from the date of grant. For all replacement options, the recipient's vesting and exercise rights are contingent upon the recipients continued employment through the applicable vesting date and subject to the other terms of the 2000 Incentive Plan and the applicable option award agreement. As is generally the case with respect to the option award agreements for options that were eligible for exchange pursuant to the stock option exchange program, the option award agreements for replacement options include provisions whereby the replacement options may be fully vested in connection with a "Change in Control" of the Company, as defined in the 2000 Incentive Plan.

Under the stock option exchange program, each replacement option has a term equal to the greater of (i) the remaining term of the surrendered option it replaces and (ii) six years from the date of grant of the replacement

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

option. This was intended to ensure that the employees who participated in the stock option exchange program would not derive any additional benefit from an extended option term unless the surrendered option had a remaining term of less than six years. In connection with the replacement options issued under the stock option exchange program, the Company will recognize total incremental compensation cost of \$2.0 million over the vesting periods of these options.

**b. Restricted Stock**

A summary of the Company's activity related to Restricted Stock awards for the years ended December 31, 2005 and 2006 is summarized below:

<u>Restricted Stock:</u>	<u>Number of Shares</u>	<u>Weighted- Average Grant Date Fair Value</u>
Outstanding at December 31, 2004	286,417	\$ 12.40
<b>2005:</b> Forfeited	(4,601)	\$ 11.70
Released	<u>(186,628)</u>	\$ 13.05
Outstanding at December 31, 2005	95,188	\$ 11.16
<b>2006:</b> Forfeited	(1,703)	\$ 9.74
Released	<u>(93,485)</u>	\$ 11.18
Outstanding at December 31, 2006	—	
<b>2007:</b> Granted	<u>500,000</u>	\$ 21.92
Outstanding at December 31, 2007	<u>500,000</u>	\$ 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, approximately two years for grants made in 2003, and 18 months for grants made in 2004. 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 Stockholder's 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 and \$0.1 million in 2006 and 2005, respectively. The Company recognized non-cash compensation expense from Restricted Stock awards of \$0.1 million, \$0.3 million, and \$1.9 million in 2007, 2006, and 2005, respectively. As of December 31, 2007, there were 500,000 unvested shares of Restricted Stock outstanding and \$10.9 million of stock-based compensation cost related to these unvested shares which had not yet been recognized in operating expenses.

**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

**REGENERON PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

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, 2007, 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 the Company to make discretionary contributions ("Contribution"), as defined. The Company recorded Contribution expense of \$1.4 million in 2007, \$1.3 million in 2006, and \$2.0 million in 2005; such amounts were accrued as liabilities at December 31, 2007, 2006, and 2005, respectively. 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 Savings Plan in satisfaction of these obligations.

**17. Income Taxes**

In 2007, 2006, and 2005, the Company incurred net losses for tax purposes and recognized a full tax valuation against deferred taxes. Accordingly, no provision or benefit for income taxes has been recorded in the accompanying financial statements.

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2007 and 2006 was as follows:

	<u>2007</u>	<u>2006</u>
Deferred tax assets:		
Net operating loss carry-forward	\$ 166,714	\$ 177,034
Fixed assets	17,245	15,640
Deferred revenue	96,148	58,739
Deferred compensation	15,159	14,213
Research and experimental tax credit carry-forward	25,446	23,248
Capitalized research and development costs	15,236	19,555
Other	7,036	3,897
Valuation allowance	<u>(342,984)</u>	<u>(312,326)</u>
	<u>—</u>	<u>—</u>

The Company's valuation allowance increased by \$30.7 million in 2007, 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 11). In 2006, the Company's valuation allowance increased by \$41.6 million, due primarily to increases in the Company's net operating loss carry-forward and the temporary difference related to deferred revenue, principally resulting from the non-refundable up-front payment received from Bayer HealthCare in 2006 (see Note 11).

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 uncertain income tax positions.

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

The Company is primarily subject to U.S. federal and New York State income tax. For all years presented, the Company's effective income tax rate is zero. The difference between the Company's effective income tax rate and the Federal statutory rate of 35% is attributable to state tax benefits and tax credit carry-forwards offset by an increase in the deferred tax valuation allowance. The Company's 1992 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 January 1 and December 31, 2007, the Company had no accruals for interest or penalties related to income tax matters.

As of December 31, 2007, the Company had available for tax purposes unused net operating loss carry-forwards of \$423.2 million which will expire in various years from 2008 to 2027 and included \$12.7 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 2008 to 2027. 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. 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 2007, 2006, and 2005, 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:

	<b>December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
Net loss (Numerator)	\$ (105,600)	\$ (102,337)	\$ (95,446)
Weighted-average shares, in thousands (Denominator)	66,334	57,970	55,950
Basic and diluted net loss per share	\$ (1.59)	\$ (1.77)	\$ (1.71)

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

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,		
	2007	2006	2005
<b>Options:</b>			
Weighted average number, in thousands	15,385	14,139	13,299
Weighted average exercise price	\$ 15.97	\$ 14.41	\$ 14.59
<b>Restricted Stock:</b>			
Weighted average number, in thousands	21	23	165
<b>Convertible Debt:</b>			
Weighted average number, in thousands	6,611	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25	\$ 30.25

In connection with the Company's stock option exchange program (see Note 14), on January 5, 2005, eligible employees elected to exchange options with a total of 3,665,819 underlying shares of Common Stock, and the Company issued 1,997,840 replacement options with an exercise price of \$8.50 per share.

**20. Segment Information**

Through 2006, the Company's operations were managed in two business segments: research and development, and contract manufacturing.

*Research and development:* 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 includes revenues and expenses related to activities conducted under research and development agreements (see Note 11) and technology licensing agreements (see Note 12).

*Contract manufacturing:* Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2006 and 2005, the Company produced a vaccine intermediate for Merck & Co., Inc. under a manufacturing agreement, which expired in October 2006 (see Note 13).

The accounting policies for the segments are the same as those described in Note 2, Summary of Significant Accounting Policies. Due to the expiration of the Company's manufacturing agreement with Merck in October 2006, beginning in 2007, the Company only has a research and development business segment. Therefore, segment information has not been provided for 2007 in the table below.

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

The following table presents information about reported segments for the years ended December 31, 2006 and 2005.

	<u>Research &amp; Development</u>	<u>Contract Manufacturing</u>	<u>Reconciling Items</u>	<u>Total</u>
<b>2006</b>				
Revenues	\$ 51,136	\$ 12,311	—	\$ 63,447
Depreciation and amortization	13,549	—(1)	\$ 1,043	14,592
Non-cash compensation expense	18,357	318	(813)(2)	17,862
Interest expense			12,043	12,043
Net income (loss)	(111,820)	4,165	5,318(3)	(102,337)
Capital expenditures	3,339			3,339
Total assets	56,843	3	528,244(4)	585,090
<b>2005</b>				
Revenues	\$ 52,447	\$ 13,746	—	\$ 66,193
Depreciation and amortization	14,461	—(1)	\$ 1,043	15,504
Non-cash compensation expense	21,492	367	—	21,859
Interest expense			12,046	12,046
Other contract income	30,640			30,640
Net income (loss)	(97,970)	4,189	(1,665)(3)	(95,446)
Capital expenditures	4,667			4,667
Total assets	95,645	4,315	323,541(4)	423,501

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

**21. Unaudited Quarterly Results**

Summarized quarterly financial data for the years ended December 31, 2007 and 2006 are set forth in the following tables.

	<u>First Quarter Ended March 31, 2007</u>	<u>Second Quarter Ended June 30, 2007</u>	<u>Third Quarter Ended September 30, 2007</u>	<u>Fourth Quarter Ended December 31, 2007 (1)</u>
	(Unaudited)			
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)

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS — (Continued)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

	<u>First Quarter Ended March 31, 2006</u>	<u>Second Quarter Ended June 30, 2006</u>	<u>Third Quarter Ended September 30, 2006</u>	<u>Fourth Quarter Ended December 31, 2006</u>
	(Unaudited)			
Revenues	\$ 18,219	\$ 19,258	\$ 15,624	\$ 10,346
Net loss before cumulative effect of a change in accounting principle	(21,193)	(23,576)	(27,410)	(30,971)
Net loss	(20,380)	(23,576)	(27,410)	(30,971)
Net loss per share, basic and diluted:				
Net loss before cumulative effect of a change in accounting principle	\$ (0.37)	\$ (0.41)	\$ (0.48)	\$ (0.51)
Net loss	\$ (0.36)	\$ (0.41)	\$ (0.48)	\$ (0.51)

- (1) As described in Note 11, 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.

## EXHIBIT INDEX

Exhibit Number	Description
3.1	— 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	(c) — 2000 Long-Term Incentive Plan.
10.3.1	(d) — Amendment No. 1 to 2000 Long-Term Incentive Plan, effective as of June 14, 2002.
10.3.2	(d) — Amendment No. 2 to 2000 Long-Term Incentive Plan, effective as of December 20, 2002.
10.3.3	(e) — Amendment No. 3 to 2000 Long-term Incentive Plan, effective as of June 14, 2004.
10.3.4	(f) — Amendment No. 4 to 2000 Long-term Incentive Plan, effective as of November 15, 2004.
10.3.5	(g) — 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.
10.3.6	(g) — 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.
10.3.7	(h) — 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.
10.4	(d) — Employment Agreement, dated as of December 20, 2002, between the Company and Leonard S. Schleifer, M.D., Ph.D.
10.5*	(i) — Employment Agreement, dated as of December 31, 1998, between the Company and P. Roy Vagelos, M.D.
10.6	(j) — Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, effective as of February 1, 2006.
10.7	(k) — Indenture, dated as of October 17, 2001, between Regeneron Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, as trustee.
10.8	(k) — Registration Rights Agreement, dated as of October 17, 2001, among Regeneron Pharmaceuticals, Inc., Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, and Robertson Stephens, Inc.
10.9*	(l) — IL-1 License Agreement, dated June 26, 2002, by and among the Company, Immunex Corporation, and Amgen Inc.
10.10*	(m) — Collaboration, License and Option Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and the Company.
10.11*	(n) — Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.11.1*	(i) — Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 31, 2004.
10.11.2	(o) — Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of January 7, 2005.
10.11.3*	(p) — Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 21, 2005.
10.11.4*	(p) — 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.
10.12	(n) — Stock Purchase Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.13*	(q) — License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
10.14*	(r) — Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007 by and between AstraZeneca UK Limited and Regeneron Pharmaceuticals, Inc.

<b>Exhibit Number</b>	<b>Description</b>
10.15	(s) — Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc.
10.16*	(t) — Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and Regeneron Pharmaceuticals, Inc.
10.17*	(u) — First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of October 24, 2007.
10.18*	— Discovery and Preclinical Development Agreement, dated as of November 28, 2007, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.19*	— 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.
10.20	— 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.
10.21	— 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.
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 and Exchange Act of 1934.
31.2	— Certification of CFO pursuant to Rule 13a-14 (a) under the Securities and Exchange Act of 1934.
32	— Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

**Description:**

- (a) Incorporated by reference from the Form 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 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2001, filed March 22, 2002.
- (d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2002, filed March 31, 2003.
- (e) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2004, filed August 5, 2004.
- (f) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 17, 2004.
- (g) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.
- (h) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.
- (i) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2004, filed March 11, 2005.
- (j) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 25, 2006.
- (k) Incorporated by reference from the Company's registration statement on Form S-3 (file number 333-74464).
- (l) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2002, filed August 13, 2002.
- (m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended March 31, 2003, filed May 15, 2003.
- (n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2003, filed November 11, 2003.
- (o)

Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.

- (p) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2005, filed February 28, 2006.
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- (q) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed October 18, 2006.
- (r) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2006, filed March 12, 2007.
- (s) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.
- (t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended March 31, 2007, filed May 4, 2007.
- (u) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended September 31, 2007, filed November 7, 2007.
- \* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

RESTATED CERTIFICATE OF INCORPORATION  
OF REGENERON PHARMACEUTICALS, INC.  
UNDER SECTION 807 THE BUSINESS CORPORATION LAW

The undersigned hereby certify that:

1. The name of the Corporation is Regeneron Pharmaceuticals, Inc. (the “Corporation”).
2. The Certificate of Incorporation of the Corporation was filed with the Department of State of the State of New York on January 11, 1988.
3. This Restated Certificate of Incorporation restates the Certificate of Incorporation, as heretofore amended, without amendment or change to read as herein set forth in full.
4. This Restated Certificate of Incorporation has been authorized by resolution duly adopted by the Corporation’s Board of Directors.

Accordingly, the Certificate of Incorporation, as heretofore amended, is hereby restated to be and read in its entirety as follows:

“ARTICLE I

NAME OF CORPORATION

The name of the corporation is Regeneron Pharmaceuticals, Inc. (the “Corporation”).

ARTICLE II

CORPORATE PURPOSES

The purpose or purposes for which the Corporation is formed is as follows, to wit:

To own, operate, manage and do everything normally associated with conducting the business of chemists, druggists, manufacturers, researchers, distributors, and dealers in medical, pharmaceutical, chemical and other preparations and compounds.

To engage in any lawful act or activity for which corporations may be formed under the Business Corporation Law. The Corporation is not formed to engage in any act or activity requiring the consent or approval of any state official, department, board, agency or other body without such consent or approval first being obtained.

To own, operate, manage, acquire and deal in property, real and personal, which may be necessary to the conduct of the business.

The Corporation shall have all of the powers enumerated in Section 202 of the Business Corporation Law, subject to any limitations provided in the Business Corporation Law or any other statutes in the State of New York.

ARTICLE III  
COUNTY OF OFFICE

The county in which the office of the Corporation is to be located in the State of New York is New York.

ARTICLE IV  
STOCK

The aggregate number of shares of all classes of capital stock which the Corporation shall have the authority to issue is two hundred and thirty million (230,000,000) shares, consisting of (a) 160,000,000 shares of common stock, par value \$.001 per share ("Common Stock"), (b) 40,000,000 shares of Class A Stock, par value \$.001 per share (the "Class A Stock", and collectively, such Common Stock and Class A Stock are referred to herein as the "Common Shares"), and (c) 30,000,000 shares of preferred stock, par value \$.01 per share.

1. Preferred Stock

The Board of Directors is hereby expressly authorized, by resolution or resolutions, to provide, out of the unissued and undesignated shares of preferred stock, for one or more series of preferred stock. Before any shares of any such series are issued, the Board of Directors shall fix, and hereby is expressly empowered to fix, by resolution or resolutions, the following provisions of the shares thereof:

(a) the designation of such series, the number of shares to constitute such series, and the stated value thereof if different from the par value thereof;

(b) whether the shares of such series shall have voting rights, in addition to any voting rights provided by law, and, if so, the terms of such voting rights, which may be general or limited;

(c) the dividends, if any, payable on such series, whether any such dividends shall be cumulative, and, if so, from what dates, the conditions and dates upon which such dividends shall be payable, the preference or relation which such dividends shall bear to the dividends payable on any shares of stock of any other class or any other series of this class;

(d) whether the shares of such series shall be subject to redemption by the Corporation, and, if so, the terms and conditions of such redemption, including the manner of selecting shares for redemption if less than all shares of such series are to be redeemed, the date or dates upon or after which they shall be redeemable, and the amount per share payable in case of redemption, which amount may vary under different conditions and at different redemption dates;

(e) the amount or amounts payable upon shares of such series upon, and the rights of the holders of such series in, the voluntary or involuntary liquidation, dissolution or winding up, or upon any distribution of the assets, of the Corporation, and whether such rights shall be in preference to, or in another relation to, the comparable rights of any other class or classes or series of stock;

(f) whether the shares of such series shall be subject to the operation of a retirement or sinking fund and, if so, the extent to and manner in which any such retirement or sinking fund shall be applied to the purchase or redemption of the shares of such series for retirement or other corporate purposes and the terms and provisions relative to the operation thereof;

(g) whether the shares of such series shall be convertible into, or exchangeable for, shares of stock of any other series of this class or any other securities and, if so, the price or prices or the rate or rates of conversion or exchange and the method, if any, of adjusting the same, and any other terms and conditions of conversion or exchange;

(h) the limitations and restrictions, if any, to be effective while any shares of such series are outstanding upon the payments of dividends or the making of other distributions on, and upon the purchase, redemption or other acquisition by the Corporation of, the Common Stock or shares of stock of any other class or any other series of this class;

(i) the conditions or restrictions, if any, upon the creation of indebtedness of the Corporation or upon the issue of any additional stock, including additional shares of such series or of any other series of this class or of any other class; and

(j) any other powers, preferences and relative, participating, optional and other special rights, and any qualifications, limitations and restrictions thereof.

The powers, preferences and relative, participating, optional and other special rights of each series of preferred stock, and the qualifications, limitations of restrictions thereof, if any, may differ from those of any and all other series at any time outstanding. All shares of any one series of preferred stock shall be identical in all respects with all other shares of such series, except that shares of any one series issued at different times may differ as to the dates from which dividends thereon shall accrue and/or be cumulative.

## 2. Common Stock and Class A Stock

(a) General. Except as hereinafter expressly set forth in Section 2, and subject to the rights of the holders of preferred stock at any time outstanding, the Class A Stock and the Common Stock, both of which are classes of common stock, shall have the same rights and privileges and shall rank equally, share ratably and be identical in respects as to all matters, including rights in liquidation.

(b) Voting Rights. Except as otherwise expressly provided by law, and subject to any voting rights provided to holders of preferred stock by this Certificate of Incorporation the Common Shares have exclusive voting rights on all matters requiring a vote of shareholders.

The holders of Common Stock shall be entitled to one vote per share on all matters to be voted on by the shareholders of the Corporation. The holders of Class A Stock shall be entitled to ten votes per share on all matters to be voted on by the shareholders of the Corporation.

Except as otherwise provided in this Certificate of Incorporation or as required by law, the holders of shares of Class A Stock and the holders of shares of Common Stock shall vote together as one class on all matters submitted to a vote of shareholders of the Corporation.

(c) Dividends and Distributions. Subject to the rights of the holders of preferred stock, and subject to any other provisions of this Certificate of Incorporation, as it may be amended from time to time, holders of Class A Stock and Common Stock shall be entitled to receive such dividends and other distributions in cash, in property or in shares of the Corporation as may be declared thereon by the Board of Directors from time to time out of assets or funds of the Corporation legally available therefore; provided, however, that no cash, property or share dividend or distribution may be declared or paid on the outstanding shares of either the Class A Stock or the Common Stock unless an identical per share dividend or distribution is simultaneously declared and paid on the outstanding shares of the other such class of common stock; provided, further, however, that a dividend of shares may be declared and paid in Class A Stock to holders of Class A Stock and in Common Stock to holders of Common Stock if the number of shares paid per share to holders of Class A Stock and to holders of Common Stock shall be the same. If the Corporation shall in any manner subdivide, combine or reclassify the outstanding shares of Class A Stock or Common Stock, the outstanding shares of the other such class of common stock shall be subdivided, combined or reclassified proportionally in the same manner and on the same basis as the outstanding shares of Class A Stock or Common Stock, as the case may be, have been subdivided, combined or reclassified.

### (d) Optional Conversion.

(1) The shares of Common Stock are not convertible into or exchangeable for shares of Class A Stock or any other shares of securities of the Corporation.

(2) Each share of Class A Stock may be converted, at any time and at the option of the holder thereof, into one fully paid and nonassessable share of Common Stock.

(e) Mandatory Conversion.

(1) Upon a Transfer by a Holder, other than to a “Permitted Transferee” of such Holder, shares of Class A Stock so Transferred shall, at midnight on the thirtieth day after delivery of written notice by the Corporation to such Holder that such Transfer has been made to a person other than a Permitted Transferee (for purposes of this paragraph (1), the “Conversion Time”), be automatically converted, without further act on anyone’s part, into an equal number of shares of Common Stock, and the stock certificates formerly representing such shares of Class A Stock shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; provided, however, that such automatic conversion of Class A Stock shall not occur if such shares of Class A Stock, prior to the Conversion Time, are Transferred back to such Holder or to one or more Permitted Transferees of such Holder.

(2) For purposes of this Section 2(e): A “Permitted Transferee” of a Holder shall mean, the following:

(i) In the case of any Holder, the Corporation or any one or more of its directly or indirectly wholly owned subsidiaries;

(ii) In the case of a Holder who is a natural person:

(A) The spouse of such Holder (the “Spouse”), any lineal ancestor of such Holder or of the Spouse, and any person who is a lineal descendent of a grandparent of such Holder or of the Spouse, or a spouse of any such lineal descendent or such lineal ancestor (collectively, the “Family Members”);

(B) A trust (including a voting trust) exclusively for the benefit of one or more of (x) such Holder, (y) one or more of his or her Family Members or (z) any organization to which contributions are deductible under 501(c)(3) of the Internal Revenue Code of 1986, as amended or any successor provision (the “Internal Revenue Code”) or for estate or gift tax purposes (a “Charitable Organization”); provided that such trust may include a general or special power of appointment for such Holder or Family Members (a “Trust”); provided, further, that if by reason of any change in the beneficiaries of such Trust, such Trust would not have qualified, at the time of the Transfer of Class A Stock to such Trust (for purposes of this sub-paragraph (B), the “Transfer Date”), as a Permitted Transferee, all shares of Class A Stock so Transferred to such Trust shall, at midnight on the thirtieth day after delivery of written notice by the Corporation to the trustee of such Trust of such change of beneficiary (for purposes of this sub-paragraph (B), the “Conversion Time”), be automatically converted, without further act on anyone’s part, into an equal number of shares of Common stock, and the stock certificates formerly representing such shares of Class A Stock

shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; provided, however, that such automatic conversion of such shares of Class A Stock shall not occur if, prior to the Conversion Time, (x) by reason of additional changes in the beneficiary of such Trust, such Trust would again have qualified as a "Permitted Transferee" of such Holder on the Transfer Date, or (y) such Trust Transfers such shares of Class A Stock to one or more persons who would qualify as a Permitted Transferee of the Holder who Transferred such shares to such Trust as if such Holder did not so Transfer such shares;

(C) A Charitable Organization established solely by one or more of such Holder or a Family Member;

(D) An Individual Retirement Account, as defined in Section 408(a) of the Internal Revenue Code, of which such Holder is a participant or beneficiary, provided that such Holder has the power to direct the investment of funds deposited into such Individual Retirement Account and to control the voting of securities held by such Individual Retirement Account (an "IRA");

(E) A pension, profit sharing, stock bonus or other type of plan or trust of which such Holder is a participant or beneficiary and which satisfies the requirements for qualification under Section 401(k) of the Internal Revenue Code, provided that such Holder has the power to direct the investment of funds deposited into such plan or trust and to control the voting of securities held by such plan or trust (a "Plan");

(F) Any corporation or partnership directly or indirectly controlled, individually or as a group, only by such Holder and/or any of his Permitted Transferees as determined under this clause (ii); provided that if by reason of any change in the direct or indirect control of such corporation or partnership, such corporation or partnership would not have qualified, at the time of the Transfer of Class A Stock to such corporation or partnership, as a Permitted Transferee of such Holder, all shares of Class A Stock so Transferred to such corporation or partnership shall in the manner set forth in paragraph (d) hereof, be converted into an equal number of shares of Common Stock; and

(G) The estate, executor, executrix or other personal representative, custodian, administrator or guardian of such Holder.

(iii) In the case of a Holder holding the shares of Class A Stock in question as trustee of an IRA, a Plan or a Trust, “Permitted Transferee” means (x) the person who transferred Class A Stock to such IRA, such Plan or such Trust, (y) any Permitted Transferee of any such person determined pursuant to this Section 2(e) and (z) any successor trustee or trustees in such capacity of such IRA, such Plan or such Trust,

(iv) In the case of a Holder which is a partnership, “Permitted Transferee” means any other person, directly or indirectly controlling, controlled by or under direct or indirect common control with such partnership, provided that, if by reason of any change in the direct or indirect control of such person, such person would not have qualified, at the time of the Transfer of the Class A Stock to such person, as a Permitted Transferee of such partnership, all shares of Class A Stock so Transferred to such person shall, in the manner set forth in paragraph (4) hereof, be converted into an equal number of shares of Common Stock;

(v) In the case of a Holder which is a corporation (other than a Charitable Organization) “Permitted Transferee” means any other person directly or indirectly controlling, controlled by or under direct or indirect common control with such corporation; provided that if by reason of any change in the direct or indirect control of such person, such person would not have qualified, at the time of the Transfer of the Class A Stock to such person, as a Permitted Transferee of such corporation, all shares of Class A Stock so Transferred to such person shall, in the manner set forth in paragraph (4) hereof, be converted into an equal number of shares of Common Stock; and

(vi) In the case of a Holder which is the estate of a deceased Holder or who is the executor, executrix or other personal representative, custodian or administrator of such Holder, or guardian of a disabled or adjudicated incompetent Holder or which is the estate of a bankrupt or insolvent Holder, which owns the shares of Class A Stock in question, “Permitted Transferee” means a Permitted Transferee of such deceased, or adjudicated incompetent, disabled, bankrupt or insolvent Holder as otherwise determined pursuant to this Section 2(e).

As used in this Section 2(e), the term “control” means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of the controlled person or entity.

As used in this Section 2(e), the term “Holder” means any holder of Class A Stock or of the proxy to vote shares of Class A Stock.

As used in this Section 2(e), the term “person” shall mean both natural persons and legal entities, unless otherwise specified. The relationship of any person that is derived by or through legal adoption shall be considered a natural relationship.

Each joint owner of shares or owner of a community property interest in shares of Class A Stock shall be considered a “Holder” of such shares. A minor for whom shares of Class A Stock are held pursuant to a Uniform Transfer to Minors Act or similar law shall be considered a Holder of such shares.

As used in this Section 2(e), a “Transfer” shall mean any Type of transfer of shares of Class A Stock, whether by sale, exchange, gift, operation of law, pledge, or otherwise or any transfer of the power to vote such shares by proxy or by transferring any proxy, and shares of Class A Stock shall refer to either (i) such shares of Class A Stock so transferred, (ii) the power to vote such shares so transferred or (iii) shares of Class A Stock for which the power to vote was so transferred, as the case may be.

(3) Notwithstanding anything to the contrary set forth herein, any Holder may pledge the shares of Class A Stock belonging to such Holder to a pledgee pursuant to a bona fide pledge of such shares as collateral security for indebtedness due to the pledgee, provided that such pledgee does not have the power to vote such shares and such shares remain subject to the provisions of this Section. In the event of foreclosure or other similar action by the pledgee, such shares, at midnight on the thirtieth day after delivery of notice by the Corporation to the pledgor of such foreclosure or other similar action (for purposes of this paragraph (3) the “Conversion Time”), shall be automatically converted, without further act on anyone’s part, into an equal number of shares of Common Stock and the stock certificates formerly representing such shares of Class A Stock shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; provided, however, that such automatic conversion of such shares of Class A Stock shall not occur if, prior to the Conversion Time, (x) such pledged shares of Class A Stock are transferred to a Permitted Transferee of the pledgor or (y) such foreclosure or other similar action is cancelled or annulled so that the pledgor retains the right to vote such shares.

(4) If by reason of any change of the direct or indirect control of a person subsequent to any Transfer to such person, such person would not have qualified, at the time of the Transfer of the Class A Stock to such person (the “Transfer Date”), as a Permitted Transferee under clause (ii)(F), clause (iv) or clause (v), as the case may be, all shares of Class A Stock Transferred pursuant to the relevant clause to such person shall, at midnight on the thirtieth day after delivery of written notice by the Corporation to such person of such change of the direct or indirect control of such person (the “Conversion Time”), be automatically converted, without further act on anyone’s part, into an equal number of shares of Common Stock, and the stock certificates formerly representing such shares of Class A Stock shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; provided, however, that such automatic conversion of Class A Stock shall not occur if, prior to the Conversion Time, (x) by reason of additional changes in the direct or indirect control of such person, such person would again have qualified on the Transfer Date as a “Permitted Transferee” under clause (ii)(F), clause (iv) or clause (v), as the case may be, or (y) such person Transfers all such shares of Class A Stock owned by such person to one or more persons who would qualify as a “Permitted Transferee” of the transferor of the Class A Stock to such person as if the transferor did not Transfer such shares on the Transfer Date.

(5) A good faith determination by the Board of Directors of the Corporation (x) that a transferee of shares of Class A Stock is or is not a Permitted Transferee of the transferor of such shares to such transferee on the date of Transfer, or (y) that, by reason of any change in the direct or indirect control of such transferee subsequent to such Transfer, such person would have or have not qualified at the time of the Transfer of the Class A Stock to such person as a Permitted Transferee shall be conclusive.

(6) All notices provided for herein shall be deemed to have been delivered three days after being sent by registered or certified mail, return receipt requested, postage prepaid, to the person to whom it is directed. If notice is to a Holder, such notice should be sent to him at the address set forth at the office of the Transfer Agent of the Corporation. If notice is to any other person, such notice should be sent to him at the address known by the Corporation at the time the notice is sent.

(7) The Corporation may, as a condition to the transfer or the registration of transfer of shares of Class A Stock to a purported Permitted Transferee, require the furnishing of such affidavits or other proof as it deems necessary to establish that such transferee is a Permitted Transferee. Each certificate representing shares of Class A Stock shall be endorsed with a legend that states that shares of Class A Stock are not transferable other than to certain transferees and are subject to certain restrictions as set forth in the Certificate of Incorporation of the Corporation filed with the Secretary of the State of New York.

(8) This Section 2(e) may not be amended without the affirmative vote of holders of the majority of the shares of Class A Stock and the affirmative vote of the holders of two-thirds of the shares of Common Stock, each voting separately as a class.

(f) Conversion Procedures.

(1) Each conversion of shares pursuant to Section 2(d) hereto will be effected by the surrender of the certificate or certificates, duly endorsed, representing the shares to be converted at the principal office of the Corporation at any time during normal business hours, together with a written notice by the holder stating the number of shares that such holder desires to convert and the names or name in which he wishes the certificate or certificates for the Common Stock to be issued. Such conversion shall be deemed to have been effected as of the close of business on the date on which such certificate or certificates have been surrendered, and at such time, the rights of any such holder with respect to the converted shares of such holder will cease and the person or persons in whose name or names the certificate or certificates for shares are to be issued upon such conversion will be deemed to have become the holder or holders of record of such shares represented thereby.

Promptly after such surrender, the Corporation will issue and deliver in accordance with the surrendering holder's instructions the certificate or certificates for the Common Stock issuable upon such conversion and a certificate representing any Class A Stock which was represented by the certificate or certificates delivered to the Corporation in connection with such conversion, but which was not converted.

(2) The issuance of certificates upon conversion of shares pursuant to Section 2(d) hereto will be made without charge to the holder or holders of such shares for any issuance tax (except stock transfer tax) in respect thereof or other costs incurred by the Corporation in connection therewith.

(3) The Corporation shall at all times reserve and keep available out of its authorized but unissued shares of Common Stock or its treasury shares, solely for the purpose of issuance upon the conversion of the Class A Stock, such number of shares of Common Stock as may be issued upon conversion, of all outstanding Class A Stock.

(4) Shares of the Class A Stock surrendered for conversion as above provided or otherwise acquired by the corporation shall be cancelled according to law and shall not be reissued.

#### ARTICLE V

##### DESIGNATION OF SECRETARY OF STATE AS AGENT FOR SERVICE OF PROCESS

The Secretary of State is designated as agent of the Corporation upon whom process against it may be served. The post office address to which the Secretary of State shall mail a copy of any process against the Corporation served upon him is:

Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591  
Attention: Secretary

#### ARTICLE VI

##### BOARD OF DIRECTORS

The number of Directors of the Corporation constituting the entire Board of Directors shall be not less than three or more than fifteen. The Board of Directors shall determine from time to time the number of Directors who shall constitute the entire Board of Directors. Any such determination made by the Board of Directors shall continue in effect unless and until changed by the Board of Directors, but no such change shall affect the term of any Directors then in office. Directors need not be shareholders of the Corporation.

Commencing at the Annual Meeting of Shareholders held in 1991, the terms of office of the Board of Directors shall be divided into three classes, Class I, Class II and Class III, as shall be determined by the Board of Directors. All classes shall be as nearly equal in number as possible, and no class shall include less than three nor more than nine Directors. Any vacancy on the Board of Directors that results from an increase in the number of Directors and any other vacancy on the Board may be filled only by the Board provided that a quorum is then in office and present, or only by a majority of the Directors then in office, if less than a quorum is then in

office, or by a sole remaining Director. Directors elected to fill a newly created directorship or other vacancies shall be classified and hold office as provided by statute.

The terms of office of the respective classes of directors initially classified shall be as follows: (1) Class I shall expire at the Annual Meeting of Shareholders to be held in 1992; (2) Class II shall expire at the Annual Meeting of Shareholders to be held in 1993; and (3) Class III shall expire at the Annual Meeting of Shareholders to be held in 1994. At each Annual Meeting of Shareholders after the aforementioned initial classification, the successors to Directors whose terms shall then expire shall be elected to serve from the time of election and qualification until the third Annual Meeting following election and until a successor shall have been duly elected and shall have qualified.

The Directors of any class of Directors of the Corporation may not be removed prior to the expiration date of their terms of office except for cause and by an affirmative vote of at least eighty percent (80%) of the outstanding shares of all classes of capital stock of the Corporation entitled to vote for such member(s) of the Board of Directors at the Annual Meeting of Shareholders or at any Special Meeting of Shareholders called by the Board of Directors or by the Chairman of the Board or by the President for this purpose.

## ARTICLE VII

### LIMITATION OF DIRECTOR AND OFFICER LIABILITY

To the fullest extent now or hereafter permitted under the New York Business Corporation Law, no director or officer of the Corporation shall be personally liable to the Corporation or its shareholders for monetary damages for any breach of fiduciary duty in such capacity. No amendment or repeal of this Article 7 shall adversely affect any right or protection of any director or officer of the Corporation existing at the time of such amendment or repeal with respect to acts or omissions occurring prior to such amendment or repeal.

## ARTICLE VIII

### PREEMPTIVE RIGHTS

No holder of Common Shares, or preferred stock of any designation or series shall, as such holder, have any right to purchase or subscribe for (i) any stock of any class, or any warrant or warrants, option or options, or other instrument or instruments that shall confer upon the holder or holders thereof the right to subscribe for or purchase or receive from the Corporation any stock of any class or classes which the Corporation may issue or sell, whether or not such stock shall be convertible into or exchangeable for any other stock of the Corporation of any class or classes and whether or not such stock shall be unissued shares authorized by the Certificate of Incorporation or by any amendment thereto or shares of stock of the Corporation acquired by it after the issuance thereof, or (ii) any obligation which the Corporation may issue or sell that shall be convertible into or exchangeable for any shares of stock of the Corporation of any class or classes, or to which shall be attached or appurtenant to any warrant or warrants, option or options or other instrument or instruments that shall confer upon the holder or holders of such obligation the right to subscribe for or purchase or receive from the Corporation any shares of its stock of any class or classes.

Upon any issuance for money or other consideration of any stock of the Corporation that may be authorized from time to time, no holder of stock, irrespective of the kind of such stock, shall have any preemptive or other right to subscribe for, purchase or receive any proportionate or other share of the stock so issued, and the Board of Directors may dispose of all or any portion of such stock as and when it may determine free of any such rights, whether by offering the same to shareholders or by sale or other disposition as said Board may deem advisable.”

IN WITNESS WHEREOF, this Restated Certificate of Incorporation has been signed as of the 25<sup>th</sup> day of January, 2008, and affirmed that the statements made herein are true under penalties of perjury.

/s/ Leonard S. Schleifer  
Leonard S. Schleifer, President

/s/ Stuart A. Kolinski  
Stuart A. Kolinski, Secretary

RESTATED CERTIFICATE OF INCORPORATION  
OF  
REGENERON PHARMACEUTICALS, INC.  
UNDER SECTION 807 OF THE BUSINESS CORPORATION LAW  
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP  
ONE RODNEY SQUARE  
WILMINGTON, DELAWARE 19801

**Portions of this Exhibit Have Been  
Omitted and Separately Filed with the Securities  
And Exchange Commission with a Request  
For Confidential Treatment**

DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT

By and Between

AVENTIS PHARMACEUTICALS INC.

and

REGENERON PHARMACEUTICALS, INC.

Dated as of November 28, 2007

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## TABLE OF CONTENTS

Page

### ARTICLE 1 DEFINITIONS

1.1	“Affiliate”	1
1.2	“Agreement”	2
1.3	“Alliance Manager”	2
1.4	“Antibody”	2
1.5	“Aventis Collaboration Agreement”	2
1.6	“Business Day”	2
1.7	“Commercially Reasonable Efforts”	2
1.8	“Competing Refused Candidate”	2
1.9	“Confidential Information”	2
1.10	“Contract Year”	2
1.11	“CPI”	3
1.12	“Damages”	3
1.13	“Default Interest Rate”	3
1.14	“Disclosing Party”	3
1.15	“Discovery Plan”	3
1.16	“Discovery Program”	3
1.17	“Discovery Program Costs”	3
1.18	“Effective Date”	3
1.19	“Excluded Candidates”	3
1.20	“Executive Officers”	3
1.21	“FDA”	3
1.22	“Force Majeure”	3
1.23	“FTE”	3
1.24	“FTE Cost”	3
1.25	“FTE Rate”	4
1.26	“GAAP”	4
1.27	“Governmental Authority”	4
1.28	“IAS/IFRS”	4
1.29	“IFM”	4
1.30	“Immunoconjugate”	4
1.31	“IND”	4
1.32	“IND Preparation”	4
1.33	“Indemnified Party”	4
1.34	“Indemnifying Party”	4
1.35	“Initial Development Plan”	4
1.36	“Investor Agreement”	4

	<u>Page</u>
1.37	5
1.38	5
1.39	5
1.40	5
1.41	5
1.42	5
1.43	5
1.44	5
1.45	5
1.46	5
1.47	5
1.48	5
1.49	5
1.50	5
1.51	5
1.52	7
1.53	7
1.54	7
1.55	7
1.56	7
1.57	7
1.58	7
1.59	7
1.60	7
1.61	7
1.62	7
1.63	7
1.64	7
1.65	8
1.66	8
1.67	8
1.68	8
1.69	8
1.70	8
1.71	8
1.72	8
1.73	8
1.74	8
1.75	8
1.76	8
1.77	8
1.78	8
1.79	8
1.80	8
1.81	8
1.82	9

	<u>Page</u>
1.83	9
1.84	9
1.85	9
1.86	9
1.87	9
1.88	9
1.89	9
1.90	9
1.91	9
1.92	9
1.93	9
1.94	9
1.95	9
1.96	9
1.97	10
1.98	10
1.99	10

ARTICLE 2  
DISCOVERY PROGRAM

2.1	10
2.2	10
2.3	10
2.4	11
2.5	11
2.6	11
2.7	11
2.8	12
2.9	14
2.10	15
2.11	15
2.12	15
2.13	15
2.14	15
2.15	16
2.16	16
2.17	16
2.18	16

ARTICLE 3  
JOINT RESEARCH COMMITTEE

3.1	16
3.2	18
3.3	18
3.4	19

	<u>Page</u>
ARTICLE 4 PAYMENTS	
4.1	Upfront Payment 19
4.2	Discovery Program Costs 19
4.3	Reports and Discovery Program Cost Payments 20
4.4	Royalty Payments for Royalty Products 20
4.5	Royalty Reporting 20
4.6	Payment Method and Currency 21
4.7	Late Payments 21
4.8	Taxes 21
ARTICLE 5 OPT-IN RIGHTS TO LICENSE PRODUCT CANDIDATES	
5.1	Opt-In Rights to License Product Candidates 21
5.2	Process for Opt-In Rights 22
5.3	Initial Development Plan 22
5.4	Opt-In Exercise 22
5.5	D114 and REGN-88 22
5.6	Refused Candidates 22
ARTICLE 6 NEWLY CREATED INVENTIONS	
6.1	Ownership of Newly Created Intellectual Property 23
6.2	Prosecution and Maintenance of Patent Rights 25
6.3	Third Party Claims 26
ARTICLE 7 BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS	
7.1	Books and Records 26
7.2	Audits and Adjustments 27
7.3	IAS/IFRS/GAAP 27
ARTICLE 8 REPRESENTATIONS, WARRANTIES AND COVENANTS	
8.1	Joint Representations and Warranties 27
8.2	Knowledge of Pending or Threatened Litigation 28
8.3	Additional Regeneration Representations, Warranties and Covenants 28
8.4	Disclaimer of Warranties 29
ARTICLE 9 CONFIDENTIALITY	
9.1	Confidential Information 29

		<u>Page</u>
9.2	Injunctive Relief	31
9.3	Publications	31
9.4	Disclosures Concerning this Agreement	31
ARTICLE 10 INDEMNITY		
10.1	Indemnity and Insurance	32
10.2	Indemnity Procedure	33
ARTICLE 11 FORCE MAJEURE		
ARTICLE 12 TERM AND TERMINATION		
12.1	Term	35
12.2	Termination For Material Breach	35
12.3	Termination for Insolvency	35
12.4	Termination by Sanofi on Notice	36
12.5	Termination for Breach of Standstill	36
12.6	Termination for Breach of License and Collaboration Agreement	36
12.7	Effect of Termination by Sanofi for Breach	36
12.8	Effect of Termination by Regeneron for Breach	37
12.9	Survival of Obligations	38
12.10	Return of Confidential Information	38
12.11	Special Damages	39
12.12	Termination by Sanofi At Will	39
ARTICLE 13 Arbitration		
13.1	Binding Arbitration	39
ARTICLE 14 MISCELLANEOUS		
14.1	Governing Law; Submission to Jurisdiction	41
14.2	Waiver	41
14.3	Notices	41
14.4	Entire Agreement	41
14.5	Amendments	41
14.6	Interpretation	42
14.7	Severability	42
14.8	Assignment	42
14.9	Successors and Assigns	42
14.10	Affiliates	42
14.11	Counterparts	43

14.12	Third Party Beneficiaries	<u>Page</u> 43
14.13	Relationship of the Parties	43
14.14	Limitation of Damages	43
14.15	Non-Solicitation	43
14.16	No Strict Construction	44

## DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT

THIS DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT (“Agreement”), dated as of November 28, 2007 (the “Effective Date”), is by and between AVENTIS PHARMACEUTICALS INC. (“Sanofi”), a corporation organized under the laws of Delaware, having a principal place of business at 55 Corporate Boulevard, Bridgewater, New Jersey 08807, an indirect wholly owned subsidiary of Sanofi-Aventis, a company organized under the laws of France with its principal headquarters at 174, avenue de France, 75103 Paris, France (“Sanofi Parent”), and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591, USA (“Regeneron”) (with each of Sanofi and Regeneron referred to herein individually as a “Party” and collectively as the “Parties”).

WHEREAS, Regeneron plans to undertake a broad therapeutic antibody discovery and development program with the objective of identifying and validating potential drug discovery targets for the purpose of discovering fully human monoclonal antibody product candidates against those targets using its proprietary VelocImmune® and related suite of technologies; and

WHEREAS, Sanofi is interested in funding and assisting with Regeneron’s plans to discover and validate potential drug discovery targets for the purpose of discovering fully human monoclonal antibody product candidates in exchange for an option to license certain rights to the resulting fully human monoclonal antibodies under the terms set forth in this Agreement and in the License and Collaboration Agreement (as further defined in Article 1 below) to be entered into between the parties contemporaneously with the execution of this Agreement;

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

**ARTICLE 1**  
**DEFINITIONS**

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 “Affiliate” shall mean, with respect to any Person, another Person which controls, is controlled by, or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract, or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of

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certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates nor shall Regeneron or any of its Affiliates be deemed Affiliates of Sanofi or any of its Affiliates. For purposes of this Agreement, neither Sanofi Pasteur nor Merial Limited, nor any of their respective subsidiaries or joint ventures, shall be deemed to be Affiliates of Sanofi or any of its Affiliates.

1.2 “Agreement” shall have the meaning set forth in the introductory paragraph, including all Schedules and Exhibits.

1.3 “Alliance Manager” shall have the meaning set forth in Section 3.2.

1.4 “Antibody” shall mean \*\*\*\*\*, and any composition or formulation that incorporates or includes any of the foregoing.

1.5 “Aventis Collaboration Agreement” shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between sanofi-aventis US (as successor in interest to Sanofi) and Regeneron, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth Amendment, dated as of January 31, 2006, and Section 11.2 of the Stock Purchase Agreement, as the same may be further amended from time to time.

1.6 “Business Day” shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, United States or Paris, France are authorized or required by Law to remain closed.

1.7 “Commercially Reasonable Efforts” shall mean the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with the efforts such Party devotes to products or research or development projects owned by it of similar scientific and commercial potential. Commercially Reasonable Efforts shall be determined on a Target-by-Target and Antibody-by-Antibody (including MTCs) basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors.

1.8 “Competing Refused Candidate” shall mean any Refused Candidate having the same Target as a Licensed Product (as long as such Licensed Product is licensed to Sanofi under the License and Collaboration Agreement).

1.9 “Confidential Information” shall have the meaning set forth in Section 9.1.

1.10 “Contract Year” shall mean the period beginning on the Effective Date and ending on December 31, 2008, and each succeeding twelve (12) month period thereafter during the term

of the Discovery Program (except that the last Contract Year shall end on the effective date of any termination or expiration of this Agreement).

1.11 “CPI” shall mean the Consumer Price Index — All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).

1.12 “Damages” shall have the meaning set forth in Section 10.1(a).

1.13 “Default Interest Rate” shall have the meaning set forth in Section 4.7.

1.14 “Disclosing Party” shall have the meaning set forth in Section 9.1.

1.15 “Discovery Plan” shall have the meaning set forth in Section 2.3.

1.16 “Discovery Program” shall mean all research and development activities to be performed under this Agreement  
\*\*\*\*\*

1.17 “Discovery Program Costs” shall mean all Out-of-Pocket Costs, FTE Costs and Manufacturing Costs incurred by Regeneron, after the Effective Date directly in connection with the performance of the Discovery Program (and, as such costs relate to a particular Licensed Product, ending on the last day of the month preceding the month in which the Opt-In Notice for such Licensed Product is received by Regeneron).

1.18 “Effective Date” shall have the meaning set forth in the introductory paragraph.

1.19 “Excluded Candidates” shall mean Antibodies (including MTCs) against Targets set forth in Schedule 1.19 as of the Effective Date and those Targets that will be notified by Sanofi to Regeneron pursuant to the second sentence of Section 2.8(b)(i).

1.20 “Executive Officers” shall mean the Chief Executive Officer of Regeneron and the most senior Research and Development Officer of Sanofi Parent, or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.

1.21 “FDA” shall mean the United States Food and Drug Administration and any successor agency thereto.

1.22 “Force Majeure” shall have the meaning set forth in Article 11.

1.23 “FTE” shall mean a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed by Regeneron (or its Affiliate) who performs work under the Discovery Program, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be \*\*\*\*\* hours per year.

1.24 “FTE Cost” shall mean, for all activities performed under the Discovery Program, the product of (a) the number of FTEs performing activities under the Discovery Program and (b) the FTE Rate.

1.25 “FTE Rate” shall mean \$\*\*\*\*\* in the first Contract Year, such amount to be adjusted as of January 1, 2009 and annually thereafter by the sum of (a) the percentage increase or decrease, if any, in the CPI for the twelve (12) months ending June 30 of the Contract Year prior to the Contract Year for which the adjustment is being made, \*\*\*\*\*.

1.26 “GAAP” shall mean generally accepted accounting principles as applicable in the United States.

1.27 “Governmental Authority” shall mean any court, agency, authority, department, regulatory body, or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city, or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.28 “IAS/IFRS” shall mean International Financial Reporting Standards adopted by the International Accounting Standards Board.

1.29 “IFM” shall have the meaning set forth in Section 2.11(d)(ii).

1.30 “Immunoconjugate” shall mean an Antibody (or derivative or fragment thereof) linked to a cytotoxic or any molecule potentially able to enhance the therapeutic activity of such Antibody (or derivative or fragment thereof).

1.31 “IND” shall mean, with respect to each Product Candidate, an Investigational New Drug Application filed with the FDA with respect to such Product Candidate pursuant to 21 C.F.R. § 312 before the commencement of clinical trials involving such Product Candidate, including all amendments and supplements to such application, or any equivalent filing with any Regulatory Authority outside the United States.

1.32 “IND Preparation” shall mean all drug development activities in support of a Lead Candidate or Product Candidate up to the filing of the IND for the Phase I Clinical Trial, including, but not limited to, assay development, sample analysis, preclinical toxicology, preclinical pharmacokinetics and toxicokinetics, pharmacological assessment (if applicable), cell line development and protein chemistry sciences, formulation development, clinical trial protocol development, IND drafting and data compilation, and manufacturing preclinical and clinical supplies.

1.33 “Indemnified Party” shall have the meaning set forth in Section 10.2(a).

1.34 “Indemnifying Party” shall have the meaning set forth in Section 10.2(a).

1.35 “Initial Development Plan” shall have the meaning set forth in Section 5.3.

1.36 “Investor Agreement” shall mean the Investor Agreement by and between (a) Sanofi, Sanofi Parent, sanofi-aventis US LLC, and Sanofi-Aventis Amerique du Nord and (b) Regeneron, substantially in the form of Exhibit B to the Stock Purchase Agreement, which will be entered into concurrently with the closing under the Stock Purchase Agreement.

- 1.37 “Joint Research Committee” or “JRC” shall mean the Joint Research Committee described in Section 3.1(a).
- 1.38 “Joint Inventions” shall have the meaning set forth in Section 6.1(b).
- 1.39 “Joint Patent Rights” shall mean Patent Rights that cover a Joint Invention.
- 1.40 “Know-How” shall mean, with respect to each Party and its Affiliates, any and all proprietary technical or scientific information, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information (whether or not patentable or otherwise protected by trade secret Law) and that are not disclosed or claimed by such Party’s Patents or Patent Applications.
- 1.41 “Law” or “Laws” shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions, and/or ordinances of any Governmental Authority in the Territory.
- 1.42 “Lead Candidate” shall mean, for any Program Target, each Antibody, including MTCs, that satisfies the applicable criteria set forth in Schedule 1.42 and is selected by Regeneron to begin IND Preparation under this Agreement.
- 1.43 “License and Collaboration Agreement” shall mean the License and Collaboration Agreement between the Parties, dated as of the date of this Agreement, the terms of which are incorporated by reference into, and are part of, this Agreement.
- 1.44 “Licensed Product” shall mean any Product Candidate for which Sanofi has exercised its Opt-In Rights pursuant to Section 5.4 below.
- 1.45 “Licensed Refused Sanofi Candidate” shall have the meaning set forth in Section 2.12.
- 1.46 “Manufacturing Cost” shall mean the fully burdened cost (without mark-up) of manufacturing Product Candidates and Lead Candidates for preclinical activities and Phase I Clinical Trials (and, if agreed by the Parties other clinical trials), and the cost for providing dedicated manufacturing capacity for Lead Candidates and Product Candidates, in each case, as calculated in accordance with Schedule 1.46.
- 1.47 “Maximum Annual Discovery Program Costs” shall have the meaning set forth in Section 4.2.
- 1.48 “Mice” shall mean \*\*\*\*\*.
- 1.49 “Mice-Derived Therapeutic (or Diagnostic) Candidate” or “MTC” shall mean any Antibody derived from Mice.
- 1.50 “Modified Clause” shall have the meaning set forth in Section 14.7.
- 1.51 “Net Sales” shall mean the gross amount invoiced for bona fide arms’ length sales of Royalty Products in the Territory by or on behalf of a Party, or its Affiliates or sublicensees to

Third Parties, less the following deductions, determined in accordance with IAS/IFRS (or GAAP for the US) consistently applied:

- (a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such Royalty Products;
- (b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;
- (c) chargebacks and other amounts paid on sale or dispensing of Royalty Products;
- (d) Third Party cash rebates and chargebacks related to sales of Royalty Products, to the extent allowed;
- (e) retroactive price reductions that are actually allowed or granted;
- (f) compulsory refunds, credits and rebates directly related to the sale of Royalty Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or governmental regulations;
- (g) freight, postage, shipment and insurance costs (or wholesaler fees in lieu of those costs) and customs duties incurred in delivering Royalty Products that are separately identified on the invoice or other documentation;
- (h) sales taxes, excess duties, or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of Royalty Products, which are separately identified on the invoice or other documentation;
- (i) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of such Royalty Product falling within categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof;
- (j) invoiced amounts that are written off as uncollectible in accordance with a Party's or its Affiliates' or sublicensees' respective accounting principles as applied consistently

Net Sales in currency other than United States Dollars shall be translated into United States Dollars according to the provisions of Section 4.6 of this Agreement.

Sales between the Parties, or between the Parties and their Affiliates or sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Royalty Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if a Party or its Affiliates or sublicensee sells such Royalty Products in the form of a combination

product containing any Royalty Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a “Combination Product”), then prior to the first commercial sale of such Combination Product, the Parties shall agree on the value of each component of such Combination Product and the appropriate method for accounting for sale of such Combination Product. For the avoidance of doubt, for the purposes of this Agreement, Immunoconjugates shall not be deemed Combination Products.

1.52 “Opt-In Notice” shall have the meaning set forth in Section 5.4.

1.53 “Opt-In Period” shall have the meaning set forth in Section 5.4.

1.54 “Opt-In Report” shall have the meaning set forth in Section 5.2.

1.55 “Opt-In Rights” shall have the meaning set forth in Section 5.1.

1.56 “Out-of-Pocket Costs” shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP) by Regeneron (or its Affiliate) directly in connection with the performance of the Discovery Program.

1.57 “Party” or “Parties” shall have the meaning set forth in the introductory paragraph.

1.58 “Patent Application” shall mean any application for a Patent.

1.59 “Patent Rights” shall mean unexpired Patents and Patent Applications.

1.60 “Patents” shall mean patents together with all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations, extensions, registrations, patent term adjustments or extensions, supplemental protection certificates and renewals of any of the foregoing, and all counterparts thereof in any country in the Territory.

1.61 “Person” shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.

1.62 “Phase I Clinical Trial” shall mean the first clinical trial of a Product Candidate following IND Preparation.

1.63 “Product Candidate” shall mean any Lead Candidate that substantially completes IND Preparation and is ready to be offered for license to Sanofi under the Opt-In Rights.

1.64 “Product Patent Rights” shall mean any Patent or Patent Application having a specification which supports a claim that may be infringed by making, using, selling, importing or exporting a Lead Candidate or Product Candidate in the Discovery Program, including, without limitation, any derivatives, fragments, compositions of matter or uses, thereof.

1.65 “Program Target” shall mean a Target that is selected by Regeneron, subject to Section 2.4, as a Target against which Antibodies are to be generated under the Discovery Program.

1.66 “Publishing Party” shall have the meaning set forth in Section 9.3.

1.67 “Receiving Party” shall have the meaning set forth in Section 9.1.

1.68 “Refused Candidate” shall have the meaning set forth in Section 5.6 (i).

1.69 “Regeneron” shall have the meaning set forth in the introductory paragraph.

1.70 “Regeneron Indemnites” shall have the meaning set forth in Section 10.1(a).

1.71 “Regeneron Intellectual Property” shall mean the Regeneron Patent Rights and the Regeneron Know-How.

1.72 “Regeneron Know-How” shall mean any and all Know-How now or hereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Know-How and Know-How included in Joint Inventions) with the right to sublicense the same necessary or useful for the performance of the Discovery Program.

1.73 “Regeneron Patent Rights” shall mean those Patent Rights now or hereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Patent Rights and Patent Rights included in Joint Inventions) with the right to sublicense the same and which include at least one (1) claim which would be infringed by the research, development, manufacture or use of the Mice or any Target, Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program.

1.74 “Regeneron Sole Inventions” shall have the meaning set forth in Section 6.1(a).

1.75 “Regeneron Target IP” shall mean \*\*\*\*\*.

1.76 “Regulatory Authority” shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the activities conducted under the Discovery Program.

1.77 “Royalty Product” shall mean \*\*\*\*\*.

1.78 “Royalty Term” shall have the meaning set forth in Section 4.5.

1.79 “Sanofi” shall have the meaning set forth in the introductory paragraph.

1.80 “Sanofi Divested Antibody” shall have the meaning set forth in Section 2.8(b)(vii).

1.81 “Sanofi Indemnites” shall have the meaning set forth in Section 10.1(b).

1.82 “Sanofi Intellectual Property” shall mean the Sanofi Patent Rights and the Sanofi Know-How.

1.83 “Sanofi Know-How” shall mean any and all Know-How now or hereafter during the term of the Discovery Program (including the Tail Period) owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Know-How and Know-How included in Joint Inventions) with the right to sublicense the same necessary or useful for the performance of the Discovery Program.

1.84 “Sanofi Patent Rights” shall mean those Patent Rights now or hereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Patent Rights and Patent Rights included in Joint Inventions) with the right to sublicense the same and which include at least one (1) claim which would be infringed by the research, development, manufacture or use of the Mice or any Target, Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program.

1.85 “Sanofi Sole Inventions” shall have the meaning set forth in Section 6.1(a).

1.86 “Sanofi Sole Projects” shall have the meaning set forth in Section 2.8(b)(iii).

1.87 “Sanofi Targets” shall have the meaning set forth in Section 2.4.

1.88 “Sanofi Target IP” shall mean \*\*\*\*\*.

1.89 “Sole Inventions” shall have the meaning set forth in Section 6.1(a).

1.90 “Solely Developed \*\*\*\*\*.” shall have the meaning set forth in Section 2.11(b).

1.91 “Stock Purchase Agreement” shall mean the Stock Purchase dated as of the Effective Date by and between (a) Sanofi, sanofi-aventis US LLC, and Sanofi-Aventis Amerique du Nord and (b) Regeneron.

1.92 “Tail Period” shall have the meaning set forth in Section 2.9.

1.93 “Target” shall mean any gene, receptor, ligand, or other molecule (a) potentially associated with a disease activity, and (b) which potentially has a biological activity that is modified by direct interaction with an Antibody, including any MTC, or (c) to which an Antibody, including any MTC, binds.

1.94 “Target List” shall mean the list of Targets in the Discovery Program, including a description of the stage of discovery or pre-clinical development of each such Target in the Discovery Program, which list shall be in the form attached as Schedule 1.94, and which list shall be updated by the JRC on a quarterly basis in accordance with Section 3.1(c) below.

1.95 “Term” shall have the meaning set forth in Section 12.1.

1.96 “Territory” shall mean all the countries and territories of the world.

1.97 “Third Party” shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.

1.98 “Third Party Opportunities” shall have the meaning set forth in Section 2.8(a)(ii).

1.99 “Valid Claim” shall mean a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) which has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Government Authority of competent jurisdiction from which no appeal may be or has been taken, and which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise.

## **ARTICLE 2**

### **DISCOVERY PROGRAM**

2.1 Discovery Program. The objective of the Parties during the Discovery Program is for Regeneron to discover, identify and/or validate Targets from which to select Program Targets, generate Antibodies, including MTCs, against such Program Targets (including Program Targets that are Sanofi Targets) from which to select Lead Candidates, and develop them through IND Preparation to offer to Sanofi for joint development and commercialization under the terms set forth herein and in the License and Collaboration Agreement. During the first five (5) years of the Discovery Program, Regeneron will use Commercially Reasonable Efforts (i) to discover, identify and validate Targets and (ii) to select Program Targets for review and discussion by the JRC pursuant to Section 3.1 herein. \*\*\*\*\* Regeneron will use Commercially Reasonable Efforts to manufacture preclinical and clinical supplies of the Lead Candidates and Product Candidates for the Discovery Program and the Phase 1 Clinical Trial. The JRC will prioritize the Antibodies, including MTCs, to be further pursued as Lead Candidates, and Regeneron will commence IND Preparation activities only for those Antibodies, including MTCs, that meet the applicable criteria set forth in Schedule 1.42. The JRC will evaluate, select and prioritize Targets for the Target List. However, Regeneron will have the right to conduct Target discovery and validation on Targets as part of the Discovery Program before they are formally approved by the JRC for selection on the Target List but shall notify the JRC of any new Target at the next meeting of the JRC. Subject to Sanofi’s selection rights under Section 3.1(e) and the other terms of this Agreement, Regeneron will have sole responsibility for the design and conduct of all activities under the Discovery Program, including, without limitation, decisions relating to initiation and termination of programs and activities, manufacturing activities, and staffing and resource allocation between different programs and activities in the Discovery Program. Sanofi, through the JRC, will provide consultation and advice to support Regeneron’s efforts.

2.2 Term of the Discovery Program. The Discovery Program shall commence on the Effective Date and shall end on December 31, 2012 unless (a) terminated earlier in accordance with the provisions of this Agreement or (b) extended by Sanofi for the Tail Period pursuant to the terms of Section 2.9.

2.3 Discovery Plans. Regeneron will prepare an annual research discovery and pre-clinical development plan (the “Discovery Plan”) for the Discovery Program setting forth the

overall strategy, plans, and estimated budget for the Discovery Program for the ensuing Contract Year, which it will submit to the JRC for review and comment. For each Lead Candidate, the Discovery Plan will include activities and a planned timeline for IND Preparation. Regeneron shall consider in good faith comments on the Discovery Plan from Sanofi's representatives on the JRC. Except for the initial Discovery Plan (which will be provided to the JRC within sixty (60) days of the Effective Date), Regeneron will present an updated Discovery Plan to the JRC at least two (2) months prior to the end of each Contract Year.

2.4 Sanofi Targets. In the event that at any time the JRC is unable to agree on the Targets to include on the Target List, Sanofi will have the right to select and maintain in each update to the Target List up to \*\*\*\*\* of the Targets included under the following headings of the Target List: \*\*\*\*\* . Neither Regeneron nor Regeneron's representatives on the JRC shall have the right to reject, replace, or discriminate against such Sanofi Targets without the agreement of Sanofi's representatives on the JRC. Sanofi shall provide Regeneron's representatives on the JRC with its proposed list of Targets at least ten (10) Business Days before each JRC meeting for consideration by the JRC and, if necessary, selection by Sanofi to make up its \*\*\*\*\* of the Target List as described in this Section 2.4.

2.5 Commercially Reasonable Efforts; Compliance with Laws. During the term of the Discovery Program, Regeneron will use Commercially Reasonable Efforts to discover and develop Product Candidates to offer for license to Sanofi pursuant to the Opt-In Rights. Without limiting the foregoing, Regeneron will use Commercially Reasonable Efforts to identify Lead Candidates and complete IND Preparation for Lead Candidates in a timely manner during the term of the Discovery Program. Each Party hereby covenants and agrees to comply with applicable Laws in performing activities connected with the Discovery Program.

2.6 Exchange of Information. Regeneron will share information with the JRC in a timely manner concerning the progress of the Discovery Program consistent with Section 3.1(b). Without limiting the foregoing, at least five (5) calendar days prior to each regular quarterly meeting of the JRC, Regeneron will use its Commercially Reasonable Efforts to provide to Sanofi's representatives on the JRC a written report (in electronic form) summarizing the material activities undertaken by Regeneron in connection with the Discovery Plan, including information concerning new Targets proposed for the Target List, new Program Targets, new Lead Candidates and new Product Candidates. In addition, Regeneron will provide Sanofi with proposed Targets for inclusion on the updated Target List and Target proposed not to be pursued further under the Discovery Program at least ten (10) Business Days prior to each regular quarterly meeting of the JRC. Sanofi shall have the right to reasonably request and to receive in a timely manner clarifications and answers to questions with respect to such reports and any other data or information it reasonably requests with respect to the conduct of the Discovery Program.

2.7 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals,

authorizations, or orders required to be obtained or made in connection with the authorization, execution, and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement, and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings, including by providing copies of all such non-confidential documents to the other Party and its advisors prior to the filing and, if requested, by accepting all reasonable additions, deletions, or changes suggested in connection therewith. Each Party will furnish all information required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

2.8 Exclusive Discovery Program.

(a) Exclusivity.

(i) General. Subject to the other subparagraphs in this Section 2.8,

\*\*\*\*\*

(ii) Third Party Opportunities. Subject to the other sub-paragraphs in this Section 2.8, as part of the Discovery Program, the Parties may evaluate new Targets, Antibodies, and antibody technologies owned or controlled by Third Parties (“Third Party Opportunities”) to determine whether such Targets, Antibodies or antibody technologies should be licensed or acquired by the Parties for the Discovery Program. Should a Party identify such a Third Party Opportunity that it is interested in acquiring or licensing for inclusion in the Discovery Program, it shall notify the other Party for consideration and discussion. If the Parties approve the inclusion of such Third Party Opportunity in the Discovery Program, the Parties shall decide which Party will license or otherwise acquire rights to the Third Party Opportunity and include the applicable Target, Antibody or antibody technology, as the case may be, in the Discovery Program. \*\*\*\*\*

(b) Exclusions. Notwithstanding subsection (a) above, the following shall apply:

(i) Excluded Candidates. Regeneron (and its Affiliates) shall have the right to develop and commercialize Excluded Candidates of Regeneron as listed in Schedule 1.19 either on its own or with Third Parties outside the Discovery Program without restriction under this Agreement, and Sanofi (and its Affiliates) shall have the right to develop and commercialize Excluded Candidates of Sanofi listed in paragraph A of Schedule 1.19 on its own or with Third Parties outside the Discovery Program without restriction under this Agreement. \*\*\*\*\* For the avoidance of doubt, each Party shall have the right to develop and commercialize Antibodies (including, in the case of Regeneron, MTCs) against Targets of the other Party’s Excluded Candidates on its own or with Third Parties outside the Discovery Program without restriction under this Agreement.

(ii) Refused Candidates. Regeneron (and its Affiliates) shall have the right to develop and commercialize Refused Candidates outside the Discovery Program as set forth in Section 5.6 below, unless \*\*\*\*\*.

(iii) Sanofi Sole Projects. Sanofi shall only be entitled to take a total of up to \*\*\*\*\* into development outside the Discovery Program, such Antibodies being defined as the “Sanofi Sole Projects”. Sanofi Sole Projects may be generated from either its internal research and/or its acquisition from Third Parties as follows:

(1) Antibodies. Sanofi and its Affiliates shall have the right to develop and commercialize Antibodies outside the Discovery Program (including Antibodies licensed or acquired from a Third Party or through the acquisition of a Third Party that owns or controls an Antibody), provided that, such Antibodies are not against Targets on the Target List. Sanofi shall notify Regeneron in writing of the Target(s) for each such Antibody at the time \*\*\*\*\*.  
Regeneron and its Affiliates shall have the right to discover, develop and commercialize Antibodies (including MTCs) against any such Target(s) without restriction under this Agreement outside the Discovery Program and this Agreement; or

(2) Targets. Sanofi shall be entitled to discover Targets that are not on the Target List and to exclude from the Target List, Targets proposed by Regeneron for the Target List, if such Targets \*\*\*\*\*.  
In order to exclude such Targets, Sanofi must provide written notice of such exclusion to Regeneron within sixty (60) days after its receipt of the Regeneron proposal together with a signed certificate from an officer of Sanofi Parent certifying that \*\*\*\*\*.  
Each Party and their respective Affiliates shall have the right to discover, develop, and commercialize Antibodies (including, in the case of Regeneron, MTCs) against any such Target outside the Discovery Program without restriction under this Agreement. \*\*\*\*\*.  
Sanofi shall notify Regeneron’s representatives on the JRC before initiating discovery efforts on a Target other than a Sanofi Target to be included in the Discovery Program that was formerly on the Target List (but is no longer on the Target List), to determine whether Regeneron’s representatives on the JRC are interested in reinitiating discovery or validation activities against such Target as part of the Discovery Program.

(iv) Third Party Antibodies In Development. Sanofi and its Affiliates shall have the right to develop and commercialize an acquired Antibody (whether such acquisition is by direct acquisition, by license or through the acquisition of a Third Party that owns or controls an Antibody(ies) (the “Acquired Antibody”) that at the time of acquisition \*\*\*\*\*.  
Sanofi shall notify promptly Regeneron of such acquisition or license (including the identity of the Target) and may continue the development of such Acquired Antibody and other Antibodies

against such Target without restriction outside of the Discovery Program and this Agreement. In the event of such an acquisition or license by Sanofi, the applicable Target shall no longer be deemed a Program Target and shall be removed from the Target List, and Sanofi shall no longer have any rights to any Antibodies, including MTCs, against such Target under this Agreement. Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any MTCs or other Antibodies against such Target and may practice and use any Regeneron Intellectual Property, including, without limitation, the Mice, in connection with such activities, without restriction outside the Discovery Program and this Agreement. \*\*\*\*\*.

(v) Company Acquisitions For clarification, where Sanofi or its Affiliates acquire rights to an Acquired Antibody by the acquisition of a Third Party or part or the whole of its business, Sanofi may as an alternative to any rights under Sections 2.8(b)(iii) and (iv) above, either include the applicable Target for the Acquired Antibody on the Target List (either with Regeneron's consent or as one of the Sanofi Targets), or commit in writing to Regeneron to divest such Acquired Antibody (by sale or license) within \*\*\*\*\*.

(vi) Regulatory Divestitures. In the event that Sanofi acquires rights to an Acquired Antibody as a result of its acquisition of a Third Party and believes, based on the reasonable advice of its outside legal counsel, that it is required by Law to divest its interest in the Antibodies against such Target in the Discovery Program, then Sanofi shall have the right to exclude such Target from the Discovery Program, and develop and commercialize such Acquired Antibodies outside the Discovery Program and the terms of this Agreement. Sanofi shall no longer have any rights to any Antibodies, including MTCs, against such Target under this Agreement ("Sanofi Divested Antibodies"); however, \*\*\*\*\*. Either Party shall have the right to develop and commercialize Antibodies against the applicable Target(s) outside the Discovery Program and the terms of this Agreement, and Regeneron shall have and retain exclusive rights to any Antibodies, including MTCs, discovered in the Discovery Program against such Target without restrictions under this Agreement.

(vii) \*\*\*\*\*.

(viii) \*\*\*\*\*.

2.9 Tail Period. At Sanofi's sole option, upon prior written notice to Regeneron, such notice to be delivered no later than June 30, 2012 (\*\*\*\*\* (as applicable, the "Tail Period Notice Date"), the term of the Discovery Program may be extended for up to three (3) additional years (as designated by Sanofi in its notice) (the "Tail Period"). If Sanofi fails to provide such written notice by the applicable Tail Period Notice Date, the Discovery Program shall expire on December 31, 2012 (\*\*\*\*\*). Sanofi

shall identify in its written notice the specific Program Targets, Lead Candidates, and Product Candidates to be included in the Discovery Program during the Tail Period. Within ninety (90) days of receipt of Sanofi's notice, the Parties shall agree on a plan and budget (which shall be on a cost basis) to perform the activities set forth below and as requested by Sanofi to be carried out for each Contract Year of the Tail Period. In the event the Parties do not agree on the commercial reasonableness of such budget, then such dispute shall be referred to binding arbitration pursuant to the provisions of Article 13. During the Tail Period, Regeneron will use Commercially Reasonable Efforts \*\*\*\*\*.

2.10 Research Licenses; Licenses Generally. Each Party hereby grants to the other Party and its Affiliates a non-exclusive, non-transferable, worldwide, royalty-free, research license, without the right to sublicense, under the Regeneron Intellectual Property and the Sanofi Intellectual Property, respectively, solely to perform the Discovery Program. For the avoidance of doubt, neither Party shall use the licenses granted in this Section 2.10 for the benefit, directly or indirectly, of any Third Party. Except as expressly provided for herein, nothing in this Agreement grants either Party any right, title or interest in and to the intellectual property rights of the other Party (either expressly or by implication or estoppel). Except as expressly provided for in this Section 2.10 or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights or Know-How, either expressly or by implication, estoppel or otherwise. Upon expiration or earlier termination of the Discovery Program, the licenses granted in Section 2.10 herein shall automatically terminate.

2.11 Immunoconjugates. \*\*\*\*\*.

2.12 Sanofi Target Licenses. With respect to any Product Candidate against a Sanofi Target that becomes a Refused Candidate ("Licensed Refused Sanofi Candidate") or any Sanofi Divested Antibody, Sanofi hereby grants to Regeneron a non-transferable, non-exclusive, worldwide, royalty-bearing (in accordance with Section 4.4 herein) license, with the right to sublicense, under the Sanofi Target IP solely to make, have made, use, sell, offer to sell and import such Licensed Refused Sanofi Candidate or Sanofi Divested Antibody, as the case may be.

Where such Licensed Refused Sanofi Candidate is an Immunoconjugate, then \*\*\*\*\*.

2.13 Non-Exclusive License to Sanofi. Regeneron hereby grants Sanofi and its Affiliates a worldwide, non-exclusive, non-transferable, royalty-free license, without the right to sublicense, under Regeneron Intellectual Property discovered directly in connection with the performance of the Discovery Program claiming Targets on the Target List and/or methods of use related to the inhibition or use of such Targets for use by Sanofi and its Affiliates in connection with the manufacture, use, sale, offer to sell, and import of small molecule drug and diagnostic products.

2.14 Invention Assignment. All of the employees, officers and consultants of each Party that are supporting the performance of its obligations under this Agreement shall have executed agreements or have existing obligations under law requiring, in the case of employees

and officers, assignment to such Party of all inventions made during the course of and as the result of their association with such Party and, in the case of employees, officers and consultants, obligating the individual to maintain as confidential such Party's Confidential Information which such Party may receive, to the extent required to support such Party's obligations under this Agreement.

2.15 Supply of VelociGene® Mice. Within ninety (90) days of the Effective Date or as otherwise mutually agreed by the Parties in writing, the Parties shall enter into a "Mouse Purchase Agreement" pursuant to which Regeneron will use its proprietary technology for the production of genetically modified mouse embryonic stem cell lines and mice derived from the corresponding mouse stem cell lines for Sanofi. The commercial terms of the "Mouse Purchase Agreement" are outlined in Exhibit B.

2.16 Option for VelocImmune® License. At Sanofi's request within sixty (60) days of the fifth anniversary of the Effective Date (or the third anniversary of the Effective Date in the event that Sanofi terminates this Agreement in accordance with Section 12.4), the Parties shall enter into a License and Material Transfer Agreement (the "License and MTA") under which Regeneron will license VelocImmune to Sanofi. \*\*\*\*\*. As used in this Section 2.16, VelocImmune shall mean Regeneron's Mice technology as previously licensed by Regeneron to Third Parties as of the Effective Date. The License and MTA shall contain such other customary terms and conditions consistent with those included in Regeneron's VelocImmune license agreements existing as of the Effective Date.

2.17 Option for \*\*\*\*\*Licenses. To the extent that Regeneron decides to license either its \*\*\*\*\*technologies or other Antibody Know How (any such technologies and Know How being licensed by Regeneron, being referred to as the "Additional Technologies") to commercial entities, then at Sanofi's request, at any time between the fifth anniversary of the Effective Date (\*\*\*\*\* and one hundred eighty (180) days following the expiration or earlier termination of the Discovery Program, the Parties shall enter into a definitive agreement under which Regeneron will license the applicable Additional Technologies to Sanofi. The definitive agreement(s) for the Additional Technologies to be licensed to Sanofi shall contain commercial and other terms and conditions that are not materially less favorable, when taken as a whole, than those included in any then-existing license agreements with Third Parties for such Additional Technologies, if any.

2.18 Third Party Platform Licenses. \*\*\*\*\*.

**ARTICLE 3**  
**JOINT RESEARCH COMMITTEE**

3.1 The Joint Research Committee.

(a) Formation, Composition and Membership. Within thirty (30) days after the Effective Date, the Parties will establish the JRC, which shall consist of at least three (3) senior representatives appointed by each of Regeneron and Sanofi. Each Party may replace its Committee members upon written notice to the other Party; provided that such replacement is of

comparable standing and authority within that Party's organization as the person he or she is replacing (or is otherwise reasonably acceptable to the other Party). The JRC will have two (2) co-chairpersons, one designated by each of Regeneron and Sanofi.

(b) Meetings of the JRC. The JRC shall hold an initial joint meeting within forty-five (45) days of the Effective Date or as otherwise agreed by the Parties. Thereafter, the JRC shall meet at least once every calendar quarter, unless the JRC co-chairpersons otherwise agree. All JRC meetings may be conducted by telephone, video-conference or in person as determined by the JRC co-chairpersons; provided, however, that the JRC shall meet in person at least once each calendar year, unless the Parties mutually agree to meet by alternative means. Unless otherwise agreed by the Parties, all in-person meetings for JRC shall be held on an alternating basis between Regeneron's facilities and Sanofi's facilities. Further, each co-chairperson shall be entitled to call meetings in addition to the regularly scheduled quarterly meetings. The co-chairpersons, with the assistance of the Alliance Managers, shall coordinate activities to prepare and circulate an agenda in advance of each meeting and prepare and issue draft minutes of each meeting within fourteen (14) days thereafter and final minutes within thirty (30) days thereafter, such final minutes to include the updated Target List. With the consent of the Parties (not to be unreasonably withheld or delayed), a reasonable number of other representatives of a Party may attend any JRC meeting as non-voting observers (provided that such additional representatives are under obligations of confidentiality and non-use applicable to the Confidential Information of the other Party that are at least as stringent as those set forth in Article 9 below). Each Party shall be responsible for all of its own personnel and travel costs and expenses relating to participation in JRC meetings.

(c) Duties. The JRC shall:

(i) discuss the objectives of the Discovery Program;

(ii) review and comment on the Discovery Plan;

(iii) exchange and review scientific information and data relating to the activities being conducted under, and the then-current progress of, the Discovery Program, including the exchange and review of data and other information resulting from the Discovery Program, and establish processes for the exchange of information relating to the progress of the Discovery Program;

(iv) discuss experiments believed by a Party's representatives on the JRC to be necessary to properly evaluate Program Targets, Lead Candidates and Product Candidates;

(v) provide assistance and recommendations on the direction of the Discovery Program;

(vi) evaluate, select and prioritize Targets proposed by each Party for inclusion on the initial Target List and all quarterly updates thereto (subject to Section 2.4, which updates shall conform to the format of the Target List;

- (vii) discuss whether an Antibody, including any MTC, satisfies the criteria of Lead Candidates attached in Schedule 1.42;
- (viii) review and prioritize Lead Candidates;
- (ix) consider and act upon such other matters as specified in this Agreement or as otherwise agreed to by the Parties;
- (x) make any such decisions as are expressly allocated to the JRC under this Agreement; and

At the request of either Party's representatives to the JRC, conduct ad hoc meetings in addition to the quarterly meetings of the JRC as reasonably necessary to coordinate and expedite all decisions made by the JRC.

(d) Decision Making. The JRC shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on the JRC and leave decisions of the JRC to representatives of the other Party.

3.2 Alliance Management. Each of Sanofi and Regeneron shall appoint a senior representative who possesses a general understanding of research, clinical, and regulatory issues to act as its Alliance Manager ("Alliance Manager"). Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between the Parties. Each Alliance Manager will also be responsible for providing single-point communication for seeking consensus both internally within the respective Party's organization and with the other Party's organization, including facilitating review of external corporate communications.

### 3.3 Resolution of Governance Matters.

(a) Generally. The Parties shall cause their respective representatives on the JRC to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible.

(b) Executive Officers' Resolution of Disputes. In the event that the JRC is, after a period of thirty (30) days from the date a matter is submitted to it for decision, unable to make a decision due to a lack of required unanimity, or the Parties are unable to agree on the budget for the Initial Development Plan for a Product Candidate in accordance with Section 5.3 below, either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, the co-chairpersons of the JRC, by written notice to each Party delivered within five (5) days after receipt of the notice from a Party pursuant to the immediately preceding sentence, shall formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within thirty (30) days of receiving such written notification or such

longer period of time as the Executive Officers may agree in writing. Regeneron's Executive Officer shall have the deciding vote over all matters referred to the Executive Officers by the JRC, other than matters related to the commercial reasonableness of the budget for the Initial Development Plan for a Product Candidate which shall be resolved in accordance with Section 13.1 below should the Executive Officers fail to resolve such matter.

3.4 Obligations of the Parties and their Affiliates. The Parties shall cause their respective designees on the JRC and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein.

#### **ARTICLE 4 PAYMENTS**

4.1 Upfront Payment. Within five (5) Business Days of the Effective Date, Sanofi will pay to Regeneron the non-refundable, non-creditable amount of US \$85,000,000 (which will not be reduced by any withholding or similar taxes) as consideration for access to Regeneron's research capabilities and suite of discovery technologies and the co-exclusive (with Regeneron) rights granted to Sanofi hereunder during the term of the Discovery Program, including the Tail Period, if any.

4.2 Discovery Program Costs. Commencing on the Effective Date and continuing during the term of the Discovery Program, Sanofi shall be responsible for paying one hundred percent (100%) of all Discovery Program Costs, including Discovery Program Costs incurred for a Product Candidate until the anticipated IND filing date for such Product Candidate, regardless of whether Sanofi exercises its Opt-In Rights in accordance with Section 5.1; provided that, except as set forth below, the total annual Discovery Program Costs to be paid by Sanofi in each of the first five (5) years of the Discovery Program (the "Maximum Annual Discovery Program Costs") shall not exceed the following amounts (as calculated for each Contract Year):

Contract Year	Maximum Annual Discovery Program Costs
1	*****
2	*****
3	*****
4	*****
5	*****

In the event that the Discovery Program Costs incurred in any Contract Year are less than the Maximum Annual Discovery Program Costs for such Contract Year, the amount of such shortfall up to ten percent (10%) of the Maximum Annual Discovery Program Costs stated immediately above for each Contract Year may be carried over to the ensuing Contract Year and added to the Maximum Annual Discovery Program Costs for such ensuing Contract Year except for any such shortfall at the end of Contract Year 5, such that Regeneron's right to carry over any shortfall shall not be applicable into or during the Tail Period. At least sixty (60) days prior to the end of each Contract Year, Regeneron shall notify Sanofi if it reasonably believes that the total Discovery Program Costs for such Contract Year will be less than the Maximum Annual

Discovery Program Costs for such Contract Year and whether Regeneron intends to apply such shortfall amount to the Discovery Program Costs for the ensuing Contract Year.

To the extent that Sanofi performs any activities under the Discovery Program, it shall do so at its sole cost and expense and such costs and expenses shall not be treated as Discovery Program Costs for purposes of calculating the Maximum Annual Discovery Program Costs unless the JRC expressly requests Sanofi to perform any such activities, in which case the mutually agreed upon costs directly related to such activities shall be included in the calculation of the Maximum Annual Discovery Program Costs. The Parties acknowledge that payments made by Sanofi pursuant to this Section 4.2 are being made as research and development expenses, as defined in the U.S. Internal Revenue Code Section 41, and agree that any and all credits or deductions to which either party may be entitled on account of research performed pursuant to such payments shall be allocated to Sanofi to the extent of such payments.

4.3 Reports and Discovery Program Cost Payments. Within forty-five (45) days following the end of each calendar quarter, Regeneron shall deliver electronically to Sanofi a written report setting forth in reasonable detail the Discovery Program Costs incurred by Regeneron in such calendar quarter along with an invoice therefore. Sanofi shall reimburse Regeneron for all undisputed Discovery Program Costs set forth in each report within thirty (30) days after its receipt thereof. Any disputed, unpaid Discovery Program Costs that are determined to be due and payable to Regeneron under this Agreement shall be paid with the Default Interest Rate.

4.4 Royalty Payments for Royalty Products(i) . If either Party, or its Affiliate or licensee successfully develops and commercializes a Royalty Product, then the commercializing Party shall pay to the non-commercializing Party, within sixty (60) days following the end of each calendar quarter, the following royalties on the aggregate Net Sales of such, respective Royalty Products during the Royalty Term: \*\*\*\*\*.

In the event that any Royalty Product requires a sub-license to Sanofi Patent Rights or Regeneron Patent Rights, as applicable, and such sub-license is granted under this Agreement, then any financial remuneration that the licensing Party is required to pay to a Third Party for its license from the Third Party shall be considered a pass-through cost to be borne by the Party developing and/or commercializing the Royalty Product.

4.5 Royalty Reporting. The royalties payable under Sections 4.4 (i), 4.4(iv), and 4.4(v) of this Agreement shall each be paid for the period of time, as determined on a Royalty Product-by-Royalty Product and country-by-country basis, commencing on the Effective Date and ending on the later to occur of (a) \*\*\*\*\* and, if applicable, (b) the expiration of the last to expire Valid Claim of the Licensed Sanofi Target IP or Regeneron Target IP, as the case may be. The royalties payable under Sections 4.4 (ii), 4.4 (iii), and 4.4(vi) of this Agreement shall each be paid on a Royalty Product-by-Royalty Product and country-by-country basis, commencing on the Effective Date and ending on the expiration of the last to expire Valid Claim of the licensed Sanofi Target IP (the applicable period of time during which royalties are payable pursuant to this sentence and the preceding sentence being referred to as the applicable "Royalty Term"). During the applicable Royalty Term, the Party owing royalties shall deliver to

the other Party with each royalty payment a report detailing in reasonable detail the information necessary to calculate the royalty payments due under this Agreement for such calendar quarter, including the following information, specified on a Royalty Product-by-Royalty Product and country-by-country basis: (a) total gross invoiced amount from sales of each Royalty Product by a Party, its Affiliates and sublicensees; (b) all relevant deductions from gross invoiced amounts to calculate Net Sales; (c) Net Sales; and (d) royalties payable.

4.6 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars using the average of the buying and selling exchange rate for conversion of the applicable foreign currency into United States Dollars, using the spot rates (the "Closing Mid-Point Rates" found in the "Dollar spot forward against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties) from the last Business Day of the preceding month.

4.7 Late Payments. All late payments made under this Agreement (including payments made pursuant to Sections 4.4 and 4.5 above), shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in *The Wall Street Journal* (U.S., Eastern Edition) effective for the date on which the payment was due \*\*\*\*\* (such sum being referred to as the "Default Interest Rate").

4.8 Taxes. Except as set forth in Section 4.1, any withholding or other taxes that a Party is required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to such other Party; provided, however, that the remitting Party shall furnish the other Party with proper evidence, including any self-reporting documentation, of the taxes so paid. Each Party shall cooperate with the other and furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable).

## **ARTICLE 5**

### **OPT-IN RIGHTS TO LICENSE PRODUCT CANDIDATES**

5.1 Opt-In Rights to License Product Candidates. Subject to the last sentence of this Section 5.1 and the other terms of this Agreement, Sanofi shall have the exclusive right during the term of the Discovery Program to elect to jointly (with Regeneron) develop and commercialize each Product Candidate as set forth below, under the terms and conditions set forth in the License and Collaboration Agreement (the "Opt-In Rights"). While the Opt-In Rights are in effect with respect to an Antibody from the Discovery Program, including a MTC in the Discovery Program, Regeneron will not grant to any Third Party rights to any such Antibody. The Opt-In Rights will expire and Sanofi will no longer have any rights or licenses to any Antibodies, including MTCs, under this Agreement upon the expiration or earlier

termination of the Discovery Program. After the first five (5) years of the Discovery Program (or if the Discovery Program is earlier terminated by Sanofi under the terms of [Section 12.4](#)), the Opt-In Rights shall remain in effect during the Tail Period solely with respect to Lead Candidates and other Antibodies and MTCs against any applicable Targets properly identified by Sanofi in its notice to extend the Discovery Program through the Tail Period provided under [Section 2.9](#).

5.2 [Process for Opt-In Rights](#). \*\*\*\*\*

5.3 [Initial Development Plan](#). Within thirty (30) days after Sanofi's receipt of the Opt-In Report, the Parties shall jointly commence, and thereafter as promptly as practicable complete, preparation of a plan and budget for the planned development activities for such Product Candidate through the completion of the Phase I Clinical Trial (the "[Initial Development Plan](#)"), the final budget included in which shall be subject to Sanofi's written approval, not to be unreasonably withheld or delayed; provided, however, that (i) the Parties shall not be required to continue or complete such preparation if the Opt-In Period for such Product Candidate has expired without Sanofi having timely exercised its Opt-In Rights with respect thereto or Sanofi shall have otherwise advised Regeneron in writing that it will not exercise its Opt-In Rights with respect to such Product Candidate and (ii) if the Parties are unable to agree on a final budget the matter shall first be referred to the Executive Officers in accordance with [Section 3.3\(b\)](#) above, and if such Executive Officers are unable to resolve such matter, it shall be submitted to binding arbitration to be conducted in accordance with [Section 13.1](#) below. If Sanofi properly exercises its Opt-In Rights with respect to a Product Candidate, such Product Candidate shall be developed in accordance with the Initial Development Plan until the Parties agree to the "[Global Development Plan](#)" as such term is defined in the License and Collaboration Agreement.

5.4 [Opt-In Exercise](#). Sanofi may exercise its Opt-In Rights under this Agreement and license a Product Candidate under the License and Collaboration Agreement by delivering to Regeneron a written notice of exercise in the form annexed hereto as [Exhibit A](#) (an "[Opt-In Notice](#)") on or before the later of (i) \*\*\*\*\* , ("the "[Opt-In Period](#)"),  
\*\*\*\*\*

5.5 [DII4 and REGN-88](#). Sanofi exercised its Opt-In Rights to REGN-88 as of the Effective Date and shall be deemed to have exercised its Opt-In Right with respect to Delta-like ligand-4 (DII4) MTCs as of the Effective Date. For clarification, development of the Delta-like ligand-4 (DII4) MTCs shall be conducted under this Agreement until such time as an IND is filed.

5.6 [Refused Candidates](#). If Sanofi does not provide Regeneron with an Opt-In Notice within the Opt-In Period with respect to a particular Product Candidate, or Sanofi notifies Regeneron that it will not exercise Opt-In Rights with respect to the Product Candidate, then the following shall apply:

(i) [Refused Candidate](#). The Opt-In Rights shall expire with respect to that Product Candidate (a "[Refused Candidate](#)"). All licenses granted in [Section 2.10](#) shall automatically expire with respect to each Product Candidate upon such Product Candidate becoming a Refused Candidate. Following such time as a Product Candidate becomes a Refused Candidate, except as set forth below, the applicable Target

shall no longer be deemed a Program Target and shall be removed from the Target List and Sanofi shall no longer have any rights to any Antibodies, including MTCs, against such Target under this Agreement. Sanofi shall have a one-time right within four (4) weeks of the date a Product Candidate becomes a Refused Candidate to designate the Target for such Refused Candidate as one of its Sanofi Targets.

(ii) Regeneron Rights. Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any Refused Candidate without restriction outside the Discovery Program and this Agreement, unless the Refused Candidate is a Competing Refused Candidate, in which case, Section 2.8(b)(ii) shall apply. In addition, unless Sanofi has exercised its right under Section 5.6(i) to designate the applicable Target for a Refused Candidate as one of its Sanofi Targets, then Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any MTCs or other Antibodies against such Target and may practice and use any Regeneron Intellectual Property, including, without limitation, the Mice, in connection with such activities. If Sanofi has designated the applicable Target for the Refused Candidate as a Sanofi Target pursuant to Section 5.6(i), then all Antibodies (including MTCs) against such Target that were generated under the Discovery Program other than the Refused Candidate shall remain part of the Discovery Program.

(iii) Sanofi Rights. Neither Sanofi nor its Affiliates, either directly or through any Third Party, may develop or commercialize an Antibody that is against the Target of a Refused Candidate \*\*\*\*\*.

## **ARTICLE 6**

### **NEWLY CREATED INVENTIONS**

#### **6.1 Ownership of Newly Created Intellectual Property.**

(a) Each Party shall exclusively own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created solely by such Party, its employees, agents and consultants under the Discovery Program ("Sole Inventions"). Sole Inventions made solely by Sanofi, its employees, agents and consultants are referred to herein as "Sanofi Sole Inventions." Sole Inventions made solely by Regeneron, its employees, agents and consultants are referred to herein as "Regeneron Sole Inventions." The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's Intellectual Property, other than the license rights expressly granted hereunder.

(b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Discovery Programs that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Sanofi (or for which ownership vests in Sanofi by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron (or for

which ownership vests in Regeneron by operation of law), on the other hand, on the basis of each Party having an undivided interest in the whole (“Joint Inventions”).

(c) Notwithstanding the foregoing in Section 6.1(b), (i) for purposes of determining whether a patentable invention is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, as determined, if necessary, by an independent third party, (ii) for purposes of determining whether a copyrighted work is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws, and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.

(d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under this Agreement vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.

(e) The Parties hereby agree that each Party’s use of the Joint Inventions shall be governed by the terms and conditions of this Agreement including the following: each Party’s interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement or the License and Collaboration Agreement); provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as otherwise set forth herein or in the License and Collaboration Agreement, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee’s written agreement to be bound by the terms of this Section 6.1(e), (iii) during the Discovery Program, each Party agrees not to license its interest in any Joint Invention with the right to use such Joint Invention for developing, manufacturing or commercializing antibodies (except for developing, manufacturing or commercializing a Party’s Antibodies that may be included in the exclusions described in Section 2.8 (b) of the Agreement), and (iv) nothing in this Article 6 shall relieve a Party or its Affiliates of their obligations under Article 9 with respect to Confidential Information provided by the other Party or such other Party’s Affiliates. Neither Party hereto shall have the obligation to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Discovery Program. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld. The provisions governing Joint Inventions set forth in this Section 6.1(e) shall survive the expiration or termination of this Agreement.

6.2 Prosecution and Maintenance of Patent Rights.

(a) Subject to the terms of the License and Collaboration Agreement with respect to Licensed Products, Regeneron shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights and Regeneron shall confer with and keep Sanofi reasonably informed regarding the status of such activities to the extent they are Product Patent Rights. \*\*\*\*\*.

(b) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of Regeneron. Regeneron shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners \*\*\*\*\*.

(c) The Parties shall have the following obligations with respect to the filing, prosecution and maintenance of any Joint Patent Rights, as well as any Product Patent Rights: (i) the prosecuting Party (the "Prosecuting Party") shall provide the other Party (the "Non-Prosecuting Party") with notice and a copy of a substantially completed draft of any Patent Application at least thirty (30) days prior to the filing of any such Patent Application by the Prosecuting Party and incorporate all reasonable comments provided by the Non-Prosecuting Party within such thirty (30) day period unless the Prosecuting Party reasonably believes that such comments will adversely affect the scope or validity of the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) the Prosecuting Party shall notify the Non-Prosecuting Party prior to its filing of a Patent Application; (iii) the Prosecuting Party shall consult with the Non-Prosecuting Party promptly following the filing of the Patent Application to mutually determine in which countries it shall file convention Patent Applications; (iv) the Prosecuting Party shall provide the Non-Prosecuting Party promptly with copies of all material communications received from or filed in patent offices with respect to such applications and incorporate all reasonable comments provided by the Non-Prosecuting Party, unless the Prosecuting Party reasonably believes that such comments will adversely affect the validity or scope of the Patent Application or resulting Patent for both Parties; and (v) the Prosecuting Party shall provide the Non-Prosecuting Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office, (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the Non-Prosecuting Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances, including assuming the Prosecuting Party's responsibility for filing, prosecution and maintenance of any such Product Patent Right or Joint Patent Right and becoming the Prosecuting Party. With respect to Joint Inventions, it is understood that the Prosecuting Party and Non-Prosecuting Party shall use all reasonable efforts to reach agreement on all material filings and amendments and no such material filings or amendments shall be made by the Non-Prosecuting Party without the prior written agreement of

the Non-Prosecuting Party, such agreement not to be unreasonably withheld or delayed. In addition, in the event that the Prosecuting Party materially breaches the foregoing obligations and such material breach is not cured within thirty (30) days of a written notice from the Non-Prosecuting Party describing such breach in reasonable detail, or in the event that the Prosecuting Party fails to undertake the filing of a Patent Application within the earlier of (i) ninety (90) days of a written request by the Non-Prosecuting Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the Non-Prosecuting Party may assume the Prosecuting Party's responsibility for filing, prosecution and maintenance of any such Product Patent Right and will thereafter be deemed the Prosecuting Party for purposes hereof. Notwithstanding the foregoing, the Prosecuting Party may withdraw from or abandon any Patent or Patent Application on thirty (30) days' prior notice to the Non-Prosecuting Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the Non-Prosecuting Party a free-of-charge option to assume the prosecution or maintenance thereof. The Parties will file and prosecute Patent Applications described in this Section 6.2(a) in the list of countries set forth in Exhibit C, unless otherwise agreed upon by the Parties.

(d) All costs incurred in the filing, prosecution and maintenance of any Joint Patent Rights and Product Patent Rights and in performing freedom to operate analyses on Program Targets or Lead Candidates shall be shared equally by the Parties.

6.3 Third Party Claims. In the normal course of business, Regeneron shall carry out patent searches in relation to the Program Targets, Lead Candidates, and Product Candidates, as well as the technologies used to discover, develop and commercialize any of the foregoing, and will disclose, along with any analysis, to Sanofi's counsel any conflict or likely conflict of which Regeneron is aware with respect to the Patent Rights of any Third Party with respect to any such Program Targets, Lead Candidates and Product Candidates prior to selection to enter IND Preparation. If either Party or its Affiliates shall learn of a Third Party claim that the activities under the Discovery Program infringe or otherwise violate the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this claim, assertion or certification. As soon as reasonably practical after the receipt of such notice, the Parties shall cause their respective legal counsel to meet to confer on such allegation of infringement. In particular, with regard to issues related to freedom to operate concerning Targets pursued under this Agreement, the Parties shall conduct and maintain ongoing and regular communications between their legal/intellectual property departments.

## ARTICLE 7

### **BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS**

7.1 Books and Records. Each Party shall keep proper books of record and account in which full, true and correct entries (in conformity with GAAP) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall permit auditors, as provided in Section 7.2, to visit and inspect, during regular business hours and under the guidance of its employees, the books of record and account of such Party to the extent relating to this Agreement and discuss its affairs, finances and accounts to the extent relating to this Agreement.

7.2 Audits and Adjustments.

(a) Each Party shall have the right, upon no less than thirty (30) days' advance written notice and at such reasonable times and intervals and to such reasonable extent as the Party shall request, not more than once during any Contract Year, to have the books and records of the other Party to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable, appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days of delivery. If a Party over billed or underpaid an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than \*\*\*\*\*, it shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the Party initiating the audit in all other cases). Such accountants shall not reveal to the Party requesting the audit the details of its review, except for the findings of such review and such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article 9.

(c) If any examination or audit of the records described above discloses an over billing or underpayment of amounts due hereunder, then unless the result of the audit is contested pursuant to Section 7.2(b) above, the Party that overbilled or underpaid shall pay the same (plus interest thereon at the Default Interest Rate from the date of such over billing or underpayment through the date of payment of the amount required to be paid pursuant to this Section 7.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section 7.2.

(d) Disputes. Any disputes with respect to the results of any audit conducted under Section 7.2 above shall be resolved by binding arbitration in accordance with Section 13.1 below.

7.3 IAS/IFRS/GAAP. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with IAS/IFRS, and for the US, if desired, GAAP, as generally and consistently applied.

**ARTICLE 8**  
**REPRESENTATIONS, WARRANTIES AND COVENANTS**

8.1 Joint Representations and Warranties. Each Party hereto represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;

(c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other material agreement or arrangement, whether written or oral, by which it is bound or requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from performing the Discovery Program or granting the rights and/or licenses hereunder; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf.

8.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any court, arbitrator, or Governmental Authority that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the term of the Discovery Program, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

8.3 Additional Regeneron Representations, Warranties and Covenants. Regeneron additionally represents and warrants to Sanofi that, as of the Effective Date:

(a) Regeneron owns or has a valid license to all Regeneron Patent Rights in existence as of the Effective Date;

(b) Regeneron has the right and authority to grant the rights (including the Opt-In Rights) granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted, and will not grant during the term of this Agreement, any rights that would be inconsistent with or in conflict with or in derogation of the rights granted herein;

(c) there is no pending litigation of which Regeneron has received notice or is otherwise aware that alleges that any of Regeneron's activities relating to the Mice or the Regeneron Intellectual Property have violated, or would violate, the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation);

(d) to Regeneron's knowledge, no litigation has been otherwise threatened which alleges that any of its activities relating to the Mice or the Regeneron Intellectual Property have violated or would violate, any intellectual property rights of any Third Party;

(e) to Regeneron's knowledge, after due inquiry, the use of the Mice and the Regeneron Intellectual Property generally in the Discovery Program (but not with respect to a specific MTC or Target) does not and will not infringe or otherwise violate any valid Patent or provisional rights to applications or other intellectual property of any Third Party claiming genetically modified mice or the use thereof to make antibodies;

(f) neither the development or reproduction of the Mice nor the conception, development and reduction to practice of any Regeneron Intellectual Property existing as of the Effective Date has constituted or involved the misappropriation of trade secrets or other rights of any Person;

(g) to Regeneron's knowledge, the issued Patents included in the Regeneron Intellectual Property existing as of the Effective Date are not invalid or unenforceable, in whole or part;

(h) Regeneron has not received any written notice of any threatened claims or litigation seeking to invalidate or otherwise challenge the Regeneron Patent Rights or Regeneron's rights therein, and, to Regeneron's knowledge, none of the Regeneron Patent Rights are subject to any pending re-examination, opposition, interference or litigation proceedings;

(i) The commercial terms of the "Mouse Purchase Agreement" referred to in Section 2.15 and as outlined in Exhibit B hereto are consistent with those contained in Regeneron's existing agreements with other commercial entities, and

(j) neither Regeneron nor any of its Affiliates shall transfer ownership, assign ownership, grant a security interest in or otherwise encumber any of its rights in, to or under any Regeneron Intellectual Property in a way that will impair Sanofi's rights or Regeneron ability to perform its obligations under this Agreement.

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8.4 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY PRODUCT. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

## **ARTICLE 9 CONFIDENTIALITY**

9.1 Confidential Information. During the term of this Agreement and for a period of five (5) years thereafter, each Party (in such capacity, the "Receiving Party") shall keep confidential, and other than as provided herein or in the License and Collaboration Agreement, shall not use or disclose, directly or indirectly, any and all trade secrets or other proprietary information, including, without limitation, any proprietary data, inventions, documents, ideas, information, discoveries, or materials, owned, developed, or possessed by the other Party (in such capacity, the "Disclosing Party"), whether in tangible or intangible form, the confidentiality of which the Disclosing Party takes reasonable measures to protect, including but not limited to Regeneron Know-How and Sanofi Know-How disclosed by the Disclosing Party under this

Agreement (the “Confidential Information”). For purposes of this Agreement, all confidential information disclosed by Regeneron under the terms of the confidentiality agreements between Sanofi Parent and Regeneron dated February 1, 2007 and October 23, 2007 is hereby deemed Confidential Information of Regeneron. Each of Sanofi and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any Confidential Information of the other Party to any Third Party except to its employees, agents, consultants or any other Person under its authorization; provided such employees, agents, consultants or other Persons are subject in writing to confidentiality obligations applicable to the Disclosing Party’s Confidential Information no less strict than those set forth herein.

(a) Notwithstanding the foregoing, Confidential Information shall not be deemed to include information and materials (and such information and materials shall not be considered Confidential Information under this Agreement) to the extent that it can be established by written documentation by the Receiving Party that such information or material is: (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the Receiving Party or any Person to whom the Receiving Party provided such information; (ii) is or was already in the possession of the Receiving Party at the time of disclosure by the Disclosing Party; (iii) is disclosed to the Receiving Party on an unrestricted basis from a Third Party not under an obligation of confidentiality to the Disclosing Party or any Affiliate of the Disclosing Party with respect to such information; (iv) information that has been independently created by the Receiving Party (or its Affiliate), as evidenced by written or electronic documentation, without any aid, application or use of the Disclosing Party’s Confidential Information; or (v) required by Law to be disclosed, provided that the Receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the Disclosing Party to seek confidential treatment for such information, and provided further that the Receiving Party provides all reasonable cooperation to assist the Disclosing Party to protect such information and limits the disclosure to that information which is required by Law to be disclosed.

(b) Information and other Know-How that is discovered by Regeneron in connection with the Discovery Program will be considered Regeneron’s Confidential Information, except to the extent it relates to a Licensed Product, in which case it shall be Confidential Information of both Parties, subject to the terms of the License and Collaboration Agreement.

(c) Specific aspects or details of Confidential Information will not be deemed to be within the public knowledge or in the prior possession of a Person merely because such aspects or details of the Confidential Information are embraced by general disclosures in the public domain. In addition, any combination of Confidential Information will not be considered in the public knowledge or in the prior possession of either Person merely because individual elements thereof are in the public domain or in the prior possession of a Person unless (i) the combination and its principles are in the public knowledge or in the prior possession of that Person and (ii) the combination is documented, in a single contemporaneous document, as in the public knowledge or in the prior possession of a Person.

(d) Notwithstanding anything else in this Agreement to the contrary, each Party hereto (and each employee, representative, or other agent of any Party) may disclose to any and all Persons, without limitation of any kind, the Federal income tax treatment and Federal

income tax structure of any and all transaction(s) contemplated herein and all materials of any kind (including opinions or other tax analyses) that are or have been provided to any Party (or to any employee, representative, or other agent of any party) relating to such tax treatment or tax structure, provided, however, that this authorization of disclosure shall not apply to restrictions reasonably necessary to comply with securities laws. This authorization of disclosure is retroactively effective immediately upon commencement of the first discussions regarding the transactions contemplated herein, and the Parties aver and affirm that this tax disclosure authorization has been given on a date which is no later than thirty (30) days from the first day that any Party hereto (or any employee, representative, or other agent of any party hereto) first made or provided a statement as to the potential tax consequences that may result from the transactions contemplated hereby.

9.2 Injunctive Relief. The Parties hereby acknowledge and agree that the rights of the Parties hereunder are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

9.3 Publications. If either Sanofi or Regeneron (the "Publishing Party") desires to publish or publicly present any results from the Discovery Program in scientific journals, publications or scientific presentations or otherwise, the Publishing Party shall provide the other Party an advance final copy of any proposed publication or summary of a proposed oral presentation relating to the information from the Discovery Program prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to preserve the confidentiality of its Confidential Information and to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it as a result of the publication or disclosure, to which the Publishing Party shall give due consideration. If such other Party informs the Publishing Party, within thirty (30) days of receipt (or such other period agreed to by the JRC) of an advance copy of a proposed publication or summary of a proposed oral presentation, that such publication in its reasonable judgment should not be published or presented, the Publishing Party shall delay or prevent such disclosure or publication as proposed by the other Party. In the case of patentable inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a patent application(s) or application(s) for a certificate of invention on the information involved. The Parties shall establish a publication review process to ensure compliance with this Section 9.3.

9.4 Disclosures Concerning this Agreement. The Parties will mutually agree upon the contents of a their respective press releases with respect to the execution of this Agreement and

the License and Collaboration Agreement which shall be issued simultaneously by both Parties on the Effective Date. Sanofi and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement or any other activities contemplated hereunder without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable cooperation to assist the other Party to protect such information and shall limit the disclosure to that information which is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement or any activities contemplated hereunder which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding this Agreement. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article 9 without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. Each Party acknowledges that the other Party as a publicly traded company is legally obligated to make timely disclosures of all material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall cooperate with one another and use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

## **ARTICLE 10** **INDEMNITY**

### 10.1 Indemnity and Insurance.

(a) Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines and expenses, including reasonable attorneys' fees and costs (collectively, "Damages"), arising from or occurring as a

result of a Third Party's claim, action, suit, judgment or settlement against a Regeneron Indemnatee that is due to or based upon:

(i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Sanofi or its Affiliates in connection with the Discovery Program, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Regeneron or its Affiliates; or

(ii) material breach by Sanofi of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.

(b) Regeneron will defend, indemnify and hold harmless Sanofi, its Affiliates and their respective officers, directors, employees and agents ("Sanofi Indemnitees") from and against all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Sanofi Indemnatee that is due to or based upon:

(i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Regeneron or its Affiliates in connection with the Discovery Program, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Sanofi or its Affiliates; or

(ii) material breach by Regeneron of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.

#### 10.2 Indemnity Procedure.

(a) The Party entitled to indemnification under this Article 10 (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within five (5) Business Days of becoming aware of any claim or claims asserted or threatened in writing against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder.

(i) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) the Indemnified Party consents to such compromise or settlement, which consent shall not be withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified hereunder or (C) the imposition of any equitable relief against the

Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon at least ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably withheld or delayed), provided, that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld or delayed.

(ii) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 10.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying and the Indemnified Party.

(iii) The amount of any Damages for which indemnification is provided under this Article 10 will be reduced by the insurance proceeds received, and any other amount recovered, if any, by the Indemnified Party in respect of any Damages.

(iv) If an Indemnified Party receives an indemnification payment pursuant to this Article 10 and subsequently receives insurance proceeds from its insurer with respect to the damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this Article 10 and (ii) the amount necessary to fully and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this Article 10.

#### **ARTICLE 11** **FORCE MAJEURE**

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions, or acts of God ("Force Majeure"). Such excuse from liability and responsibility

shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

## **ARTICLE 12**

### **TERM AND TERMINATION**

12.1 Term. The “Term” of this Agreement shall commence on the Effective Date and end on the later to occur of (a) the expiration or earlier termination of the Discovery Program, including any Tail Period, unless this Agreement is earlier terminated in accordance with this Article 12 in which event the Term shall end on the effective date of such termination.

12.2 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 12.2, this Agreement shall be terminable by a Party in its entirety if the other Party commits a material breach of this Agreement. Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period. Notwithstanding the foregoing, in the case of breach of a payment obligation not subject to a bona fide dispute hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall instead be forty-five (45) days. For purposes of this Section 12.2, the term “material breach” shall mean an intentional, continuing (and uncured within the time period described above), material breach by a Party as determined by binding arbitration consistent with the provisions of Section 13.1 of this Agreement.

12.3 Termination for Insolvency. Either Party shall have the right to terminate this Agreement in its entirety if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, or (b) if the other Party proposes a written agreement of composition or extension of its debts, or (c) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or (d) if the other Party shall propose or be a party to any dissolution or liquidation, or (e) if the other Party shall make an assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party’s bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to “intellectual property” as defined under Section 101(52) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including, without limitation, any Patent Rights in any country of a Party covered by the license grants under this Agreement, are part of the “intellectual property” as defined under Section 101(52) of the Bankruptcy Code subject to

the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

12.4 Termination by Sanofi on Notice. \*\*\*\*\*

12.5 Termination for Breach of Standstill. Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have breached their obligations under any of Sections 3, 4 or 5 of the Investor Agreement (to the extent such sections of the Investor Agreement is then in effect). Furthermore, Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have (a) breached their obligations under Section 20.16 of the Aventis Collaboration Agreement, to the extent that such Section 20.16 remains in effect after the Effective Date, or (b) breached its obligations under Section 5.3 of the Stock Purchase Agreement, dated as of September 5, 2003, by and between Sanofi and Regeneron (the "Aventis Stock Purchase Agreement"), to the extent that such Section 5.3 remains in effect after the Effective Date. Any such breach of the Investor Agreement, the Aventis Stock Purchase Agreement or the Aventis Collaboration Agreement, as the case may be, shall be treated as a breach of this Agreement. Notwithstanding the foregoing and for the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of (i) a de minimus breach of Section 3.1(a) of the Investor Agreement (to the extent such Section 3.1(a) is in effect after the Effective Date) or of Section 20.16(a) of the Aventis Collaboration Agreement (to the extent such Section 20.16(a) remains in effect after the Effective Date) or (ii) an inadvertent breach of Section 3.1(g) of the Investor Agreement (to the extent such Section 3.1(g) is in effect after the Effective Date) or an inadvertent breach of Section 20.16(g) of the Aventis Collaboration Agreement (to the extent such Section 20.16(g) remains in effect after the Effective Date), arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of such Section 20.16 or of paragraphs (a) through (e) of Section 3.1 of the Investor Agreement, as applicable. Sanofi's rights under Sections 2.16 and 2.17 shall survive termination for breach of the standstill or lock-up under Section 12.5 of the Agreement

12.6 Termination for Breach of License and Collaboration Agreement. Notwithstanding anything to the contrary herein, (a) Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon providing written notice to Sanofi, if Regeneron has terminated the License and Collaboration Agreement, in its entirety, pursuant to Section 19.3, 19.4, or 19.5 of the License and Collaboration Agreement, and (b) Sanofi shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon providing written notice to Regeneron, if Sanofi has terminated the License and Collaboration Agreement, in its entirety, pursuant to Section 19.3 or 19.4 of the License and Collaboration Agreement.

12.7 Effect of Termination by Sanofi for Breach. In addition to the provisions of Section 12.9 below, notwithstanding anything herein to the contrary, in the event that Sanofi terminates this Agreement pursuant to Section 12.2 of this Agreement the following shall apply:

(a) Sanofi shall be granted a non-exclusive, non-transferable, royalty free, worldwide license, without the right to sublicense, for a period that shall expire six (6) years from the Effective Date, to the Mice and the underlying Regeneron Intellectual Property for Sanofi and its Affiliates to use to discover and develop MTCs for any and all purposes;

(b) Regeneron shall perform a timely and expeditious technology transfer as required by Sanofi to pursue its rights under subsection (a) without delay above subject to the execution of a material transfer agreement containing non-financial terms and conditions related to the use of the Mice consistent with Regeneron's commercial license agreements for the Mice;

(c) the licenses granted to Regeneron under this Agreement shall automatically terminate;

(d) Sanofi shall be granted an exclusive, fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense, under Regeneron Target IP existing at the effective time of termination solely for use to develop and commercialize Antibodies against Sanofi Discovery Targets (and for no other uses), and the co-exclusive (with Regeneron and its Affiliates) fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense under Regeneron Target IP to develop and commercialize Antibodies against all other Program Targets at the time of termination (and for no other uses); and

(e) Sanofi's rights under Sections 2.15, 2.16 and 2.17 shall survive; and

(f) Sanofi shall have no further funding obligations under Section 4.2 of the Agreement.

12.8 Effect of Termination by Regeneron for Breach. In addition to the provisions of Sections 12.9 and 12.11 below, notwithstanding anything herein to the contrary, in the event that Regeneron terminates this Agreement pursuant to Section 12.2 or 12.5 of this Agreement, the following shall apply:

(a) the licenses granted to Sanofi under this Agreement shall automatically terminate;

(b) the rights granted to Sanofi under this Agreement in Sections 2.15, 2.16, and 2.17 and Article 5 shall automatically terminate;

(c) Regeneron shall be granted an exclusive, fully paid-up, non-transferable, royalty-free, worldwide, exclusive license, with the right to sublicense, under Sanofi Target IP existing at the effective time of termination solely for use to develop and commercialize Antibodies against Program Targets other than Sanofi Discovery Targets (and for no other uses), and the co-exclusive (with Sanofi and its Affiliates) fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense under Sanofi Target IP to develop and commercialize Antibodies against all Sanofi Discovery Targets at the time of termination (and for no other uses).

12.9 Survival of Obligations. Subject to Sections 12.7 and 12.8 above and except as otherwise provided below, upon expiration or termination of this Agreement, the rights and obligations of the Parties hereunder shall terminate, and this Agreement shall cease to be of further force or effect, provided that notwithstanding any expiration or termination of this Agreement:

(a) neither Sanofi nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of the Discovery Program (even if such costs and expenses arise following termination or expiration, as the case may be); provided, however, that Sanofi shall not be obligated to pay or reimburse Regeneron for any such costs or expenses in the event Sanofi terminates this Agreement pursuant to Section 12.2 above (and with respect to 12.4, Sanofi shall have no further obligations to pay for costs and expenses beyond the effective date of its termination notice);

(b) the obligations of the Parties with respect to the protection and nondisclosure of the other Party's Confidential Information in accordance with Article 9, as well as other provisions (including, without limitation, Sections 2.11(b), 2.11(c), 2.12 (except as set forth in Section 12.8 above), 2.13 (except as set forth in Section 12.8 above), 2.16, 2.17, 6.1(e), 6.2(b), 6.2(c), 6.2(d) (as it relates to Joint Patent Rights), 7.2, 10.1, 10.2, this Article 12, and Article 13) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable;

(c) for the avoidance of doubt, the early termination of this Agreement by either Party, and the expiration of this Agreement shall not relieve either Party of any of its royalty or other obligations under Article 4 with respect to any Royalty Product, for which royalties remain payable to the other Party under this Agreement; and such royalty provisions of Article 4 shall survive;

(d) for the avoidance of doubt, the obligations of the Parties with respect to the licenses granted in Sections 2.10, 2.11 (b), 2.11(c), 2.12, 2.13 shall survive the termination or expiration of this Agreement; and

(e) such expiration or termination and this Article 12 shall be without prejudice to any rights or remedies a Party may have for breach of this Agreement.

12.10 Return of Confidential Information. Subject to either Parties' licenses that survive termination or expiration, Confidential Information disclosed by the Disclosing Party, including permitted copies, shall remain the property of the Disclosing Party. Subject to the terms of the License and Collaboration Agreement (with respect to Licensed Products), upon the earlier to occur of (a) the termination of this Agreement or (b) the expiration of the Discovery Program, or upon written request of the Disclosing Party, the Receiving Party shall promptly return to the Disclosing Party or, at the Disclosing Party's request, destroy, all documents or other tangible materials representing the Disclosing Party's Confidential Information (or any designated portion thereof); provided that one (1) copy may be maintained in the confidential files of the Receiving Party for the purpose of complying with the terms of this Agreement. An officer of the

Receiving Party also shall certify in writing that it has satisfied its obligations under this Section 12.10 within ten (10) days of a written request by the Disclosing Party.

12.11 Special Damages. If Regeneron terminates this Agreement pursuant to Section 12.2 or 12.5, then Sanofi shall pay to Regeneron, within sixty (60) days of the termination of this Agreement, in addition to any other amount payable by Sanofi to Regeneron under this Agreement under Laws, or pursuant to any contractual remedies available to Regeneron, an amount equal to the sum of the Maximum Annual Discovery Program Costs for each of the years, including the remaining unpaid Maximum Annual Discovery Program Cost for the Contract Year in which such termination is effective, that would have been the remainder of the term of the Discovery Program but for the termination of this Agreement.

12.12 Termination by Sanofi At Will. Sanofi shall be entitled to terminate this Agreement at any time (except following a material breach of this Agreement by Sanofi pursuant to Section 12.2) without cause upon three months' written notice to Regeneron. If Sanofi terminates the Agreement under this Section 12.12, then Sanofi shall pay to Regeneron within five (5) days of its notice of termination, an amount equal to the sum of the Maximum Annual Discovery Program Costs for each of the years, including the Remaining Unpaid Maximum Annual Discovery Program Cost for the Contract Year in which such termination is effective, that would have been the remainder of the term of the Discovery Program but for the termination of this Agreement. In addition, Sanofi shall complete GLP toxicology studies conducted by Sanofi at the time of termination, if applicable, and such other critical activities conducted by Sanofi at the time of termination that cannot be transferred to Regeneron without a material adverse effect on the completion of such activities. In the event of such termination, in addition to the provisions of Section 12.9, the following shall apply:

(a) the rights granted to Sanofi under Sections 2.16, and 2.17 and Article 5 shall automatically terminate; and

(b) Regeneron shall be granted a non-exclusive, non-transferable, royalty bearing (in accordance with Section 4.4) worldwide license with the right to sublicense under Sanofi Target IP existing at the effective time of termination solely for use to develop and commercialize (i) MTCs against Program Targets, and (ii) any other Antibodies against Program Targets in the Discovery Program in existence at the effective time of termination of this Agreement.

### **ARTICLE 13** **ARBITRATION**

13.1 Binding Arbitration. In the event the Parties cannot reach agreement with respect to (i) the commercial reasonableness of the budget for the Initial Development Plan for a Product Candidate, (ii) the royalty on Net Sales of Immunoconjugates under Section 2.11(d)(i) and (iii) of this Agreement, (iii) whether a breach constitutes a "material breach" as described in Section 12.2 of this Agreement, and (iv) audits under Section 7.2(d) above, and such disputes are not resolved by the Executive Officers in accordance with Section 3.3(b) above, then the following shall apply:

(a) General. The respective disputed issue shall be referred to binding arbitration by one (1) arbitrator who shall be an independent expert in the pharmaceutical or biotechnology industry mutually acceptable to the Parties. The Parties shall use their best efforts to mutually agree upon one (1) arbitrator; provided, however, that if the Parties have not done so within ten (10) days after initiation of arbitration hereunder, or such longer period of time as the Parties have agreed to in writing, then such arbitrator shall be an independent expert as described in the preceding sentence selected by the New York office of the American Arbitration Association. Such arbitration shall be limited to casting the deciding vote with respect to the disputed issues as more fully described in Sections 13.1 (b)-(e) below. In connection therewith, each Party shall submit to the arbitrator in writing its position on and desired resolution of such matter. Such submission shall be made within ten (10) days of the selection or appointment of the arbitrator, and the arbitrator shall rule on such matter within ten (10) days of receipt of the written submissions by both Parties. The arbitrator shall select one of the Party's positions as his or her decision, and shall not have authority to render any substantive decision other than to so select the position of either Regeneron or Sanofi. Except as provided in the preceding sentence, such arbitration shall be conducted in accordance with the then-current Commercial Arbitration Rules of the American Arbitration Association. The arbitrator's ruling shall be final and binding upon the Parties. The costs of any arbitration conducted pursuant to this Section 13.1 shall be borne equally by the Parties. The Parties shall use diligent efforts to cause the completion of any such arbitration within sixty (60) days following a request by any Party for such arbitration.

(b) Initial Development Plan Budget. The specific issue that shall be submitted to the arbitrator shall be limited to determining the overall commercial reasonableness of the budget that is the subject of the dispute. If the arbitrator determines that such budget is commercially reasonable, then the dispute shall be deemed finally resolved and such resolution shall be binding on the Parties. However, if the arbitrator determines that such budget is not commercially reasonable, then the arbitrator shall, within fifteen (15) days after such determination, render a final decision as to what modifications must be made to such budget in order for it to be commercially reasonable (the "Budget Modification Decision"). In connection with reaching a Budget Modification Decision, the arbitrator may order the Parties to produce any documents or other information which are relevant to such final decision, and the Parties shall submit such documents or other information, together with their respective proposed resolutions which shall consist of their respective proposed modifications to the budget in order for it to be commercially reasonable, at least five (5) days prior to the date a Budget Modification Decision is required to be rendered as provided above. In rendering the final decision, the arbitrator shall be limited to choosing a resolution proposed by a Party without modification.

(c) Royalty on Net Sales \*\*\*\*\*: The issue that shall be submitted to the arbitrator shall be the royalty rate to apply under Section 2.11(d)(i).

(d) Material Breach Under Section 12.2: The issue that shall be submitted to the arbitrator shall be whether the breach committed by a Party meets the requirements for a material breach under Section 12.2 of this Agreement.

(e) Audit Disputes. The issue that shall be submitted to the arbitrator shall be disputes as described under Section 7.2(d) of this Agreement.

**ARTICLE 14**  
**MISCELLANEOUS**

14.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Except as set forth in Article 13 and 7.2(d), the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

14.2 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

14.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 14.3 attached hereto and shall be (a) delivered personally, (b) sent via a reputable nationwide overnight courier service, or (c) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, one (2) Business Days after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.

14.4 Entire Agreement. This Agreement and the License and Collaboration Agreement contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersede all prior understandings and writings relating to the subject matter hereof and thereof. It is understood and agreed that in the event of any conflict or inconsistency between this Agreement and the License and Collaboration Agreement, this Agreement shall control regarding the Parties' rights and obligations with respect to any Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program (prior to Sanofi's exercise of its Opt-In Rights with respect to such Product Candidate), and the License and Collaboration Agreement shall control regarding the Parties' rights and obligations with respect to any Licensed Product from and after the time a Product Candidate becomes a Licensed Product.

14.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Sanofi and Regeneron.

14.6 Interpretation. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; and (d) the words “herein” or “hereunder” relate to this Agreement. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP, but only to the extent consistent with its usage and the other definitions in this Agreement.

14.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction (“Modified Clause”), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

14.8 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Sanofi or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Sanofi or (b) the prior written consent of Sanofi in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any Third Party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

14.9 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Sanofi Indemnitees to the extent provided in the last sentence of Section 14.12 below.

14.10 Affiliates. Each Party may carry out its obligations under this Agreement through its Affiliates and absolutely, unconditionally and irrevocably guarantees to the other Party prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, neither Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. Sanofi shall not, directly or indirectly, cause or direct Sanofi Pasteur or Merial Limited to take any action for which Sanofi and its Affiliates are prohibited hereunder from committing. Each Party represents and warrants to the other Party that it has licensed or

will license from its Affiliates the Patents and Know-How owned by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement.

14.11 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

14.12 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, Article 10 is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Sanofi Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.

14.13 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as expressly provided in this Agreement. Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

14.14 Limitation of Damages. EXCEPT AS SET FORTH IN SECTION 12.11, IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 14.14 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD PARTY CLAIMS .

14.15 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the performance of the Discovery Program to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

14.16 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party.

**[Remainder of page intentionally left blank; signature page follows]**

IN WITNESS WHEREOF, Sanofi and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMACEUTICALS INC.

By /s/ Karen Linehan  
Name: Karen Linehan  
Title: Authorized Signatory

By /s/ Robin White  
Name: Robin White  
Title: Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By /s/ Leonard Schleifer  
Name: Leonard Schleifer  
Title: President & CEO  
45

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SCHEDULE 1.19  
Excluded Candidates

Regeneron's Excluded Candidates

\*\*\*\*\*

Sanofi's Excluded Candidates

\*\*\*\*\*

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SCHEDULE 1.42  
Lead Candidate Criteria

\*\*\*\*\*

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SCHEDULE 1.46  
Manufacturing Cost

\*\*\*\*\*

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SCHEDULE 1.94  
Form of Target List

\*\*\*\*\*

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Schedule 4.4

\*\*\*\*\*

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SCHEDULE 8.3

\*\*\*\*\*

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SCHEDULE 14.3

Notices

If to Sanofi:

Aventis Pharmaceuticals Inc.  
200 Crossing Boulevard  
Bridgewater, New Jersey 08807  
United States  
Attn: President US Research and Development

Copy: Sanofi Aventis  
174 Avenue de France  
75013 Paris  
France

Attn: Senior Vice President and General Counsel

If to Regeneron:

Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591  
Attention: President & CEO  
Copy: General Counsel

---

EXHIBIT A  
Form of Opt-In Notice  
[Sanofi Letterhead]  
[DATE]

Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591  
Attention: President & CEO  
Copy: General Counsel Regeneron Pharmaceuticals, Inc.

Reference is hereby made to the Discovery and Preclinical Development Agreement (the “Discovery Agreement”) by and between Aventis Pharmaceuticals Inc., a [ ], corporation with a principal place of business located at [ ], and Regeneron Pharmaceuticals, Inc., a New York corporation with a principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591. Capitalized terms used herein shall have the defined meanings set forth in the Discovery Agreement.

Pursuant to Section 5.4 of the Discovery Agreement, Sanofi hereby provides this Opt-In Notice to Regeneron to license [INSERT PRODUCT CANDIDATE] under the License and Collaboration Agreement. Effective immediately, [INSERT PRODUCT CANDIDATE] shall be considered a Licensed Product.

AVENTIS PHARMACEUTICALS INC.

\_\_\_\_\_  
Name:  
Title:

---

EXHIBIT B

\*\*\*\*\*

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EXHIBIT C

\*\*\*\*\*

Portions of this Exhibit Have Been  
Omitted and Separately Filed with the Securities  
And Exchange Commission with a Request  
For Confidential Treatment

LICENSE AND COLLABORATION AGREEMENT

By and Among

AVENTIS PHARMACEUTICALS INC.,

SANOFI-AVENTIS AMERIQUE DU NORD

and

REGENERON PHARMACEUTICALS, INC.

Dated as of November 28, 2007

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## TABLE OF CONTENTS

	<u>Page</u>
ARTICLE I DEFINITIONS	1
1.1 “Additional Major Market Country”	1
1.2 “Affiliate”	2
1.3 “Ancillary Agreements”	2
1.4 “Anticipated First Commercial Sale”	2
1.5 “Approval”	2
1.6 “Aventis LLC”	2
1.7 “Aventis Collaboration Agreement”	2
1.8 “Aventis Stock Purchase Agreement”	3
1.9 “BLA”	3
1.10 “Business Day”	3
1.11 “Clinical Supply Cost”	3
1.12 “Clinical Supply Requirements”	3
1.13 “Co-Commercialize” or “Co-Commercialization”	3
1.14 “Co-Commercialization Country”	3
1.15 “COGS”	4
1.16 “Commercial Overhead Charge”	4
1.17 “Commercial Supply Cost”	4
1.18 “Commercial Supply Requirements”	4
1.19 “Commercialize” or “Commercialization”	4
1.20 “Commercially Reasonable Efforts”	4
1.21 “Committee”	5
1.22 “Competing Opt-Out Product”	5
1.23 “Competing Product”	5
1.24 “Confidentiality Agreements”	5
1.25 “Consolidated Payment Report”	5
1.26 “Contract Sales Force”	5
1.27 “Contract Year”	5
1.28 “Controlling Party”	5
1.29 “Co-Promote” or “Co-Promotion”	5
1.30 “Country/Region Commercialization Budget”	5
1.31 “Country/Region Commercialization Plan”	5
1.32 “Country/Region Commercialization Committee”, or “CRCC”	6
1.33 “Detail”	6
1.34 “Develop” or “Development”	6
1.35 “Development Costs”	6
1.36 “Development FTE Cost”	7
1.37 “Development FTE Rate”	7
1.38 “Development Plan”	7
1.39 “Discovery Program”	7
1.40 “EMEA”	7

	<u>Page</u>
1.41 “Executive Officers”	8
1.42 “FDA”	8
1.43 “Field”	8
1.44 “Finished Product”	8
1.45 “First Commercial Sale”	8
1.46 “Formulated Bulk Product”	8
1.47 “FTE”	8
1.48 “GAAP”	8
1.49 “Global Commercialization Budget”	8
1.50 “Global Commercialization Plan”	8
1.51 “Global Development Budget”	8
1.52 “Global Development Plan”	9
1.53 “Good Practices”	9
1.54 “Governmental Authority”	9
1.55 “IAS/IFRS”	9
1.56 “ICH”	9
1.57 “IND”	9
1.58 “Indication”	9
1.59 “Initial Development Plan”	9
1.60 “Initial IND Filing Date”	9
1.61 “Investor Agreement”	9
1.62 “Joint Patent Rights”	9
1.63 “Know-How”	9
1.64 “Law” or “Laws”	10
1.65 “Lead Regulatory Party”	10
1.66 “Legal Dispute”	10
1.67 “License”	10
1.68 “Licensed Products”	10
1.69 “Major Market Country”	10
1.70 “Manufacture” or “Manufacturing”	10
1.71 “Marketing Approval”	10
1.72 “Manufacturing Plan”	10
1.73 “Medical Post-Approval Cost”	10
1.74 “Medical Post-Approval FTE Rate”	11
1.75 “Net Sales”	11
1.76 “New Information”	12
1.77 “Non-Approval Trials”	12
1.78 “Opt-In Right”	12
1.79 “Opt-Out Product”	12
1.80 “Other Shared Expenses”	12
1.81 “Out-of-Pocket Costs”	13
1.82 “Party Information”	13
1.83 “Patent Application”	13
1.84 “Patent Rights”	13
1.85 “Patents”	13
1.86 “Person”	13

	<u>Page</u>	
1.87	“Phase 3 Trial”	13
1.88	“Plan”	13
1.89	“Positive Phase 3 Trial Results”	13
1.90	“Pre-Launch Marketing Expenses”	13
1.91	“Pricing Approval”	14
1.92	“Product Candidate”	14
1.93	“Product Trademark”	14
1.94	“Promotional Materials”	14
1.95	“Quarter” or “Quarterly”	14
1.96	“Regeneron Intellectual Property”	14
1.97	“Regeneron Know-How”	14
1.98	“Regeneron Patent Rights”	14
1.99	“Region”	14
1.100	“Registration Filing”	15
1.101	“Regulatory Authority”	15
1.102	“Reporting Country/Region”	15
1.103	“Rest of World” or “ROW”	15
1.104	“Rest of World Country”	15
1.105	“ROW CPI”	15
1.106	“Sales Force Cost”	15
1.107	“Sales Force FTE Rate”	15
1.108	“Sanofi Intellectual Property”	16
1.109	“Sanofi Know-How”	16
1.110	“Sanofi Patent Rights”	16
1.111	“Sanofi Stock Purchase Agreement”	16
1.112	“Shared Commercial Expenses”	16
1.113	“Shared Phase 3 Trial Costs”	17
1.114	“Sublicensee”	17
1.115	“Target”	18
1.116	“Terminated Licensed Product”	18
1.117	“Termination Notice Period”	18
1.118	“Territory”	18
1.119	“Third Party”	18
1.120	“United States,” “US” or “U.S.”	18
1.121	“US CPI”	18
1.122	“Valid Claim”	18
1.123	Additional Definitions	18
 ARTICLE II COLLABORATION		 20
2.1	Scope of Collaboration	20
2.2	Compliance With Law	21
2.3	Further Assurances and Transaction Approvals	21
2.4	Compliance with Third Party Agreements	21
2.5	Plans	21
2.6	Limitation on Exercise of Rights Outside of Collaboration	21

	<u>Page</u>
ARTICLE III MANAGEMENT	26
3.1    Committees/Management	26
3.2    Joint Steering Committee	27
3.3    Joint Development Committee	28
3.4    Joint Commercialization Committee	29
3.5    Country/Region Commercialization Committees	31
3.6    Joint Finance Committee	31
3.7    Joint Manufacturing Committee	31
3.8    Membership	31
3.9    Meetings	32
3.10   Decision-Making	32
3.11   Resolution of Governance Matters	32
ARTICLE IV LICENSE GRANTS	33
4.1    Regeneron License Grants	33
4.2    Sanofi License Grants	33
4.3    Newly Created Intellectual Property	34
4.4    Sublicensing	34
4.5    No Implied License	35
4.6    Retained Rights	35
ARTICLE V DEVELOPMENT ACTIVITIES	35
5.1    Development of Licensed Products	35
5.2    Global Development Plans	35
5.3    Global Development Budgets	36
5.4    Development Reports	36
5.5    Review of Clinical Trial Protocols	37
5.6    Regeneron Early Development Opt-Out	37
ARTICLE VI COMMERCIALIZATION	38
6.1    Commercialization of Licensed Products in the Field in the Territory	38
6.2    Global Commercialization Plan(s)	38
6.3    Country/Region Commercialization Plans	39
6.4    Commercialization Efforts; Sharing of Commercial Information	39
6.5    Co-Commercialization of Licensed Products	40
6.6    Licensed Product Pricing and Pricing Approvals in the Territory	42
6.7    Sales and Licensed Product Distribution in the Territory; Other Responsibilities	42
6.8    Contract Sales Force	43
6.9    Promotional Materials	43
6.10   Promotional Claims/Compliance	44
6.11   Restriction on Bundling in the Territory	44
6.12   Inventory Management	44
6.13   Medical and Consumer Inquiries	44
6.14   Market Exclusivity Extensions	44
6.15   Post Marketing Clinical Trials	44

	<u>Page</u>
ARTICLE VII CLINICAL AND REGULATORY AFFAIRS	44
7.1    Ownership of Approvals and Registration Filings	44
7.2    Regulatory Coordination	45
7.3    Regulatory Events	46
7.4    Pharmacovigilance and Product Complaints	47
7.5    Regulatory Inspection or Audit	47
7.6    Recalls and Other Corrective Actions	47
ARTICLE VIII MANUFACTURING AND SUPPLY	48
8.1    Manufacture and Supply of Clinical Supply Requirements of Formulated Bulk Product	48
8.2    Finished Product Supply of Clinical Supply Requirements	48
8.3    Manufacture and Supply of Commercial Supply Requirements	48
8.4    Supply Agreement	49
8.5    Process Development and Manufacturing Plans	50
8.6    Manufacturing Shortfall	50
8.7    Manufacturing Compliance	50
ARTICLE IX PERIODIC REPORTS; PAYMENTS	51
9.1    Development Costs	51
9.2    Milestone Payments	51
9.3    Royalties	51
9.4    Sharing of Profits from Licensed Products	51
9.5    Periodic Reports	51
9.6    Funds Flow	52
9.7    Invoices and Documentation	53
9.8    Payment Method and Currency	53
9.9    Late Payments	53
9.10   Taxes	53
9.11   Adjustments to FTE Rates	53
9.12   Resolution of Payment Disputes	54
ARTICLE X DISPUTE RESOLUTION	54
10.1   Resolution of Disputes	54
10.2   Governance Disputes	54
10.3   Legal Disputes	54
10.4   Expert Panel	54
10.5   No Waiver	57
ARTICLE XI TRADEMARKS AND CORPORATE LOGOS	57
11.1   Corporate Names	57
11.2   Selection of Product Trademarks	57
11.3   Ownership of Product Trademarks	57
11.4   Prosecution and Maintenance of Product Trademark(s)	57
11.5   License to the Product Trademark(s)	57
11.6   Use of Corporate Names	58

	<u>Page</u>
ARTICLE XII NEWLY CREATED INVENTIONS AND KNOW-HOW	58
12.1    Ownership of Newly Created Intellectual Property	58
12.2    Prosecution and Maintenance of Patent Rights	60
12.3    Interference, Opposition and Reissue	63
ARTICLE XIII INTELLECTUAL PROPERTY LITIGATION AND LICENSES	64
13.1    Third Party Infringement Suits	64
13.2    Patent Marking	65
13.3    Third Party Infringement Claims; New Licenses	65
ARTICLE XIV BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS	66
14.1    Books and Records	66
14.2    Audits and Adjustments	66
14.3    GAAP/IAS/IFRS	67
ARTICLE XV REPRESENTATIONS, WARRANTIES and Covenants	67
15.1    Due Organization, Valid Existence and Due Authorization; Financial Capability	67
15.2    Knowledge of Pending or Threatened Litigation	68
15.3    Additional Regeneration Representations, Warranties and Covenants	68
15.4    Disclaimer of Warranties	69
15.5    Mutual Covenants	69
ARTICLE XVI CONFIDENTIALITY	69
16.1    Confidential Information	69
16.2    Injunctive Relief	71
16.3    Publication of New Information	71
16.4    Disclosures Concerning this Agreement	71
ARTICLE XVII INDEMNITY	72
17.1    Indemnity and Insurance	72
17.2    Indemnity Procedure	74
ARTICLE XVIII FORCE MAJEURE	75
ARTICLE XIX TERM AND TERMINATION	75
19.1    Term/Expiration of Term	75
19.2    Termination Without Cause	76
19.3    Termination For Material Breach	78
19.4    Termination for Insolvency	78
19.5    Termination for Breach of Standstill or Lock-Up	79
19.6    Termination of Discovery Agreement	79
19.7    Effect of Termination	79
19.8    Survival of Obligations	80

	<u>Page</u>
ARTICLE XX MISCELLANEOUS	81
20.1 Governing Law; Submission to Jurisdiction	81
20.2 Waiver	81
20.3 Notices	81
20.4 Entire Agreement	82
20.5 Amendments	82
20.6 Interpretation	82
20.7 Severability	82
20.8 Registration and Filing of the Agreement	82
20.9 Assignment	82
20.10 Successors and Assigns	83
20.11 Affiliates	83
20.12 Counterparts	83
20.13 Third-Party Beneficiaries	83
20.14 Relationship of the Parties	84
20.15 Limitation of Damages	84
20.16 Non-Solicitation	84
20.17 No Strict Construction	84

## LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT (this "Agreement"), dated as of November 28, 2007 (the "Effective Date"), is by and between AVENTIS PHARMACEUTICALS INC., a corporation organized under the laws of the state of Delaware having a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807 ("Sanofi"), an indirect wholly owned subsidiary of sanofi-aventis, a company organized under the laws of France with its principal headquarters at 174, avenue de France, 75013 Paris, France ("Sanofi Parent"), SANOFI-AVENTIS AMERIQUE DU NORD, a partnership organized under the laws of France with its principal headquarters at 174 avenue de France, 75013 Paris, France ("Sanofi Amerique"), and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of the state of New York having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Sanofi and Regeneron being sometimes referred to herein individually as a "Party" and collectively as the "Parties", and with Sanofi Amerique being a party to this Agreement for purposes of Sections 15.1, 15.2 and 20.11 only).

WHEREAS, concurrently with the execution and delivery of this Agreement, the Parties have entered into a Discovery and Preclinical Development Agreement (the "Discovery Agreement") whereby, upon the terms and conditions set forth therein, Regeneron will use its proprietary VelocImmune® technology and related suite of technologies with the objective of discovering Product Candidates (as defined below) which Sanofi may elect, in accordance with the Discovery Agreement, to advance into Development (as defined below) and thereupon automatically obtain from Regeneron a license of certain rights thereto upon the terms and conditions set forth herein;

WHEREAS, Sanofi and its Affiliates possess knowledge and expertise in, and resources for, developing and commercializing pharmaceutical products in the Field in the Territory (each as defined below);

WHEREAS, Regeneron and Sanofi desire to collaborate on the Development, Manufacture and Commercialization of Licensed Products (each as defined below) in the Field in the Territory upon the terms and conditions set forth herein (the "Collaboration"); and

NOW, THEREFORE, in consideration of the following mutual covenants contained herein, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

### ARTICLE I DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 "Additional Major Market Country" shall mean any country in the Territory, other than the Major Market Countries referred to in clause (i) of the definition thereof, in which Net Sales in the immediately preceding Contract Year were \*\*\*\*\* or more of

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aggregate Net Sales in the Territory, and such designation shall remain effective from and after the determination of such Net Sales amount; provided, however, that a country shall not be deemed an Additional Major Market Country if, at the time that Net Sales in such country in a given Contract Year first exceed \*\*\*\*\* of aggregate Net Sales in the Territory, the Parties mutually agree otherwise.

1.2 “Affiliate” shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates. For purposes of this Agreement, neither Sanofi Pasteur nor Merial Limited, nor any of their respective subsidiaries or joint ventures, shall be deemed to be Affiliates of Sanofi or any of its Affiliates.

1.3 “Ancillary Agreements” means the Sanofi Stock Purchase Agreement and the Investor Agreement.

1.4 “Anticipated First Commercial Sale” shall mean, with respect to a Licensed Product in the Field, the date agreed upon by the JSC in advance as the expected date of First Commercial Sale of such Licensed Product in the Field in a country in the Territory.

1.5 “Approval” shall mean, with respect to each Licensed Product, any approval (including Marketing Approvals and Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the Development, Manufacture or Commercialization of such Licensed Product in the Field in a regulatory jurisdiction anywhere in the world, and shall include, without limitation, an approval, registration, license or authorization granted in connection with any Registration Filing.

1.6 “Aventis LLC” shall mean sanofi-aventis US LLC (successor in interest under the Aventis Collaboration Agreement to Aventis Pharmaceuticals Inc.).

1.7 “Aventis Collaboration Agreement” shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between Aventis LLC and Regeneron, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth

Amendment, dated as of January 31, 2006, and Section 11.2 of the Sanofi Stock Purchase Agreement, as the same may be further amended from time to time.

1.8 “Aventis Stock Purchase Agreement” shall mean the Stock Purchase Agreement dated as of September 5, 2003 by and between Aventis Pharmaceuticals Inc. and Regeneron, as amended by Sections 4.2(b) and 4.4 of the Investor Agreement effective upon the execution and delivery of the Investor Agreement, and as may be further amended from time to time.

1.9 “BLA” shall mean, with respect to each Licensed Product, a biologics license application filed with respect to such Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority.

1.10 “Business Day” shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, the United States or Paris, France are authorized or required by Law to remain closed.

1.11 “Clinical Supply Cost” shall mean (a) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture Formulated Bulk Product for Clinical Supply Requirements under the applicable Global Development Plan, (b) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture, comparator agent or placebo requirements for activities contemplated under the applicable Global Development Plan, (c) the Out-of-Pocket Cost and/or the Manufacturing Cost for filling, packaging, labeling and delivery of such Clinical Supply Requirements, comparator agent, combination agent and/or placebo, as the case may be, for activities contemplated under the applicable Global Development Plan and (d) any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of Clinical Supply Requirements. To the extent that manufacturing cost for comparator agent, combination agent or placebo includes any markup over Manufacturing Cost to the benefit of one of the Parties or its Affiliates, such markup shall be deducted in the calculation of Clinical Supply Cost.

1.12 “Clinical Supply Requirements” shall mean, with respect to a Licensed Product, the quantities of such Licensed Product which are required by a Party or the Parties for Development in the Field under this Agreement, including, without limitation, the conduct of research, pre-clinical studies and clinical trials in connection with a Development Plan and quantities of such Licensed Product which are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in the Field in any regulatory jurisdiction in the Territory.

1.13 “Co-Commercialize” or “Co-Commercialization” shall mean the act of Co-Promoting in a Co-Commercialization Country.

1.14 “Co-Commercialization Country” shall mean each country in which Regeneron has elected to Co-Promote a Licensed Product, so long as, after commencing such Co-Promotion, Regeneron is Co-Promoting at least one Licensed Product in such country.

1.15 “COGS” for a Licensed Product for a Quarter shall mean cost (calculated in accordance with IAS/IFRS) of Manufacturing the Licensed Product sold in the Field in the Territory in the Quarter.

1.16 “Commercial Overhead Charge” shall mean, on a country-by-country and Licensed Product-by-Licensed Product basis in the Territory, beginning in the Contract Year of First Commercial Sale in the applicable country, an amount (agreed upon by the JFC at least six (6) months prior to the Anticipated First Commercial Sale in the country) to cover  
\*\*\*\*\*, such amount to be determined by the JFC as of January 1 of each following Contract Year. For the avoidance of doubt, “Commercial Overhead Charge” shall not include any amounts included in Medical Post-Approval Cost, Sales Force Cost, Other Shared Expenses or Shared Commercial Expenses.

1.17 “Commercial Supply Cost” shall mean the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost for the Manufacture of Commercial Supply Requirements, including, without limitation, scale-up after First Commercial Sale, any filling, packaging and labeling costs, and any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of such Commercial Supply Requirements.

1.18 “Commercial Supply Requirements” shall mean, with respect to each Licensed Product, quantities of Finished Product as are required to fulfill requirements for commercial sales, Non-Approval Trials and product sampling with respect to such Licensed Product in the Field in the Territory.

1.19 “Commercialize” or “Commercialization” shall mean, with respect to a Licensed Product, any and all activities directed to marketing, promoting (including, if applicable, Co-Promoting), detailing, distributing, importing, offering for sale, having sold and/or selling such Licensed Product in the Field in the Territory, including, without limitation, market research, obtaining Pricing Approvals, pre-launch marketing \*\*\*\*\*.

1.20 “Commercially Reasonable Efforts” shall mean the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with the efforts such Party devotes to products or research or development projects owned by it of similar scientific and commercial potential. Commercially Reasonable Efforts shall be determined on a market-by-market and Licensed Product-by-Licensed Product basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including without limitation, the efficacy, safety, anticipated regulatory authority approved labeling, competitiveness of the Licensed Product or alternative products that are in the marketplace or under development by Third Parties and other technical, scientific, legal, medical marketing and competitiveness factors. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time. In determining whether a Party has used Commercially Reasonable Efforts, neither the profit sharing nor other payments made or required to be made hereunder shall be factor weighed (that is, a Party may not apply lesser resources or efforts in support of a Licensed Product because it must share profits from sales of such Licensed Product or make any other payments hereunder).

1.21 “Committee” means any of the JSC, JDC, JCC, JMC, JFC, any CRCC, and any other committee established by the Parties or by the Committees referenced above, each as described in Article III (together with Working Groups or other committees contemplated herein or established in accordance with this Agreement).

1.22 “Competing Opt-Out Product” shall mean any Opt-Out Product having the same Target as a Licensed Product.

1.23 “Competing Product” shall mean, with respect to a Licensed Product, \*\*\*\*\*.

1.24 “Confidentiality Agreements” shall mean the confidentiality agreements between Regeneron and Sanofi Parent dated February 1, 2007 and October 23, 2007, respectively.

1.25 “Consolidated Payment Report” shall mean a consolidated Quarterly report prepared by Sanofi (based on information reported under Sections 5.4 and 9.5) setting forth in reasonable detail, for each Major Market Country in the Territory, for each Region in the Territory, and in the aggregate for all countries in the Territory, (a) Net Sales, COGS and Shared Commercial Expenses incurred by each Party for such Quarter, (b) Development Costs incurred by each Party for such Quarter, (c) Other Shared Expenses incurred by each Party for such Quarter, and (d) the Quarterly True-Up, and the component items and calculations in determining such Quarterly True-Up, calculated in accordance with Schedule 2.

1.26 “Contract Sales Force” shall mean sales representatives employed by a Third Party.

1.27 “Contract Year” shall mean the period beginning on the Effective Date and ending on December 31, 2008, and each succeeding consecutive twelve (12) month period thereafter during the Term. The last Contract Year of the Term shall begin on January 1 for the year during which termination or expiration of the Agreement will occur, and the last day of such Contract Year shall be the effective date of such termination or expiration.

1.28 “Controlling Party” shall mean \*\*\*\*\*.

1.29 “Co-Promote” or “Co-Promotion” shall mean the joint marketing and promotion of Licensed Product(s) by the Parties (or their respective Affiliates) under the same trademark in a Major Market Country pursuant to the applicable Country/Region Commercialization Plan.

1.30 “Country/Region Commercialization Budget” shall mean the budget for a particular calendar year approved by the JCC for the applicable Country/Region Commercialization Plan.

1.31 “Country/Region Commercialization Plan” shall mean, for each Reporting Country/Region, the three (3) year rolling plan for Commercializing Licensed Products in the Field in such country or Region and the related Country/Region Commercialization Budget and a

non-binding budget forecast for the next two (2) calendar years, approved by the JCC, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Country/Region Commercialization Plan shall set forth, for each Licensed Product, the information, plans and forecasts set forth in Section 6.3.

1.32 “Country/Region Commercialization Committee”, or “CRCC”, shall mean the committee established by the JCC for a particular Reporting Country/Region as described in Section 3.5.

1.33 “Detail” shall mean, with respect to each Licensed Product in the Field, a selling presentation for such product by a representative of each Party’s sales force, or another employee of each Party who may be deemed to be part of the Commercialization effort for such Licensed Product (e.g., such as a key account manager, etc.).

1.34 “Develop” or “Development” shall mean, with respect to a Licensed Product, the following activities undertaken or performed after the Initial IND Filing Date for such Licensed Product: (a) activities relating to research, pre-clinical and clinical drug development of such Licensed Product in the Field, including, without limitation, test method development and stability testing, assay development, toxicology, pharmacology, formulation, quality assurance/quality control development, technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, clinical studies (including research to design clinical studies), regulatory affairs, project management, drug safety surveillance activities related to clinical studies, the preparation and submission of Registration Filings but excluding activities necessary to obtain a Pricing Approval, reimbursement and/or listing on health care providers’ and payers’ formularies, (b) \*\*\*\*\* and (c) any other research and development activities with respect to such Licensed Product in the Field, including, without limitation, activities to support the discovery of biomarkers and activities to support new product formulations, delivery technologies and/or new indications in the Field, either before or after the First Commercial Sale.

1.35 “Development Costs” shall mean costs incurred by a Party (for each Licensed Product, commencing with the first (1st) day of the month in which the Opt-In Notice (as such term is defined in the Discovery Agreement) for such Licensed Product is received by Regeneron) directly in connection with the Development of Licensed Products in the Field in accordance with this Agreement and the applicable Global Development Plan, including without limitation:

- (a) all Out-of-Pocket Costs, including, without limitation, fees and expenses associated with obtaining Registration Filings and Marketing Approvals necessary for the Development and Commercialization of the Licensed Products in the Field under this Agreement;
- (b) Development FTE Costs;
- (c) Clinical Supply Costs;

(d) the costs and expenses incurred in connection with (i) Manufacturing process, formulation, cleaning, and shipping development and validation (other than validation batches which are sold), (ii), Manufacturing scale-up and improvements, (iii) stability testing, (iv) quality assurance/quality control development (including management of Third Party fillers, packagers and labelers), and (v) internal and Third Party costs and expenses incurred in connection with (A) qualification and validation of Third Party contract manufacturers and vendors and (B) subject to the terms of this Agreement, establishing a primary or secondary source supplier, including, without limitation, the transfer of process and Manufacturing technology and analytical methods, scale-up up to First Commercial Sale, process and equipment validation, cleaning validation and initial Manufacturing licenses, approvals and Regulatory Authority inspections (in each case, to the extent not included in Clinical Supply Costs or Commercial Supply Costs);

(e) any license fees and other payments under Licenses to the extent attributable to the Manufacture of Clinical Supply Requirements and/or the Development of Licensed Products in the Field under the Plans for the Territory subject to Section 13.3(e) in this Agreement; and

(f) any other costs or expenses specifically identified and included in the applicable Development Plan or included as Development Costs under this Agreement.

1.36 “Development FTE Cost” shall mean, for all Development activities performed in accordance with the Development Plan(s), including regulatory activities, the product of (a) the number of FTEs required for such Development activity as set forth in the approved Development Plan and (b) the Development FTE Rate. For the avoidance of doubt, the activity of contract personnel shall be charged as Out-of-Pocket Costs.

1.37 “Development FTE Rate” shall mean \*\*\*\*\* in the first (1st) Contract Year, such amount to be adjusted as of January 1, 2009 and annually thereafter by the sum of (a) the average of the percentage increases or decreases, if any, in the US CPI and the ROW CPI for the twelve (12) months ending June 30 of the Contract Year prior to the Contract Year for which the adjustment is being made \*\*\*\*\* , the Parties shall meet to consider a revision to the Development FTE Rate.

1.38 “Development Plan” shall mean a Global Development Plan or an Initial Development Plan, as the context requires.

1.39 “Discovery Program” shall have the meaning set forth in the Discovery Agreement.

1.40 “EMEA” shall mean the European Medicines Evaluation Agency or any successor agency thereto.

1.41 “Executive Officers” shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer of Sanofi Parent, or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.

1.42 “FDA” shall mean the United States Food and Drug Administration and any successor agency thereto.

1.43 “Field” shall mean the treatment, prevention, palliation and/or diagnosis of any disease.

1.44 “Finished Product” shall mean a Licensed Product in the Field in its finished, labeled and packaged form, ready for sale to the market or use in clinical or pre-clinical trials, as the case may be.

1.45 “First Commercial Sale” shall mean, with respect to a Licensed Product in a country in the Territory, the first commercial sale of the Finished Product to non-Sublicensee Third Parties for use in the Field in such country (or group of countries) following receipt of Marketing Approval. Sales for test marketing or clinical trial purposes or compassionate or similar use shall not constitute a First Commercial Sale.

1.46 “Formulated Bulk Product” shall mean Licensed Product in the Field formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.

1.47 “FTE” shall mean a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes of Development shall be \*\*\*\*\* per year.

1.48 “GAAP” shall mean generally accepted accounting principles as applicable in the United States.

1.49 “Global Commercialization Budget” shall mean the budget(s) for a particular Contract Year approved by the JCC for the applicable Global Commercialization Plan.

1.50 “Global Commercialization Plan” shall mean, with respect to a Licensed Product, the three (3) year rolling plan approved by the JSC for Commercializing such Licensed Product throughout the world, including the related Global Commercialization Budget and a non-binding budget forecast for the next two (2) Contract Years, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Global Commercialization Plan shall set forth (if not otherwise set forth in the applicable Country/Region Commercialization Plan(s)) for a Licensed Product, the information, plans and forecasts set forth in Section 6.2.

1.51 “Global Development Budget” shall mean the budget(s) for a particular Contract Year approved by the JSC for the applicable Global Development Plan.

1.52 “Global Development Plan” shall mean, with respect to a Licensed Product, the Initial Development Plan and the three (3) year rolling plan approved by the JSC for the worldwide Development of such Licensed Product, including the related Global Development Budget and a non-binding budget forecast for the next two (2) Contract Years, as the same may be amended from time-to-time in accordance with the terms of this Agreement. For the avoidance of doubt, a Global Development Plan will not include Non-Approval Trials.

1.53 “Good Practices” shall mean compliance with the applicable standards contained in then-current “Good Laboratory Practices,” “Good Manufacturing Practices” and/or “Good Clinical Practices,” as promulgated by the FDA and all analogous guidelines promulgated by the EMEA or the ICH, as applicable.

1.54 “Governmental Authority” shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.55 “IAS/IFRS” shall mean International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board.

1.56 “ICH” shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.57 “IND” shall mean, with respect to each Licensed Product in the Field, an Investigational New Drug Application filed with respect to such Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority outside the United States.

1.58 “Indication” means any disease.

1.59 “Initial Development Plan” shall have the meaning set forth in the Discovery Agreement.

1.60 “Initial IND Filing Date” means, with respect to a Licensed Product, the date an IND for such Licensed Product is first filed.

1.61 “Investor Agreement” means the Investor Agreement by and among Sanofi Parent, Sanofi, Aventis LLC, Sanofi Amerique and Regeneron, substantially in the form of Exhibit B to the Sanofi Stock Purchase Agreement, which will be entered into concurrently with the closing under the Sanofi Stock Purchase Agreement.

1.62 “Joint Patent Rights” shall mean Patent Rights that cover a Joint Invention.

1.63 “Know-How” shall mean, with respect to each Party and its Affiliates, any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information, including marketing and supply information, (whether or not patentable or

otherwise protected by trade secret Law) and that are not disclosed or claimed by such Party's Patents or Patent Applications.

1.64 "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

1.65 "Lead Regulatory Party" shall mean the Party having responsibility for preparing, prosecuting and maintaining Registration Filings and any Approvals for Licensed Products in the Field under this Agreement, and for related regulatory duties.

1.66 "Legal Dispute" shall mean any dispute related to a Party's alleged failure to comply with this Agreement or the validity, breach, termination or interpretation of this Agreement.

1.67 "License" shall mean any license from a Third Party approved by the JSC required for the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.

1.68 "Licensed Products" shall mean (i) Product Candidates as to which Sanofi has exercised its Opt-In Rights in accordance with Section 5.4 of the Discovery Agreement, (ii) any Competing Product that is included in the Collaboration pursuant to Section 2.6(c) below, (iii) REGN88 (IL-6RmAB) and Delta-like ligand-4(D-ll4) and (iv) \*\*\*\*\* (as defined in the Discovery Agreement) once included in the Collaboration pursuant to Section 2.11(b) of the Discovery Agreement.

1.69 "Major Market Country" shall mean any of the following: \*\*\*\*\*.

1.70 "Manufacture" or "Manufacturing" shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and/or storage of Formulated Bulk Product, Finished Product, placebo or a comparator agent, as the case may be.

1.71 "Marketing Approval" shall mean an approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in an indication in the Field in any country, but excluding any separate Pricing Approval.

1.72 "Manufacturing Plan" shall mean the manufacturing plan as prepared by the JMC as described in Section 8.5.

1.73 "Medical Post-Approval Cost" shall mean, for Licensed Product(s) in each country in the Territory, the product of (a) the number of office-based people supporting (i) the coordination of Non-Approval Trials, (ii) post-Approval non-clinical pharmacovigilance, (iii) the maintenance of Approvals, and (iv) Pricing Approvals (with the number and the method of calculating such number set forth in the applicable Country/Region Commercialization Plan or Global Commercialization Plan) and (b) the applicable Medical Post-Approval FTE Rate. The calculation of the number of people in (a) above will be designed to ensure the proper reporting

and auditing of such information in accordance with this Agreement. For the avoidance of doubt, the activities of contract personnel shall be charged as an Out-of-Pocket Cost.

1.74 “Medical Post-Approval FTE Rate” shall mean, on a Region-by-Region or one or more Major Market Countries basis in the Territory (determined based on the location of the medical affairs professional), a rate agreed upon in local currency by the Parties prior to the expected start of the first Non-Approval Trial in such Region or Major Market Country, as applicable, based upon the fully burdened cost of medical affairs professionals of pharmaceutical companies in the Field in the applicable country, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Medical Post-Approval FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.

1.75 “Net Sales” shall mean the gross amount invoiced for bona fide arms’ length sales of Licensed Products in the Field in the Territory by or on behalf of a Party or its Affiliates or Sublicensees to Third Parties, less the following deductions, determined in accordance with IAS/IFRS (or GAAP for the US) consistently applied:

- (a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such Licensed Products;
- (b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;
- (c) chargebacks and other amounts paid on sale or dispensing of Licensed Products;
- (d) Third Party cash rebates and chargebacks related to sales of Licensed Products, to the extent allowed;
- (e) retroactive price reductions that are actually allowed or granted;
- (f) compulsory refunds, credits and rebates directly related to the sale of Licensed Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or government regulations;
- (g) freight, postage, shipment and costs (or wholesale fees in lieu of those costs) and customs duties incurred in delivering Licensed Products that are separately identified on the invoice or other documentation;
- (h) sales taxes, excess duties, or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of Licensed Products, which are separately identified on the invoice or other documentation; and
- (i) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of such Licensed Product falling within

categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof.

Net Sales in currency other than United States Dollars shall be translated into United States Dollars according to the provisions of Section 9.8 of this Agreement. Sales between the Parties, or between the Parties and their Affiliates or Sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Licensed Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if Sanofi or its Affiliate or Sublicensee sells such Licensed Products in the form of a combination product containing any Licensed Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), then prior to the First Commercial Sale of such Combination Product, the Parties shall agree through the JFC to the value of each component of such Combination Product and the appropriate method for accounting for sale of such Combination Product. For the avoidance of doubt, for the purposes of this Agreement, Immunoconjugates (as such term is defined in the Discovery Agreement) shall not be deemed Combination Products.

Solely for the purposes of Section 2.6(d) of this Agreement, the term "Licensed Product" as used in the definition of Net Sales shall refer to Opt-Out Products.

1.76 "New Information" shall mean any and all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public, which may arise or be conceived or developed by either Party or its Affiliates, or by the Parties or their Affiliates jointly, during the Term pursuant to this Agreement, to the extent specifically related to any Licensed Product in the Field, including, without limitation, information and data included in any Plans or Registration Filings made under this Agreement.

1.77 "Non-Approval Trials" shall mean any post-marketing surveys, registries and clinical trials post-first Marketing Approval not intended to gain additional labeled Indications, but excluding any post-first Marketing Approval clinical trials required by Regulatory Authorities to maintain Marketing Approvals of existing labeled Indication(s).

1.78 "Opt-In Right" shall have the meaning set forth in the Discovery Agreement.

1.79 "Opt-Out Product" shall mean a Licensed Product as to which this Agreement has been terminated in accordance with Section 19.2. For clarity, an Early Development Opt-Out Product shall not constitute an Opt-Out Product.

1.80 "Other Shared Expenses" shall mean those costs and expenses specifically referred to in Sections 7.6, 12.1(a), 12.2(e), 12.3(b), 13.1(c), 13.3(b), 13.3(d) and 17.1(c).

1.81 “Out-of-Pocket Costs” shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP or IAS/IFRS) by either Party and/or its Affiliates in accordance with a Plan, if applicable.

1.82 “Party Information” shall mean any and all trade secrets or other proprietary information, including, without limitation, any proprietary data, inventions, ideas, discoveries and materials (whether or not patentable or protectable as a trade secret) not generally known to the public regarding a Party’s or its Affiliates’ technology, products, business or objectives, in each case, other than New Information, which are disclosed or made available by a Party or such Party’s Affiliates to the other Party or the other Party’s Affiliates in connection with this Agreement.

1.83 “Patent Application” shall mean any application for a Patent.

1.84 “Patent Rights” shall mean unexpired Patents and Patent Applications.

1.85 “Patents” shall mean patents and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations and extensions thereof and supplemental protection certificates relating thereto, and all counterparts thereof in any country in the world.

1.86 “Person” shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.

1.87 “Phase 3 Trial” shall mean a clinical trial that is designed to gather further evidence of safety and efficacy of a Licensed Product in the Field (and to help evaluate its overall risks and benefits) and is intended to support Marketing Approval for a Licensed Product in the Field in one or more countries in the Territory. A Phase 3 Trial typically follows at least one dose ranging clinical trial to evaluate further the efficacy and safety of a Licensed Product in the Field in the targeted patient population and to help define the optimal dose and/or dosing regimen.

1.88 “Plan” shall mean any Country/Region Commercialization Plan, Global Commercialization Plan, Global Development Plan, Initial Development Plan, Manufacturing Plan or other plan approved through the Committee process relating to the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.

1.89 “Positive Phase 3 Trial Results” shall mean a Phase 3 Trial that meets its primary end-point as defined in the study protocol for such Phase 3 Trial, and the safety profile supports continued clinical testing in the applicable Indication and/or filing of an application for Marketing Approval.

1.90 “Pre-Launch Marketing Expenses” shall mean, with respect to a Licensed Product, on a country-by-country basis in the Territory, with respect to each Licensed Product, all Commercialization expenses to support such Licensed Product in the Field incurred \*\*\*\*\*.

1.91 “Pricing Approval” shall mean such approval, agreement, determination or governmental decision establishing prices for a Licensed Product that can be charged to consumers and will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.92 “Product Candidate” shall have the meaning set forth in the Discovery Agreement.

1.93 “Product Trademark” shall mean, with respect to each Licensed Product in the Field in the Territory, the trademark(s) selected by the JCC and approved by the JSC for use on such Licensed Product throughout the Territory and/or accompanying logos, slogans, trade names, trade dress and/or other indicia of origin, in each case as selected by the JCC and approved by the JSC.

1.94 “Promotional Materials” shall mean, with respect to each Licensed Product, promotional, advertising, communication and educational materials relating to such Licensed Product for use in connection with the marketing, promotion and sale of such Licensed Product in the Field in the Territory, and the content thereof, and shall include, without limitation, promotional literature, product support materials and promotional giveaways.

1.95 “Quarter” or “Quarterly” shall refer to a calendar quarter, except that the first (1st) Quarter shall commence on the Effective Date and extend to the end of the then-current calendar quarter and the last calendar quarter shall extend from the first day of such calendar quarter until the effective date of the termination or expiration of the Agreement.

1.96 “Regeneron Intellectual Property” shall mean the Regeneron Patent Rights and any Know-How of Regeneron or any of its Affiliates.

1.97 “Regeneron Know-How” shall mean any and all Know-How now or hereafter during the term of the Discovery Program or the Collaboration owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Know-How and Know-How included in Joint Inventions) with the right to sublicense the same that relate to a Licensed Product in the Field and are necessary or useful for the Development, Manufacture or Commercialization of a Licensed Product in the Field, including, without limitation, New Information.

1.98 “Regeneron Patent Rights” shall mean those Patent Rights which, (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Patent Rights and Patent Rights included in Joint Inventions), with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Licensed Product in the Field, but only to such extent.

1.99 “Region” shall mean such countries or group of countries as determined by the JCC.

1.100 “Registration Filing” shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, without limitation, any IND or Marketing Approval application in the Field.

1.101 “Regulatory Authority” shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement. The term “Regulatory Authority” includes, without limitation, the FDA, the EMEA and the Japanese Ministry of Health, Labour and Welfare.

1.102 “Reporting Country/Region” shall mean each Major Market Country, and each other country or Region for which a Country/Region Commercialization Committee has been established by the JCC.

1.103 “Rest of World” or “ROW” shall mean all Rest of World Countries.

1.104 “Rest of World Country” shall mean any country in the Territory other than the United States.

1.105 “ROW CPI” shall mean the “EU15 CPI” (or its successor equivalent index), which is published monthly and available via *The Bloomberg Professional*, as published by Bloomberg L.P.

1.106 “Sales Force Cost” shall mean, for Licensed Product(s) in each country in the Territory, the product of (a) the number of detailing people (with the number and the method of calculating such number set forth in the applicable Country/Region Commercialization Plan or Global Commercialization Plan), and (b) \*\*\*\*\*. The calculation of the number of detailing people in (a) above will be based on \*\*\*\*\*. For the avoidance of doubt, the activities of contract personnel, including contract Sales Force, shall be charged as Out-of-Pocket Costs.

1.107 “Sales Force FTE Rate” shall mean, on a Region-by-Region or one or more Major Market Countries basis (determined based on the location of the sales representative), a rate agreed upon in local currency by the Parties at least eighteen (18) months prior to the Anticipated First Commercial Sale in the Region or Major Market Country, as applicable, based upon the fully burdened cost of sales representatives of pharmaceutical companies in the Field in the applicable country, and including an allocation of regional and country sales force management cost, to be approved six (6) months prior to the first Commercial Sale, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Sales Force FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs, information systems and allocated costs, such as, for example, allocated overhead costs.

1.108 “Sanofi Intellectual Property” shall mean the Sanofi Patent Rights and the Sanofi Know-How.

1.109 “Sanofi Know-How” shall mean any and all Know-How now or hereafter during the term of the Discovery Program or the Collaboration owned by, licensed to or otherwise held by Sanofi or its Affiliates (other than Regeneron Know-How and Know-How included in Joint Inventions) with the right to sublicense the same that relate to a Licensed Product in the Field and are necessary or useful for the Development, Manufacture or Commercialization of a Licensed Product in the Field, including, without limitation, New Information.

1.110 “Sanofi Patent Rights” shall mean those Patent Rights which, (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Patent Rights and Patent Rights included in Joint Inventions), with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Licensed Product in the Field, but only to such extent.

1.111 “Sanofi Stock Purchase Agreement” means the Stock Purchase Agreement dated as of the Effective Date by and between Sanofi Amerique, Aventis LLC and Regeneron.

1.112 “Shared Commercial Expenses” shall mean the sum of the following items, in each case to the extent directly attributable to Commercialization of Licensed Products in the Field in the Territory in accordance with an approved Country/Region Commercialization Plan or Global Commercialization Plan:

(a) \*\*\*\*\* to cover the cost of distribution, freight, insurance and warehousing, related to the sale of Licensed Products in the Field in the Territory, less any amount deducted from Net Sales pursuant to clause (g) of the definition of Net Sales;

(b) bad debt attributable to Licensed Products in the Field sold in the Territory;

(c) Sales Force Cost;

(d) Medical Post-Approval Cost;

(e) Out-of-Pocket Costs related to (i) the marketing, advertising and/or promotion of Licensed Products in the Field in the Territory (including, without limitation, pricing activities, commercial pharmacovigilance, educational expenses, advocate development programs and symposia and Promotional Materials), (ii) market research for Licensed Products in the Field in the Territory and (iii) the preparation of training and communication materials for Licensed Products in the Field in the Territory;

(f) a portion of Out-of-Pocket Costs agreed upon by the Parties related to the marketing, advertising and promotion of Licensed Products in the Field in the

Territory (including, without limitation, educational expenses, advocate development programs and symposia, and promotional materials) to the extent such marketing, advertising and promotion relate to both Licensed Products and other products developed or commercialized by Sanofi or its Affiliates as agreed upon in an approved Global Commercialization Plan or Country/Region Commercialization Plan;

(g) Out-of-Pocket Costs related to Non-Approval Trials for Licensed Products in the Field in the Territory, including, without limitation, the Out-of-Pocket Cost of clinical research organizations, investigator and expert fees, lab fees and scientific service fees, the Out-of-Pocket Cost of shipping clinical supplies to centers or disposal of clinical supplies, in each case, to the extent not included in Commercial Supply Cost;

(h) Out-of-Pocket Costs related to Pricing Approvals and the maintenance of all Approvals directly related to the Commercialization of Licensed Products in the Field in the Territory;

(i) Commercial Overhead Charge;

(j) Pre-Launch Marketing Expenses;

(k) Out-of-Pocket Costs related to regulatory affairs activities, other than activities to secure Registration Filing of indications and line extensions; and

(l) any other costs or expenses directly related to the Commercialization of a Licensed Product after First Commercial Sale of such Licensed Product and not included in clauses (a) through (k) above.

The foregoing shall not include any costs which have been included in Development Costs. For clarity, it is the intent of the Parties that costs and headcount included in the foregoing will be fairly allocated to the Licensed Products in the Field in the Territory (to the extent that any Shared Commercial Expense is attributable, in part, to products or activities other than the Licensed Products in the Field in the Territory) and, in each case, will only be included once in the calculation of the Quarterly True-Up.

1.113 “Shared Phase 3 Trial Costs” shall mean Development Costs associated with Phase 3 Trials of any Licensed Product incurred after the receipt of first Positive Phase 3 Trial Results for such Licensed Product.

1.114 “Sublicensee” shall mean a Third Party or an Affiliate to whom Sanofi will have granted a license or sublicense under Sanofi’s rights pursuant to Section 4.3 to Commercialize Licensed Products in the Field in the Territory. For the avoidance of doubt, a “Sublicensee” will include a Third Party to whom Sanofi will have granted the right to distribute Licensed Products in the Field wherein such distributor pays to Sanofi a royalty (or other amount) based upon the revenues received by the distributor for the sale (or resale) of Licensed Products by such distributor.

1.115 “Target” shall mean any gene, receptor, ligand or other molecule (a) associated with a disease activity that may be modified by direct interaction with a Licensed Product or (b) to which a Licensed Product binds.

1.116 “Terminated Licensed Product” shall mean a Licensed Product as to which this Agreement has been terminated in accordance with its terms in accordance with Article XIX, and shall include any Opt-Out Product.

1.117 “Termination Notice Period” shall mean the Sanofi Termination Notice Period or the Regeneron Termination Notice Period, as applicable.

1.118 “Territory” shall mean all the countries and territories of the world.

1.119 “Third Party” shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.

1.120 “United States,” “US” or “U.S.” shall mean the United States of America (including its territories and possessions) and Puerto Rico.

1.121 “US CPI” shall mean the Consumer Price Index — All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).

1.122 “Valid Claim” shall mean (a) a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) which has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Governmental Authority of competent jurisdiction from which no appeal may be or has been taken, and which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise; or (b) a claim of a Patent Application, which claim has been pending less than five (5) years from the original priority date of such claim in a given jurisdiction, unless or until such claim thereafter issues as a claim of an issued Patent (from and after which time the same shall be deemed a Valid Claim subject to paragraph (a) above).

1.123 Additional Definitions. Each of the following definitions is set forth in the Sections (or Schedules) of this Agreement indicated below:

<u>DEFINITION</u>	<u>SECTION/SCHEDULE</u>
Acquired Entity	2.6(c)
Acquiring Party	2.6(c)
Agreement	Preamble
Alliance Manager	3.2(a)
Annual True-Up	SCHEDULE 2
Applicable ROW Percentages	SCHEDULE 2
Budget Dispute	Section 3.11(b)
Collaboration	Preamble
Collaboration Purpose	3.1(b)

DEFINITION	SECTION/SCHEDULE
Combination Product	1.76
Cost	SCHEDULE 1
Damages	17.1(a)
Default Interest Rate	9.9
Development Balance	SCHEDULE 2
Discovery Agreement	Preamble
Disputed Budget	Section 3.11(b)
Early Development Opt-Out Product	5.6
Effective Date	Preamble
Excluded Rights	4.3
Expert Panel	10.4(a)
First Year	5.3
Force Majeure	ARTICLE XVIII
Global Development Budget(s)	5.3
Governance Dispute	10.2
Incomplete Activity	5.3
Indemnified Party	17.2
Indemnifying Party	17.2
JCC	3.1(a)
JDC	3.1(a)
JFC	3.1(a)
JMC	3.1(a)
Joint Invention	12.1(b)
JSC	3.1(a)
Lead Litigation Party	13.1(c)
Manufacturing Cost	SCHEDULE 1
Manufacturing Notice	8.3(a)
Manufacturing Plan	8.5
Marketing Guidelines	3.4(b)(vi)
Maximum Regeneron Effort	6.5(e)(i)
Modified Clause	20.7
Non-Acquiring Party	2.6(c)
Non-Approval Trials	6.2(h)
Non-Incurred Amount	5.3
Opt-Out Partner	2.6(d)
Opt-Out Product Notice	2.6(c)
OverPaying Party	Section 13.3(e)
Party(ies)	Preamble
Patent Jurisdictions	12.2(a)
POC Principal Party	5.2
POC Time	5.2
Post-POC Principal Party	5.2
Publishing Party	16.3
Quarterly True-Up	SCHEDULE 2
Regeneron	Preamble

DEFINITION	SECTION/SCHEDULE
Regeneron Commitment Level	6.5(e)(i)
Regeneron Early Development Opt-Out Right	5.6
Regeneron Early Opt-Out Notice	5.6
Regeneron Indemnitees	17.1(a)
Regeneron Profit Split	SCHEDULE 2
Regeneron Reimbursement Amount	SCHEDULE 2
Regeneron Sole Inventions	12.1(a)
Regeneron Termination Notice Period	19.2(b)
Reimbursement Payment	SCHEDULE 2
Required Divestiture Notice Period	2.6(c)
Rest of World Profit Split	SCHEDULE 2
Royalty Term	9.3
ROW Profit Split	SCHEDULE 2
ROW Profit Split Annual True-Up	SCHEDULE 2
Sanofi	Preamble
Sanofi Amerique	Preamble
Sanofi Indemnitees	17.1(b)
Sanofi Parent	Preamble
Sanofi Sole Inventions	12.1(a)
Sanofi Termination Notice Period	19.2(a)
SDEA	7.4
Shared Phase 3 Trial Costs Balance	SCHEDULE 2
Sole Developer	2.6(d)
Sole Inventions	12.1(a)
Succeeding Year(s)	5.3
Target Labeling	7.2(d)
Target ROW Profit Split	SCHEDULE 2
Technical Development Matter	10.2
Term	19.1(a)
Third Party	2.6(c)
Third Party Acquisition	2.6(c)
U.S. Profit Split	SCHEDULE 2
US Profits	SCHEDULE 2
VelocImmune Royalties	Section 13.3(e)
Working Group	3.1(a)

## ARTICLE II COLLABORATION

2.1 Scope of Collaboration . Upon and subject to terms and conditions of this Agreement, the Parties will cooperate in good faith to Develop, Manufacture and Commercialize Licensed Products in the Field in the Territory in such a manner so as to optimize the commercial potential of each Licensed Product. The Parties shall establish various Committees as set forth in Article III of this Agreement to oversee and/or coordinate the Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory, and each

Party shall, subject to the terms and conditions set forth in Article XVI, provide (or cause its Affiliates to provide) to any relevant Committee any necessary Party Information, New Information and such other information and materials as may be reasonably required for the Parties to operate effectively and efficiently under and in accordance with the terms and conditions of this Agreement.

2.2 Compliance With Law. Both Sanofi and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable Law.

2.3 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement and the consummation by such Party of the transactions contemplated by this Agreement and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required to be made by such Party under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings. Each Party will furnish to the other Party all information in its possession or under its control required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

2.4 Compliance with Third Party Agreements. Each Party agrees to comply with the obligations set forth in (a) the Licenses to which it is a party and to notify the other Party of any terms or conditions in any such License with which such other Party is required to comply as a licensee or sublicensee, as the case may be, and (b) any other material agreement, including any sublicense under a License referenced in subsection (a) above, to which it is a party and that is related to the Collaboration, including, without limitation, any obligations to pay royalties, fees or other amounts due thereunder. Neither Party may terminate or amend any License or any other material agreement entered into pursuant to a Plan without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, if the amendment or termination imposes any material liability or restriction on either Party with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory.

2.5 Plans. The Parties shall undertake all Development and Commercialization activities under this Agreement solely in accordance with the Committee approved Plans. The Parties may agree to amend all Plans and budgets from time to time as circumstances may require.

2.6 Limitation on Exercise of Rights Outside of Collaboration.

(a) Non-Compete. Without limitation of and in addition and subject to Section 2.8 of the Discovery Agreement, during the Term, except as set forth in this Agreement or Section 2.8 of the Discovery Agreement, neither Party nor any of its Affiliates, either alone or through any Third Party, shall Develop or Commercialize any Competing Product.

(b) Regeneron Sole Development. If Regeneron presents a proposal to the JDC to undertake additional clinical trials not contemplated in a Global Development Plan to support a Licensed Product in the Field and the JDC fails to approve the proposal within the timeframe established by the JDC pursuant to Section 5.5, then Regeneron may, at its option and at its sole expense, conduct such additional clinical trial(s) outside the scope of the applicable Global Development Plan; provided, however, Regeneron must first present the proposed protocols and clinical trial designs to Sanofi for approval, such approval not to be unreasonably withheld or delayed and, for other than Non-Approval Trials, shall also present to Sanofi the related budgets for Clinical Supply Costs and Out-of-Pocket Costs and applicable FTE costs (provided that such budgets shall be provided for informational purposes only and may not be used to disapprove such protocols and designs). Regeneron shall also provide to Sanofi drug safety data from such additional clinical trials in accordance with Section 7.4. The Sanofi representatives on the JDC may disapprove any such protocols or clinical trial designs for reasons of safety or Sanofi reasonably believes that the development as described in this Section 2.6(b) would have a material adverse effect on the overall development strategy for the Licensed Product and/or the commercial viability of such License Product, including the magnitude of sales for such Licensed Product. If, in compliance with this Section 2.6(b), Sanofi does not approve any such protocols or clinical trial designs for reasons as described herein, Regeneron may not proceed with the proposed clinical trials unless Regeneron disputes such disapproval and until the dispute has been resolved, as provided in Section 3.11(b) and, if necessary, Section 10.4, in Regeneron's favor. In the event that Regeneron conducts any such additional clinical trials, all results, Know-How and Patent Rights generated in or arising from any such clinical trial shall be subject to the grants of rights pursuant to Article IV of this Agreement. For the avoidance of doubt, no consideration or reimbursement shall be paid to Regeneron with respect to the conduct of any such additional clinical trials; provided, however, that if the Parties subsequently agree to commence a further clinical trial based on the results of such additional clinical trial(s) or data is used from such additional clinical trial(s) to support an Approval in the Territory, then Sanofi shall be required to reimburse Regeneron for \*\*\*\*\* of the actual Out-of-Pocket Costs and Clinical Supply Costs and applicable FTE costs incurred in connection with the conduct of such additional clinical trial(s) that are consistent with the budgets provided to Sanofi pursuant to this Section 2.6(b) and the other terms of this Agreement. Publication of any results or data obtained in conducting the additional clinical trial(s) allowed under this Section 2.6(b) shall be subject to Article XVI.

(c) Company Acquisitions. Notwithstanding Section 2.6(a), if as the result of an acquisition of a Third Party (such acquisition a "Third Party Acquisition") by a Party or one or more of its Affiliates (the "Acquiring Party"), the Acquiring Party

acquires rights to a product that is a Competing Product (the “Acquired Competing Product”) to a Licensed Product (the “Competing Licensed Product”), the Acquiring Party, at its sole discretion, shall do one of the following: (W) present a proposal to the JDC to include the Acquired Competing Product in the Collaboration in accordance with Section 2.6(c)(i); (X) deliver to the other Party (the “Non-Acquiring Party”) a termination notice, pursuant to Section 19.2(a) or 19.2 (b), as appropriate, and Section 2.6(c)(ii), with regard to the Competing Licensed Product; or (Y) transfer its rights in the Acquired Competing Product to a Third Party pursuant to Section 2.6(c)(iii).

(i) Proposal for Inclusion. If the Acquiring Party chooses this alternative, within ten (10) Business Days after the closing of such Third Party Acquisition, the Acquiring Party shall present a proposal to the JDC to include such Acquired Competing Product in the Collaboration based on the terms of this Agreement. As part of such presentation, the Acquiring party shall provide the JDC with all information with respect to such Acquired Competing Product reasonably available to the Acquiring Party and material to a decision by the Non-Acquiring Party’s representatives on the JDC as to whether to approve the inclusion of such Acquired Competing Product in the Collaboration. The JDC shall, on or before the date which is twenty (20) Business Days after the closing of such Third Party Acquisition, decide whether to approve the inclusion of such Acquired Competing Product in the Collaboration under the terms of this Agreement. If the JDC timely approves the inclusion of such Acquired Competing Product in the Collaboration, then upon the closing of such Third Party Acquisition the Acquired Competing Product shall automatically be included in the Collaboration as a Licensed Product hereunder. If the JDC does not approve such inclusion, the Acquiring Party shall elect whether to deliver to the Non-Acquiring Party a termination notice, pursuant to Section 19.2(a) or 19.2 (b), as appropriate, and Section 2.6(c)(ii), with regard to the Competing Licensed Product or transfer its rights to the Acquired Competing Product to a Third Party (without any consideration or payment to the Non-Acquiring Party in accordance with Section 2.6(c)(iii) below).

(ii) Termination of Licensed Product. If the Acquiring Party chooses this alternative, the Acquiring Party shall deliver to the Non-Acquiring Party, within ten (10) Business Days after the decision of the JDC not to include the Acquired Competing Product in the Collaboration pursuant to Section 2.6(c)(i), a termination notice pursuant to Section 19.2(a) or 19.2(b), as applicable, with respect to the Competing Licensed Product (the “Opt-Out Product Notice”). The provisions of Section 19.2(a) or 19.2(b), as applicable, and the provisions of Sections 19.7, 19.8 and Schedule 4 or 5, as applicable, shall then apply to such Competing Licensed Product. For the avoidance of doubt, such Competing Licensed Product shall then be an Opt-Out Product, and notwithstanding any other provision of this Agreement, the Acquiring Party shall be deemed (without any requirement of notice to the Non-Acquiring Party) to have irrevocably ceded all decision-making authority with respect to such Opt-Out Product to the Non-Acquiring Party. In addition, if such Opt-Out Product is being marketed and sold

at the time of the closing of the Third Party Acquisition, then during the Sanofi Termination Notice Period or Regeneron Termination Notice Period, as applicable, the following shall apply:

(1) In any Quarter in which the U.S. Profits are positive, the U.S. Profit Split shall be zero percent (0%) to the Acquiring Party and one hundred percent (100%) to the Non-Acquiring Party, and in any Quarter in which the ROW Profits are positive, the ROW Profit Split shall be zero percent (0%) to the Acquiring Party and one hundred percent (100%) to the Non-Acquiring Party.

(2) In any Quarter, in which U.S. Profits are negative, the U.S. Profit Split shall be one hundred percent (100%) to the Acquiring Party and zero percent (0%) to the Non-Acquiring Party, and in any Quarter in which ROW Profits are negative, the ROW Profit Split shall be one hundred percent (100%) to the Acquiring Party and zero percent (0%) to the Non-Acquiring Party.

(iii) Transfer of Rights. If the Acquiring Party chooses this alternative, the Acquiring Party shall commit in writing to the Non-Acquiring Party, within ten (10) Business Days after the closing of such Third Party Acquisition, to license or otherwise transfer rights to such Acquired Competing Product to a Third Party (without any consideration or payment to the Non-Acquiring Party) and/or cease all development, manufacturing and/or commercialization, as applicable, of such Acquired Competing Product within six (6) months after the closing of the Third Party Acquisition, and shall do so within such six (6) month period.

(iv) Required Divestiture of Licensed Product. Notwithstanding any of the foregoing in this Section 2.6(c), in the event the Acquiring Party believes, based on the written advice of its counsel, that it is required by Law to divest its interest either in the Acquired Competing Product or the Competing Licensed Product, the Acquiring Party may terminate this Agreement with respect to such Competing Licensed Product pursuant to Section 19.2(a) or 19.2 (b), as appropriate, Section 2.6(c)(ii) and this Section 2.6(c)(iv), with regards to the Competing Licensed Product, or transfer its interest in the Competing Licensed Product pursuant to Section 2.6(c)(iii). If the Acquiring Party terminates this Agreement with respect to the Competing Licensed Product pursuant to this Section 2.6(c)(iv), it shall give the Non-Acquiring Party the maximum advance notice (up to twelve (12) months) of termination consistent with such divestiture requirement imposed by Law (the “Required Divestiture Notice Period”), following which the provisions of 2.6(c)(ii) shall apply and the Competing Licensed Product shall be an Opt-Out Product. During this period, the Acquiring Party will reasonably cooperate (at the Acquiring Party’s sole cost and expense) with the Non-Acquiring Party to enable the Non-Acquiring Party to assume, within the Required Divestiture Notice Period, the continued Development,

Manufacture and Commercialization of such Opt-Out Product in the Field in the Territory. The Acquiring Party shall also be responsible for, and shall promptly pay upon demand, all reasonable costs and expenses incurred by the Non-Acquiring Party in assuming such continued Development, Manufacture and Commercialization of such Opt-Out Product to the extent such costs and expenses, other than capital investments, would not have been incurred and/or would have been paid by the Acquiring Party, absent such Acquiring Party's termination with respect to such Opt-Out Product pursuant to Section 19.2(a) or (b). For the avoidance of doubt, if the Required Divestiture Notice Period is less than the twelve (12) months required by Section 19.2, the Acquiring Party shall have continuing payment obligations (though no performance obligations beyond those described above) to the Non-Acquiring Party with respect to such Opt-Out Product for the entire Sanofi Termination Notice Period (if Sanofi is the Acquiring Party) or Regeneron Termination Notice Period (if Regeneron is the Acquiring Party).

(d) Subject to the further provisions of this Section 2.6(d), in the case of any Opt-Out Product, the non-terminating Party (the "Sole Developer") shall have the right to Develop and Commercialize such Opt-Out Product, unless such Opt-Out Product is (or becomes) a Competing Opt-Out Product, in which case the Sole Developer may not (either directly or through an Affiliate or Third Party), Develop or Commercialize such Competing Opt-Out Product for a period of \*\*\*\*\* following the date it becomes a Competing Opt-Out Product (or, if shorter, such period ending on the date such Competing Opt-Out Product ceases to be a Competing Opt-Out Product), unless otherwise agreed by the terminating Party (the "Opt-Out Partner"). If an Opt-Out Product is Commercialized by the Sole Developer (either directly or through an Affiliate or Third Party) in compliance with this Section 2.6(d), then the Sole Developer shall pay the Opt-Out Partner royalties based on Net Sales of such Opt-Out Product and the stage of Development of the Licensed Product at the time it became an Opt-Out Product, at the royalty rate(s) described on Exhibit A. Notwithstanding the foregoing or any other provision of this Agreement, in the case of any Opt-Out Product, including any Competing Opt-Out Product, resulting from termination of this Agreement with respect to a Licensed Product pursuant to Section 19.2 in the circumstances described in Section 2.6(c), the Sole Developer shall have no obligation either to delay Developing or Commercializing, or to pay royalties with respect to, such Opt-Out Product.

(e) Clinical Trials for Combination Products. Notwithstanding anything in this Section 2.6(e) to the contrary, each Party and/or its respective Affiliates shall be entitled to (i) initiate, sponsor and/or conduct a clinical trial and/or (ii) participate, directly or indirectly, whether through the provision of funds, grants or otherwise, in any clinical trial, initiated, sponsored and/or conducted by any Third Party, in each of the foregoing cases with respect to the combination of any Party's (or its Affiliate's) product, together with any Competing Product that has been granted a Marketing Approval for at least one Indication in the applicable country, unless (A) a Licensed Product Developed under this Agreement has been granted a Marketing Approval in the applicable country for use in combination with such Party's (or its Affiliate's) product in the same

Indication(s) as the one to be studied in the intended clinical trial with the Competing Product which is not approved in such Indication or (B) both the Competing Product and a Licensed Product Developed under this Agreement have been granted a Marketing Approval in the applicable country for use in combination with such Party (or its Affiliate's) product as the same Indication to be studied in the intended clinical trial with the Competing Product and the relevant labeling of both the Licensed Product and the Competing Product for such Indication is substantially similar. For any combination study with a Competing Product covered by this Section 2.6(e), the applicable Party shall notify the other Party prior to initiating such trial, such notice to include a brief synopsis of the protocol and a description of the Party's (or its Affiliate's) role(s) and responsibilities in connection with the study. Further, for any combination study with a Competing Product covered by this Section 2.6(e), each Party shall promptly provide the other Party with available results of such combination study, unless such disclosure is prohibited by Law or contract. Each Party and/or its Affiliates shall be entitled to use data from clinical trials permitted by this Section 2.6(e) to promote the combination of such Party product together with such Competing Product, unless a Licensed Product Developed has been granted a Marketing Approval in the applicable country for use in combination with such Third Party product, in the same Indication. Neither Party nor its respective Affiliates shall receive any compensation or other payments (either in cash or in kind) based on the development, promotion, or sale of a Competing Product. Neither Party will intentionally delay the commencement, enrollment or completion of a clinical study of a Licensed Product as a result of any ongoing or pending clinical trial permitted by this Section 2.6(e). For the avoidance of doubt, neither Party nor its respective Affiliates shall use or disclose any Party Information or New Information subject to the confidentiality provisions of Article XVI in connection with any of the activities described in this Section 2.6(e).

### **ARTICLE III MANAGEMENT**

#### **3.1 Committees/Management.**

(a) The Parties agree to establish, for the purposes specified herein, a Joint Steering Committee (the "JSC"), a Joint Development Committee (the "JDC"), a Joint Commercialization Committee (the "JCC"), CRCCs to the extent provided in Section 3.5, and such other commercialization sub-committee as JCC shall deem to be appropriate, a Joint Manufacturing Committee ("JMC"), a Joint Finance Committee (the "JFC") and such other Committees as the Parties deem appropriate. The JSC, JDC, JFC and JMC shall each be established within thirty (30) days after the Effective Date. The JCC shall be established at least two (2) years prior to the anticipated filing date for Marketing Approval for the first Licensed Product under this Agreement. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the JSC for Committees established in the future and not described herein) and may be further designated by the JSC. From time to time, each Committee may establish working groups (each, a "Working Group") to oversee particular projects or

activities, and each such Working Group shall be constituted and shall operate as the Committee which establishes the Working Group determines.

(b) Each of the Committees and the Executive Officers shall exercise its decision-making authority hereunder in good faith and in a commercially reasonable manner for the purpose of optimizing the commercial potential of and financial returns from the Licensed Products in the Field in the Territory consistent with Commercially Reasonable Efforts and without regard to any other pharmaceutical product being developed or commercialized in the Field by or through a Party or any of its Affiliates (the “Collaboration Purpose”). The Parties acknowledge and agree that none of the Committees or the Executive Officers shall have the power to amend any of the terms or conditions of this Agreement, other than by mutual agreement of the Parties as set forth in Section 20.5.

### 3.2 Joint Steering Committee.

(a) Composition and Purpose. The JSC shall have overall responsibility for the oversight of the Collaboration. The purpose of the JSC shall be (i) to review and approve the overall strategy for an integrated worldwide Development program for each Licensed Product, including the Manufacture of Licensed Products in the Field for use in activities under the Plans and for the Commercialization of Licensed Products in the Field in the Territory; (ii) to review the efforts of the Parties in performing their responsibilities under the Plans and (iii) to oversee the Committees and resolve matters pursuant to the provisions of Section 3.11 below on which such Committees are unable to reach consensus. The JSC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives). In addition, each Party shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Alliance Manager (“Alliance Manager”) to the JSC. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among all Committees and providing single-point communication for seeking consensus both within the respective Party’s organization and with the other Party’s organization.

(b) Specific Responsibilities. In addition to its overall responsibility for overseeing the Collaboration, the JSC shall in particular (i) annually review and approve the Global Development Plan(s) if any, Manufacturing Plan(s), Global Commercialization Plan(s) and Country/Region Commercialization Plan(s); (ii) at least semi-annually review the efforts of the Parties in performing their respective Development and Commercialization activities under the then-effective Plans; (iii) attempt in good faith to resolve any disputes referred to it by any of the Committees and provide a single-point of communication for seeking consensus regarding key global strategy and Plan issues; (iv) establish sub-committees of the JSC, as the JSC deems appropriate and (v) consider and act upon such other matters as are specifically assigned to the JSC under this Agreement or otherwise agreed by the Parties.

### 3.3 Joint Development Committee.

(a) Composition and Purpose. The purpose of the JDC shall be (i) to advise the JSC on the strategy for the worldwide Development of each Licensed Product in the Field; (ii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Global Development Plan(s) (and related Global Development Budget(s)) and (iii) to oversee the implementation of the Global Development Plan(s) and the Development operational aspects of the Collaboration. The JDC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

(b) Specific Responsibilities. In particular, the JDC shall be responsible for:

(i) advising the JSC on the overall global Development strategy for each Licensed Product in the Field;

(ii) developing (or overseeing the development of), and updating at least annually, the Global Development Plan(s) (and related Global Development Budget(s)), as described in Sections 5.2 and 5.3, for final approval by the JSC;

(iii) reviewing and overseeing the implementation of, and compliance with, the Global Development Plan(s) (including the Global Development Budget(s));

(iv) developing forecasts for Clinical Supply Requirements to enable the timely preparation of the Manufacturing Plan;

(v) overseeing clinical and regulatory matters pertaining to Licensed Products in the Field arising from the Plans, and reviewing and approving protocols, statistical analysis plans, clinical study endpoints, clinical methodology and monitoring requirements for clinical trials of Licensed Products in the Field as contemplated under the Global Development Plan(s) and for Non-Approval Trials;

(vi) reviewing and approving proposed target Licensed Product labeling and reviewing and, to the extent set forth herein, approving proposed changes to product labeling with respect to Licensed Products in the Field in accordance with Section 7.2;

(vii) developing a target profile for each Licensed Product;

(viii) facilitating an exchange between the Parties of data, information, material and results relating to the Development of Licensed Products in the Field;

(ix) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new formulations, delivery systems and improvements in concert with the JCC;

(x) establishing a regulatory Working Group responsible for overseeing, monitoring and coordinating the submission of Registration Filings in countries in the Territory, including coordinating material communications, filings and correspondence with Regulatory Authorities in the Territory in connection with the Licensed Products in the Field;

(xi) establishing a Working Group responsible for overseeing all basic research activities for Licensed Products in the Field conducted under the Global Development Plan(s); and

(xii) considering and acting upon such other matters as specifically assigned to the JDC under this Agreement or by the JSC.

#### 3.4 Joint Commercialization Committee.

(a) Composition and Purpose. The purpose of the JCC shall be to develop and propose to the JDC and JSC the strategy for the global Commercialization of Licensed Products in the Field in the Territory, and to oversee the implementation of the Global Commercialization Plans and the Commercialization operational aspects of the Collaboration on a country-by-country basis. The JCC shall be composed of at least two (2) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

(b) JCC Responsibilities. In particular, the JCC shall be responsible for:

(i) developing and proposing to the JSC the global strategy for the Commercialization of each Licensed Product in the Field in the Territory;

(ii) commencing no later than two (2) years prior to the Anticipated First Commercial Sale anywhere in the Territory, (A) developing (or overseeing the development of), and updating not less frequently than once per Contract Year, the Global Commercialization Plan(s) and related Global Commercialization Budget(s) on a country-by-country basis for final approval by the JSC and (B) establishing, to the extent provided in Section 3.5, Country/Region Commercialization Committees to establish Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) and any updates thereto and carry out the other activities described in Section 3.5;

(iii) \*\*\*\*\*;

- (iv) Establishing the trade dress for each Licensed Product, consistent with the guidelines established by the JCC, in the applicable Major Market Country;
- (v) developing forecasts for Commercial Supply Requirements for the Territory to enable the timely preparation of the Manufacturing Plan(s) for review by the JMC and approval by the JSC;
- (vi) for each Licensed Product, on a country-by-country basis for the Major Market Countries, developing and updating, as necessary, \*\*\*\*\*;
- (vii) reviewing and overseeing compliance with the Global Commercialization Plan (including the related Global Commercialization Budget), and Country/Region Commercialization Plans (including the Country/Region Commercialization Budgets), to the extent applicable, for each Licensed Product, including ensuring that country specific launch plans are consistent with the Marketing Guidelines, and reviewing and validating latest annual estimates for the current calendar year compared to the Global Commercialization Budget and Country/Region Commercialization Budgets;
- (viii) establishing or validating the number and position of Details required to meet market and sales forecasts and their conversion into the equivalent number of Detailing FTEs according to applicable weighting factors, based upon sales force and market practices, on a country-by-country basis, consistent, however, with the applicable Marketing Guidelines;
- (ix) for each Licensed Product, selecting a Product Trademark in accordance with Section 11.2 and giving guidance on trade dress for such Licensed Product;
- (x) determining the launch date for each Licensed Product on a country-by-country basis in Major Market Countries;
- (xi) \*\*\*\*\*;
- (xii) preparing short-term and long-term sales forecasts for each Licensed Product on a country-by-basis for Major Market Countries and reviewing such forecasts for the remaining countries;
- (xiii) \*\*\*\*\*;
- (xiv) validating the contents, design and layout of packaging for each Licensed Product in the Field;
- (xv) validating plans and policies regarding journal and other publications with respect to each Licensed Product in the Field in concert with the JDC;

(xvi) formulating a life-cycle management strategy for each Licensed Product in the Field and evaluating new opportunities for new indications, formulations, delivery systems and improvements in concert with the JDC;

(xvii) matters relating to Regeneron's Commitment Level with respect to a Licensed Product in a Co-Commercialization Country, including consenting to changes therein; and

(xviii) considering and acting upon such other matters as specifically assigned to the JCC under this Agreement or by the JSC, JDC JFCor JMC.

3.5 Country/Region Commercialization Committees. The JCC will establish a Country/Region Commercialization Committee in each Major Market Country, and in each other Reporting Country/Region as and when determined by the JCC. The Country/Region Commercialization Committees will be responsible for establishing the Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) and any updates thereto with respect to the applicable Reporting Countries/Region(s). The Country/Region Commercialization Committees will also serve as a forum to consider and discuss and, if so empowered by the JCC, decide, in a more detailed and focused manner with respect to the applicable Reporting Countries/Region(s), and make suggestions or recommendations to the JCC with respect to, the matters referred to in Section 3.4, as applicable, including the implementation of decisions with respect thereto made by the JCC as contemplated by such Section 3.4.

3.6 Joint Finance Committee. The JFC shall be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to the Collaboration and this Agreement, including such specific responsibilities set forth in Article IX and such other responsibilities determined by the JSC. The JFC also shall respond to inquiries from the JDC, the JMC and the JCC, as needed.

3.7 Joint Manufacturing Committee. Working with the JDC and JCC, as appropriate, the Joint Manufacturing Committee shall be responsible for overseeing process development and Manufacturing activities, including preparing and updating the Manufacturing Plan for approval by the JSC and carrying out such other responsibilities set forth in Article VIII, process and technology selection, process improvements and related intellectual property filing strategy and obtaining a common process for manufacturing, recalls, market withdrawals, and any other corrective actions related to any Licensed Product in the Territory, and for any other matters specifically assigned to the JMC by the JSC. For process development activities, the Joint Manufacturing Committee shall consult the appropriate expert functions within both Parties or their Affiliates as appropriate.

3.8 Membership. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and Sanofi. Each Party may replace its Committee members upon written notice to the other Party. Each Committee will have two (2) co-chairpersons, one designated by each of Regeneron and Sanofi. Each co-chairperson shall be

entitled to call meetings. The co-chairpersons shall coordinate activities to prepare and circulate an agenda in advance of the meeting and prepare and issue final minutes within thirty (30) days thereafter.

3.9 Meetings. Each Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than once every Quarter during the Term, commencing from and after the time such Committee is established as provided herein. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the Parties or their Affiliates) or when agreed by the Parties, by video or telephone conference. Other representatives of each Party or of Third Parties involved in the Development, Manufacture or Commercialization of any Licensed Product in the Field (under obligations of confidentiality) may be invited by the Committee co-chairs to attend meetings of the Committees as nonvoting participants. Each Party shall be responsible for all of its own expenses of participating in the Committees. Either Party's representatives on a Committee may call a special meeting of the applicable Committee upon at least five (5) Business Days' prior written notice, except that emergency meetings may be called with at least two (2) Business Days' prior written notice.

3.10 Decision-Making. The Committees shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on a Committee and leave decisions of such Committee(s) to representatives of the other Party.

3.11 Resolution of Governance Matters. As provided in Section 10.2, this Section 3.11 shall apply to matters constituting, or which if not resolved would constitute, a Governance Dispute.

(a) Generally. The Parties shall cause their respective representatives on the Committees to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible, provided that, in the case of any matter which cannot be resolved by the JDC, JCC, CRCC, JMC, JFC or other relevant Committee established hereunder, at the request of either Party, such matter shall promptly, and in any event within ten (10) Business Days (or two (2) Business Day in the event of an urgent matter) after such request, be referred to the JSC with a request for resolution.

(b) Referral to Executive Officers. In the event that the JSC is, after a period of five (5) Business Days from the date a matter is submitted to it for resolution pursuant to Section 3.11(a), unable to make a decision due to a lack of required unanimity, then either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, either Party may, in a written notice to the other Party, formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in

good faith, attempt to resolve the referred dispute within five (5) Business Days of receiving such written notification, failing which, \*\*\*\*\*.

(c) Notwithstanding the foregoing, and subject to Section 10.4, Legal Disputes and disputes referred to in the third sentence of Section 2.6(b) which involve a Technical Development Matter shall be referred to the Executive Officers with no Party's Executive Officer having final decision making authority.

(d) Interim Budgets. Pending resolution by the Executive Officers of any referred dispute under Section 3.11(b) and subject to the terms of Section 19.2, the Executive Officers shall negotiate in good faith in an effort to agree to appropriate interim budgets and plans to allow the Parties to continue to use Commercially Reasonable Efforts to Develop, Manufacture and Commercialize the Licensed Products in the Field in the Territory pursuant to this Agreement. The most recent Committee approved Plan(s) shall be extended pending approval by the Executive Officers of the interim budget(s) and Plan(s) referred to in this Section 3.11(c).

(e) Obligations of the Parties. The Parties shall cause their respective designees on the Committees and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein. To the extent a Party performs any of its obligations hereunder through any Affiliate of such Party, such Party shall be fully responsible and liable hereunder and thereunder for any failure of such performance, and each Party agrees that it will cause each of its Affiliates to comply with any provision of this Agreement which restricts or prohibits a Party from taking any specified action.

#### ARTICLE IV LICENSE GRANTS

4.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement (including, without limitation, Section 4.6) and any License to which Regeneron is a party, Regeneron hereby grants to Sanofi (a) the nontransferable (except as permitted by Section 20.9), co-exclusive (with Regeneron and its Affiliates) right and license under the Regeneron Intellectual Property to make, have made, use, develop and import Licensed Products for use in the Field in the Territory, and (b) the nontransferable (except as permitted by Section 20.9), exclusive (except as otherwise provided below in this Section 4.1) right and license under the Regeneron Intellectual Property to sell and offer to sell Licensed Products in the Field in the Territory, except that the right and license granted pursuant to this clause (b) shall be co-exclusive (with Regeneron and its Affiliates) to the extent of Regeneron's right to Co-Promote Licensed Products and Regeneron's right to supply Licensed Products to Sanofi, as contemplated by this Agreement. Sanofi will have the right to grant sublicenses under the foregoing license only as set forth in Section 4.4.

4.2 Sanofi License Grants. Subject to the terms and conditions of this Agreement and any License to which Sanofi or any of its Affiliates is a party, Sanofi hereby grants to Regeneron the nontransferable (except as permitted by Section 20.9), royalty-free, co-

exclusive (with Sanofi and its Affiliates) right and license under the Sanofi Intellectual Property to the extent necessary to make, have made, use, develop and import Licensed Products for use in the Field in the Territory and to Co-Promote Licensed Products to the extent provided in this Agreement.

4.3 Newly Created Intellectual Property. In addition to the other licenses granted under this Article IV and subject to the other terms and conditions of this Agreement, to the extent permitted under any relevant Third Party agreement, each Party grants to the other Party and its Affiliates the perpetual, royalty-free, paid-up, non-exclusive, worldwide right and license, with the right to grant sublicenses, to use and practice for any and all purposes: all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights), other than Know-How jointly owned pursuant to Section 12.1(e) and other than Excluded Rights, discovered, invented, authored or otherwise created by it (or its Affiliate) after the Effective Date directly in connection with the performance of the research and clinical activities approved by the JDC, in each case, as included in the Global Development Plans. As used above, the term “Excluded Rights” shall mean any Patents or Know-How claiming or covering composition (including any formulation) of a Licensed Product. For the avoidance of doubt, nothing in this Section 4.3 shall be construed to grant either Party any license to Patents or Know-How of the other Party discovered, invented, authored or otherwise created by it outside the performance of the research activities approved by the JDC and/or the clinical development activities approved by the JDC, in each case, as included in Global Development Plans.

4.4 Sublicensing. Unless otherwise restricted by any License, Sanofi will have the right to sublicense any of its rights under the first sentence of Section 4.1 only with the prior written consent of Regeneron, such consent not to be unreasonably withheld or delayed with respect to rights outside the Major Market Countries (and only with the prior written consent of Regeneron, which consent may be withheld for any reason, in the Major Market Countries), except that Sanofi may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Regeneron’s consent. Unless otherwise restricted by any License, Regeneron will have the right to sublicense any of its rights under Section 4.2 with the prior written consent of Sanofi, such consent not to be unreasonably withheld or delayed, except that Regeneron may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Sanofi’s consent. Each Party shall remain responsible and liable for the compliance by its Affiliates and Sublicensees with applicable terms and conditions set forth in this Agreement. Any such sublicense agreement will require the Sublicensee of a Party to comply with the obligations of such Party as contained herein, including, without limitation, the confidentiality and non-use obligations set forth in Article XVI, and will include, with respect to a Sublicensee of Sanofi, an obligation of the Sublicensee to account for and report its sales of Licensed Products to Sanofi on the same basis as if such sales were Net Sales by Sanofi. For the avoidance of doubt, Regeneron shall be entitled to receive its share of the applicable Profit Split based on Net Sales of Licensed Products sold by Sublicensees under this Agreement. In the event of a breach by a Sublicensee of any sublicense agreement which has or is reasonably likely to have an adverse effect on either Party or any of its Affiliates or any Party’s Intellectual Property, then the harmed Party may cause the other Party or its Affiliate to exercise, and the other Party or its Affiliate will promptly exercise, any termination rights it may have under the sublicense with the Sublicensee. Any

sublicense agreement will provide for the termination of the sublicense or the conversion of the sublicense to a license directly between the Sublicensee and the other Party, at the option of the other Party, upon termination of this Agreement. Furthermore, any such sublicense shall prohibit any further sublicense or assignment. Each Party will forward to the other Party a complete copy of each applicable fully executed sublicense agreement (and any amendment(s) thereto) within ten (10) days of the execution of such agreement.

4.5 No Implied License. Except as expressly provided in this Article IV or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights, Know-How, or Party Information either expressly or by implication, estoppel or otherwise.

4.6 Retained Rights. With respect to the licenses granted under this Article IV, and for the avoidance of doubt, Regeneron expressly reserves for itself and its Affiliates and Third Party licensees under the Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions, the right to Manufacture and to Commercialize Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the further avoidance of doubt, Regeneron retains all rights in Regeneron Intellectual Property, Regeneron's interest in the Joint Inventions and Licensed Products not expressly licensed hereunder, including, without limitation the right to exploit Regeneron Intellectual Property and Regeneron's interest in Joint Inventions for purposes unrelated to the Licensed Products in the Field. With respect to the licenses granted under this Article IV, and for the avoidance of doubt, Sanofi expressly reserves for itself and its Affiliates and Third Party licensees under the Sanofi Intellectual Property and Sanofi's interest in the Joint Inventions, the right to Manufacture and to Commercialize Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the avoidance of doubt, Sanofi retains all rights in Sanofi Intellectual Property, Sanofi's interest in the Joint Inventions and Licensed Products not expressly licensed hereunder, including, without limitation, the right to exploit Sanofi Intellectual Property and Sanofi's interest in Joint Inventions for purposes unrelated to the Licensed Products in the Field.

## **ARTICLE V DEVELOPMENT ACTIVITIES**

5.1 Development of Licensed Products. Subject to the terms of this Agreement, the Parties shall undertake Development activities with respect to Licensed Products in the Field pursuant to the Global Development Plans under the general direction and oversight of the JDC. Each Party shall use Commercially Reasonable Efforts to Develop Licensed Products in the Field, carry out the Development activities assigned to it in Development Plans in a timely manner and conduct all such activities in compliance with applicable Laws, including, without limitation, Good Practices.

5.2 Global Development Plans. With respect to each Licensed Product, the JDC shall prepare and present a Global Development Plan for approval by the JSC, and the JSC shall approve a Global Development Plan for such Licensed Product, within three (3) months after the time such Licensed Product first becomes a Licensed Product in accordance with the terms of the Discovery Agreement and this Agreement, and shall, subject to the further provisions of this Section 5.2, determine which Party will take the lead in the Development of

such Licensed Product. Prior to such JSC approval of the first Global Development Plan for any Licensed Product, the Parties shall Develop the Licensed Product in accordance with the applicable Initial Development Plan, including, in the case of REGN88 (IL-6RmAb), a summary outline of an Initial Development Plan attached hereto as Exhibit B. An updated Global Development Plan for such Licensed Product will be presented by the JDC for approval by the JSC, and approved by the JSC, at least two (2) months prior to the end of each Contract Year. Each Global Development Plan for a Licensed Product will set forth the plan for Development of such Licensed Product in the Field over at least three (3) Contract Years and will include (a) strategies and timelines for Developing and obtaining Approvals for such Licensed Product in the Field in the Territory, and (b) the allocation of responsibilities for Development activities between the Parties, and/or Third Party service providers. Each Global Development Plan will be reviewed and informally updated by the JDC not less frequently than once every six (6) months for the ensuing three (3) year period. Unless and to the extent otherwise agreed by the Parties with respect to a particular Licensed Product, (i) the Parties shall alternate, on a Licensed Product-by-Licensed Product basis, in being allocated principal responsibility for formulating, and carrying out, the principal Development activities for the applicable Licensed Product under the applicable Global Development Plan(s) from the time the applicable Product Candidate is advanced into Development in accordance with the Discovery Agreement (whereupon such Product Candidate automatically constitutes a Licensed Product) through proof of concept as defined in the Global Development Plan for the Licensed Product (the “POC Time”) (with respect to any Licensed Product, the Party with such principal responsibility through the POC Time being referred to as the “POC Principal Party”) and (ii) the Parties shall alternate being allocated principal responsibility for formulating, and carrying out, all clinical trials conducted subsequent to the POC Time for the applicable Licensed Product(s) under the applicable Global Development Plan(s) (with respect to a Licensed Product, the Party with such principal responsibility being referred to as the “Post-POC Principal Party”), with Sanofi being the Post-POC Principal Party for two (2), and Regeneron being the Post-POC Principal Party for one (1), out of each three (3) Licensed Products. The Parties shall cause their respective representatives on the JDC and the JSC, in preparing, updating and approving Global Development Plans, to allocate principal Development responsibilities thereunder as provided in this Section 5.2.

**5.3 Global Development Budgets.** Each Global Development Plan for a Licensed Product shall include a related Global Development Budget (each individually, a “Global Development Budget” and collectively, “Global Development Budgets”) and each Global Development Budget shall be prepared, updated, reviewed and approved as part of the preparation, update and approval of the Global Development Plan of which such Global Development Budget is a part in accordance with this Agreement. Amendments and updates to any Global Development Budget shall not be effective without the approval of the JSC.

**5.4 Development Reports.** Within forty-five (45) days after the end of each Quarter, commencing in the first Quarter in which Development activities commence hereunder with respect to the first Licensed Product, Regeneron and Sanofi shall each provide to the other Party a written report (in electronic form) summarizing the material activities undertaken by such Party during such Quarter in connection with each Global Development Plan, together with a statement of Development Costs incurred by such Party during such Quarter, which statement shall detail those amounts to be included in the Consolidated Payment Report for such Quarter

and shall be in such form, format and of such level of detail as approved by the JFC. At the next JSC meeting held following such forty-five (45) day period, the JSC will approve the final Development Costs which will be used in calculating the Global Development Balance.

5.5 Review of Clinical Trial Protocols. The JDC will establish procedures for the expeditious review of clinical trial protocols for the Licensed Products submitted to the JDC by Regeneron pursuant to Section 2.6(b), including, without limitation, pre-approval authorizations for Non-Approval Trials.

5.6 Regeneron Early Development Opt-Out. Within thirty (30) days of the date that Sanofi exercises its Opt-In Rights with respect to any Licensed Product thereby including such Licensed Product under this Agreement, Regeneron shall have a one-time right to opt-out of the further Development of such Licensed Product (such right of Regeneron, the "Regeneron Early Development Opt-Out Right", and each such Licensed Product as to which Regeneron has exercised the Regeneron Early Development Opt-Out Right, an "Early Development Opt-Out Product") by delivering written notice of such opt-out (a "Regeneron Early Opt-Out Notice") to Sanofi. Effective immediately upon the delivery by Regeneron to Sanofi of a Regeneron Early Opt-Out Notice with respect to a Licensed Product, (i) such Licensed Product shall automatically constitute an Early Development Opt-Out Product, (ii) the rights and licenses granted by Regeneron to Sanofi hereunder with respect to such Early Development Opt-Out Product shall automatically terminate, (iii) Sanofi and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than for amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or the Collaboration by Regeneron), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Regeneron Intellectual Property existing at the time the Regeneron Early Opt-Out Notice was delivered to Sanofi, to Develop, Manufacture and Commercialize in the Field in the Territory (and solely to the extent that such Regeneron Intellectual Property has, as of the date of the Regeneron Early Opt-Out Notice, actually been incorporated into such Early Development Opt-Out Product or otherwise claims or covers its use) the Early Development Opt-Out Product with respect to which such Regeneron Early Development Opt-Out Notice was delivered, (iv) \*\*\*\*\* (v) Regeneron shall, as promptly as reasonably practicable, transfer to Sanofi all clinical activities related to the Early Development Opt-Out Product, (vi) except as set forth in this Section 5.6, Regeneron shall have no further rights or obligations with respect to such Early Development Opt-Out Product, (vii) Sanofi shall be free to Develop and Commercialize such Early Development Opt-Out Product in the Field in the Territory free of any obligations to Regeneron hereunder, except for reimbursing Regeneron for any pass through costs to Third Party licensors of Regeneron Intellectual Property, to the extent attributable to the Development or Commercialization of Licensed Products by Sanofi, and (viii) \*\*\*\*\* As used in clause (viii) immediately above, "antibody" shall mean any actual or potential therapeutic or diagnostic antibody (whether fully human, humanized, phage display, chimeric, polyclonal, or any other type of antibody), or any derivative, or fragment thereof, including any immunoconjugates or fusions comprising any such gene product, derivative or fragment, and any composition or formulation that incorporates or includes any of the foregoing. Except as provided in this Section 5.6, a Party's obligations under this Agreement with respect to the Development of a Licensed Product shall terminate only upon termination of this Agreement

with respect to such Licensed Product or in its entirety in accordance with, and only to the extent and upon the terms and conditions set forth in, Article XIX.

## ARTICLE VI COMMERCIALIZATION

6.1 Commercialization of Licensed Products in the Field in the Territory. Subject to the terms of this Agreement, the Parties shall undertake Commercialization activities with respect to Licensed Products in the Field in the Territory under the direction and oversight of the JCC. Sanofi shall be the lead Party with respect to the Commercialization of Licensed Products in the Field. Sanofi shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field, and carry out the Commercialization activities in accordance with the applicable Global Commercialization Plan and the applicable Country/Region Commercialization Plans in a timely manner and conduct all such activities in compliance with applicable Laws. Except as otherwise provided in this Agreement, Sanofi shall bear all costs and expenses to Commercialize the Licensed Products in the Field in the Territory. Sanofi or its Affiliate shall invoice and book all sales of the Licensed Products in the Field in the Territory and shall appropriately record all such sales. Sanofi or its Affiliate shall also be responsible for the distribution of the Licensed Products in the Field in the Territory and for paying all governmental rebates which are due or owing with respect to the Licensed Products in the Field in the Territory. Commencing with the initiation of Phase 3 Trials for a Licensed Product in the Field in the Territory, the Parties will commence regular ad hoc discussions concerning the Commercialization strategy for the Licensed Product.

6.2 Global Commercialization Plan(s). Each Global Commercialization Plan and all updates and amendments thereto will be consistent with the principles of the Collaboration Purpose. Each Global Commercialization Plan shall be prepared by Sanofi (with assistance from Regeneron) at the direction of the JCC, and submitted to the JCC for review and approval. Once approved by the JCC, a Global Commercialization Plan will be presented to the JSC for review and approval at least \*\*\*\*\*. Such Global Commercialization Plan for each subsequent Contract Year shall be updated by the JCC and approved by the JSC at least one (1) month prior to the end of the then current Contract Year. The Global Commercialization Plan with respect to each Licensed Product shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC and JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

- (a) the overall global strategy for Commercializing such Licensed Product in the Field in the Territory, including target product profiles, branding, positioning, promotional materials and core messages for such Licensed Product;
- (b) \*\*\*\*\*;
- (c) the related Global Commercialization Budget;
- (d) anticipated launch dates for such Licensed Product for Major Market Countries;

- (e) market and sales forecasts for such Licensed Product in the Field in the Territory in a form to be agreed between the Parties;
- (f) strategies for the detailing and promotion of such Licensed Product in the Field in the Territory;
- (g) anticipated major advertising, public relations and patient advocacy programs for such Licensed Product in the Field in the Territory;
- (h) Non-Approval Trials; and
- (i) all other Marketing Guidelines.

6.3 Country/Region Commercialization Plans. Each Country/Region Commercialization Plan and all updates and amendments thereto will be consistent with the principles of the Collaboration Purpose. It is anticipated that each Country/Region Commercialization Plan for each Licensed Product will be prepared by Sanofi (with assistance from Regeneron in the U.S. and all Co-Commercialization Countries), and approved by the JCC, at least \*\*\*\*\*. Such Country/Region Commercialization Plan for each subsequent Contract Year shall be updated by the applicable Country/Region Commercialization Committee, and approved by the JCC, at least two (2) months prior to the end of the then current Contract Year. Each Country/Region Commercialization Plan with respect to each Licensed Product shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including the overall strategy for Commercializing such Licensed Product, \*\*\*\*\*, market and sales forecasts, and estimated FTE and Shared Commercial Expenses. In those countries where the Parties are Co-Promoting a Licensed Product, such Country/Region Commercialization Plans shall include more detailed information on the coordination of detailing and promotional efforts, including the estimated number of detailing FTEs for each Party (based on the number and position of Details required to meet the market and sales forecasts) and the specific allocation of Co-Promotion efforts between the Parties.

6.4 Commercialization Efforts; Sharing of Commercial Information.

(a) Sanofi (through its Affiliates where appropriate) shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory in accordance with the Global Commercialization Plans, the Marketing Guidelines and, as applicable, the Country/Region Commercialization Plan(s). Without limiting the generality of the foregoing, (i) Sanofi will, as necessary, build, train and apply a field force necessary to Commercialize the Licensed Products in the Field in accordance with the applicable Global Commercialization Plans and Country/Region

Commercialization Plans, (ii) Sanofi's, and in the Co-Commercialization Countries each Party's, sales representatives shall provide the FTE effort and detail the Licensed Products in the Field in accordance with the approved Country/Region Commercialization Plan (if applicable), Global Commercialization Plan(s) and all applicable Laws.

(b) Sanofi will provide Regeneron with full access to material information directly relating to the Commercialization of each Licensed Product in the Field, including, without limitation, information relating to anticipated launch dates, key market metrics, market research, and sales. Without limiting the foregoing, beginning in the Quarter of the First Commercial Sale in each Major Market Country, Sanofi will provide Regeneron, and with respect to each Co-Commercialization Country, Regeneron will provide Sanofi, on a quarterly basis, with reports of the activity within its field force in each such Major Market Country, which will include reasonable data from reports created by Sanofi or Regeneron for its internal management purposes.

(c) Each Party shall, on a periodic and reasonably current basis, keep the other Party informed regarding major market developments, acceptance of the Licensed Products in the Field, Licensed Product quality complaints and similar information.

(d) No Party may initiate or support any Non-Approval Trial for a Licensed Product in the Field in the Territory without the prior approval of the JDC.

#### 6.5 Co-Commercialization of Licensed Products.

(a) Exercise of Co-Promote Option by Regeneron. In the event that Regeneron desires to Co-Promote a Licensed Product in a particular country, Regeneron shall notify Sanofi of (i) its preliminary indication of intent regarding such Co-Promotion of such Licensed Product at least \*\*\*\*\* and (ii) its final decision regarding whether to Co-Promote such Licensed Product in such country at \*\*\*\*\*. If Regeneron does not timely notify Sanofi of its preliminary indication or of its final decision within the periods set forth in clause (i) or (ii) above, as applicable, Regeneron shall not be entitled to exercise its option to Co-Promote such Licensed Product in such country until on or after the \*\*\*\*\*.

(b) Co-Commercialization. Sanofi and Regeneron (through their respective Affiliates where appropriate) shall Co-Commercialize Licensed Products under the applicable Product Trademarks in each Co-Commercialization Country in accordance with the then-current and applicable Country/Region Commercialization Plan. Each Party shall use, or shall cause its local Affiliates to use, Commercially Reasonable Efforts to Co-Commercialize the Licensed Products in the Co-Commercialization Countries, and carry out the activities assigned to it in the applicable Country/Region Commercialization Plan. Each Party shall ensure that its Co-Commercialization activities conform with the parameters in the applicable approved Country/Region Commercialization Plan and the applicable Global Commercialization Plan.

(c) Decision to Discontinue Co-Commercialization. In the event that Regeneron decides it no longer wishes to Co-Commercialize a Licensed Product in a

particular Co-Commercialization Country or does not wish to maintain its minimum sales force FTE requirement for Co-Commercialization of such Licensed Product in such Co-Commercialization Country, provided that Regeneron has Co-Commercialized Licensed Product and maintained its minimum sales force FTE requirement for \*\*\*\*\* in such Co-Commercialization Country from the date it commences Co-Promoting in such Co-Commercialization Country, Regeneron must give the JCC and Sanofi \*\*\*\*\* prior written notice of such decision. At the end of such \*\*\*\*\* period, Regeneron shall cease all Co-Commercialization activities with respect to such Licensed Product in such Co-Commercialization Country.  
\*\*\*\*\*

(d) Field Force Coordination. The JCC or the applicable Committee shall coordinate the Co-Promotion of each Licensed Product by Sanofi, Regeneron, their respective local Affiliates and their respective sales representatives in each Co-Commercialization Country. The Parties will cooperate in the conduct of such activities with respect to scheduling, geographical allocation, and Professional or other customer targeting in order to optimize profits under the applicable Country/Region Commercialization Plan. Without limiting the generality of the foregoing, in each Co-Commercialization Country the Parties will share and, to the extent appropriate, cooperate to implement consistent policies and procedures with respect to the manner in which details and other sales visits are conducted.

(e) Co-Commercialization FTE Efforts.

(i) FTE Efforts. Upon the exercise of its election pursuant to Section 6.5(a) to Co-Promote in a country, Regeneron will provide to Sanofi a binding notice of the FTE effort that Regeneron commits to deliver in Co-Promoting such Licensed Product in such country during the first (1st) Contract Year for which Regeneron exercised its right to Co-Promote (the "Regeneron Commitment Level"). Subject to the provisions of Section 6.4(e)(ii), if Regeneron elects to Co-Promote a Licensed Product in a country, in no event shall the Regeneron Commitment Level be less than \*\*\*\*\* of the total anticipated FTE effort by both Parties (taken together) in Co-Promoting such Licensed Product in such Co-Commercialization Country, unless otherwise agreed by the Parties. Such FTE effort shall be based upon the forecasted number and position of Details required to meet the market and sales forecasts in such Co-Commercialization Country, and their conversion (by the JCC or applicable Country/Region Commercialization Committee) into the equivalent number of Detailing FTEs according to applicable weighting factors, based upon the sales force and marketing practices in such Co-Commercialization Country. In no event shall the Regeneron Commitment Level in Co-Promoting such Licensed Product in such Co-Commercialization Country exceed \*\*\*\*\* of the anticipated total FTE effort by both Parties in Co-Promoting such Licensed Product in such Co-Commercialization Country or such other maximum percentage agreed by the Parties (the "Maximum Regeneron Effort"). Regeneron's binding notice referred to above in this Section 4(e)(i) shall be accompanied by a plan (which shall be developed by Regeneron in cooperation

with Sanofi and shall be intended to coordinate and integrate the Parties' respective FTE efforts and detailing activities) for ensuring that Regeneron will have in place a field force of qualified sales representatives to satisfy the Regeneron Commitment Level. In each Co-Commercialization Country, Sanofi shall perform the anticipated total FTE effort above the Regeneron Commitment Level.

(ii) Ophthalmology. In the event that a Licensed Product receives Marketing Approval for an Indication related to ophthalmology, then, at Regeneron's option, Regeneron shall have the lead in the promotion of such Licensed Product in such Indication, provided, however, that the limitations set forth in Section 6.5(e)(i) shall apply.

(f) Training. The Parties will coordinate sales force training efforts in Co-Commercialization Countries and will share training materials (and conduct joint training, where appropriate) to facilitate joint sales force training efforts.

(g) Samples. Sanofi shall provide Regeneron with Licensed Product samples for use in Co-Commercialization Countries as required in the applicable Country/Region Commercialization Plan. Sanofi and Regeneron (and their respective Affiliates) shall use samples strictly in accordance with the then-applicable approved Country/Region Commercialization Plan and shall store and distribute samples in compliance with applicable Laws. Each Party (and its local Affiliates) will maintain those records required by all applicable Laws and shall allow representatives of the other Party to inspect such records and storage facilities for the Licensed Product samples on request.

6.6 Licensed Product Pricing and Pricing Approvals in the Territory. \*\*\*\*\*

6.7 Sales and Licensed Product Distribution in the Territory; Other Responsibilities.

(a) Sanofi (or its Affiliate) shall invoice and book, and appropriately record, all sales of the Licensed Products in the Field in the Territory. Sanofi (or its Affiliate) also shall be responsible for (i) the distribution of Licensed Products in the Field in the Territory and for paying all governmental rebates which are due and owing with respect to the Licensed Products in the Field in the Territory, (ii) handling all returns of Licensed Product sold under this Agreement and (iii) handling all aspects of ordering, processing, invoicing, collection, distribution and receivables with respect to Licensed Products in the Field in the Territory.

(b) Sanofi (through its local Affiliates where appropriate), and with respect to the Co-Commercialization Countries, Regeneron (through its local Affiliates where appropriate), shall maintain records relating to its sales representative FTEs for the Licensed Products in the Field in the countries in a manner sufficient to permit the

determination of Sales Force Cost and Medical Post-Approval Cost and the incentive compensation requirements set forth in the Marketing Guidelines.

6.8 Contract Sales Force. Each Party shall be entitled to engage a Contract Sales Force for up to \*\*\*\*\* of such Party's Sales Force utilized for any Licensed Product to discharge its annual FTE effort with respect to Commercialization of such Licensed Product, provided that in the event that Regeneron discontinues Co-Commercialization in a particular Co-Commercialization pursuant to Section 6.5(c), then Sanofi shall be entitled to engage a Contract Sales Force for more than \*\*\*\*\* for that Co-Commercialization Country. If a Party (or its local Affiliate) retains a Contract Sales Force, that Party (or its local Affiliate) will be responsible for (i) all costs associated with retaining such Contract Sales Force above approved Sales Force Costs included in the applicable Country/Region Commercialization Budget and for the Contract Sales Force's compliance with this Agreement, including, without limitation, the training and monitoring of such Contract Sales Force and ensuring compliance with all applicable Laws, and (ii) ensuring that sales representatives in such Contract Sales Force have minimum skill levels customary for sales representatives in major pharmaceutical companies in such country in the relevant therapeutic area.

#### 6.9 Promotional Materials.

(a) Except as provided in and subject to Section 6.9(b): Sanofi will be responsible, consistent with the Marketing Guidelines, the Global Commercialization Plan and the Country/Region Commercialization Plans (as applicable) and the decisions of the JCC with respect to Promotional Materials as contemplated by Section 3.4(b)(vi), for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities in the Territory, except where Regeneron shall perform such responsibilities as the Lead Regulatory Party. Upon request, Regeneron will have the right to review and comment on all major Promotional Materials for use in any country in the Territory prior to their distribution by Sanofi for use in the Territory.

(b) The Parties and their Affiliates shall only use the Promotional Materials and only conduct marketing and promotional activities for the Licensed Products which, in each case, are approved by the JCC or the applicable Country/Region Commercialization Committee if so delegated by the JCC for the applicable Major Market Country. Sanofi shall ensure that Regeneron's sales representatives are provided with reasonable quantities of Promotional Materials for use in a Co-Commercialization Country consistent with the Regeneron Commitment Level for such Co-Commercialization Country in accordance with the applicable approved Country/Region Commercialization Plan. All Promotional Materials generated for a Co-Commercialization Country shall be maintained in confidence and shall not be disclosed or distributed to Third Parties, until such time as they have been reviewed and approved as set forth in this Section.

(c) Sanofi shall own all rights to all Promotional Materials, including all copyrights thereto, in the Major Market Countries.

6.10 Promotional Claims/Compliance. Neither Party nor any of its Affiliates shall make any medical or promotional claims for any Licensed Product in the Field other than as permitted by applicable Laws. When distributing information related to any Licensed Product or its use in the Field in the Territory (including information contained in scientific articles, reference publications and publicly available healthcare economic information), each Party and its Affiliates shall comply with all applicable Laws and any guidelines established by the pharmaceutical industry in the applicable country.

6.11 Restriction on Bundling in the Territory. If Sanofi or its Affiliates or Sublicensees sell a Licensed Product in the Field in the Territory to a customer who also purchases other products or services from any such entity, Sanofi agrees not to, and to require its Affiliates and Sublicensees not to, bundle or include any Licensed Product as part of any multiple product offering or discount or price the Licensed Products in a manner that (a) is reasonably likely to disadvantage a Licensed Product in order to benefit sales or prices of other products offered for sale by a Party or its Affiliates to such customer, (b) is inconsistent with the Collaboration Purpose or (c) would result in pricing and discounting inconsistent with the applicable Marketing Guidelines.

6.12 Inventory Management. Sanofi shall use Commercially Reasonable Efforts to manage Licensed Product inventory on hand at wholesalers and Sublicensees so as to maintain levels of inventory appropriate for expected demand and to avoid taking action that would result in unusual levels of inventory fluctuation.

6.13 Medical and Consumer Inquiries. The JCC shall establish guidelines to handle medical questions or inquiries from consumers relative to Licensed Products.

6.14 Market Exclusivity Extensions. Each Party shall use Commercially Reasonable Efforts to maintain, and, to the extent available, legally extend, the period of time during which, in any country in the Territory, (a) a Party(ies) has the exclusive legal right, whether by means of a Patent Right or through other rights granted by a Governmental Authority in such country, to Commercialize a Licensed Product in the Field in such country and (b) no generic equivalent of a Licensed Product in the Field may be marketed in such country.

6.15 Post Marketing Clinical Trials. Subject to the provision of this Agreement, the Parties shall comply with any clinical trials obligations with respect to a Marketing Approval with respect to any Licensed Product use in the Field in any country in the Territory, imposed by applicable Law, pursuant to the Approvals or required by a Regulatory Authority.

## **ARTICLE VII CLINICAL AND REGULATORY AFFAIRS**

### 7.1 Ownership of Approvals and Registration Filings.

(a) Unless otherwise agreed to by the Parties, the Post-POC Principal Party shall be the Lead Regulatory Party and shall own (i) all Approvals with respect to Licensed Product in the Territory and (ii) the IND for Licensed Products during such time

as it is the Post-POC Principal Party and shall have the rights and obligations set forth in Sections 7.2 to 7.4 (inclusive) with respect thereto. \*\*\*\*\*

(b) The Lead Regulatory Party shall license, transfer, provide a letter of reference with respect to, or take other action necessary to make available the relevant Registration Filings and Approvals to and for the benefit of the other Party.

(c) The non-Lead Regulatory Party shall provide such assistance with respect to regulatory matters as is reasonably requested by the Lead Regulatory Party and consistent with the terms of this Agreement.

#### 7.2 Regulatory Coordination.

(a) The Lead Regulatory Party shall oversee, monitor and coordinate applicable regulatory actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to each Licensed Product in the Field in each jurisdiction as to which it is the Lead Regulatory Party; provided that it shall adhere to the obligations in this Article VII. Without limiting the foregoing, the Lead Regulatory Party will be responsible for, and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining the applicable Approval or other Registration Filing for each Licensed Product in the Field for which it has responsibility as the Lead Regulatory Party. To the extent applicable, the Lead Regulatory Party shall perform all such activities in accordance with the Plans and all applicable Laws.

(b) The Parties shall establish procedures, through the JDC or the JCC, to ensure that the Parties exchange on a timely basis all necessary information to enable the other Party and its licensees, as applicable, (i) to comply with its regulatory obligations in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field, including, without limitation, filing updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements and investigator notifications to Regulatory Authorities and (ii) to comply with Laws in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field anywhere in the Territory. The Parties shall provide to each other prompt written notice of any Approval of a Licensed Product in the Field anywhere in the world. The Parties shall work together cooperatively through the JDC in the preparation of regulatory strategies and with respect to all material regulatory actions, communications and Regulatory Filings for Licensed Products in the Field in the Territory.

(c) The Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party as promptly as practicable with written notice and copies of any material (i) draft filings with, (ii) submissions to and (iii) correspondence (including Approvals) with, Regulatory Authorities pertaining to the Development and/or Commercialization of a Licensed Product in the Field under the Plans, and shall use reasonable efforts to afford the other Party's representatives an opportunity to actively participate in the drafting and review of such material filings and submissions (including,

without limitation, all annual and periodic safety reports for Licensed Products in the Field), and consistent with applicable laws, to have up to two (2) representatives from the other Party attend and actively participate in all material, pre-scheduled meetings, telephone conferences and/or discussions with Regulatory Authorities to the extent such material meetings, telephone conferences and/or discussions pertain to the Development and/or Commercialization of any Licensed Product in the Field. Without limiting the foregoing, the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party on a timely basis with all material information, data and materials reasonably necessary for the other Party to participate in the preparation of the material filings and submissions referred to in this paragraph (c), said items to be provided to the other Party in a timely manner. The Parties will discuss in good faith any disputes on the contents of filings or submissions referred to in this paragraph (c) to the Regulatory Authorities and disputes shall be submitted to the JDC for timely resolution.

(d) For each Licensed Product, the JDC shall develop and the JSC shall approve proposed target Licensed Product labeling (“Target Labeling”) for use in the Territory.

7.3 Regulatory Events. Each Party shall keep the other Party informed, commencing within forty-eight (48) hours after notification (or other time period specified below), of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority, Third Party or other Governmental Authority, which:

(a) raises any material concerns regarding the safety or efficacy of any Licensed Product in the Field;

(b) indicates or suggests a potential investigation or formal inquiry by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of a Licensed Product in the Field under the Plans; provided, however, that each Party shall inform the other Party of the foregoing no later than twenty-four (24) hours after receipt of a notification referred to in this clause (b); or

(c) is reasonably likely to lead to a recall or market withdrawal of any Licensed Product in the Field anywhere in the Territory.

Information that shall be disclosed pursuant to this Section 7.3 shall include, but not be limited to the following matters with respect to Licensed Products:

(i) Governmental Authority inspections of Manufacturing, Development, distribution or other facilities;

(ii) inquiries by Regulatory Authorities or other Governmental Authorities concerning clinical investigation activities (including inquiries of investigators, clinical research organizations and other related parties) or pharmacovigilance activities, in each case, to the extent involving matters described in clauses (a), (b) or (c) of this Section 7.3;

- (iii) receipt of a warning letter issued by a Regulatory Authority;
- (iv) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction; and
- (v) receipt of product complaints concerning actual or suspected Licensed Product tampering, contamination, or mix-up (e.g., wrong ingredients).

7.4 Pharmacovigilance and Product Complaints. While the Lead Regulatory Party shall be responsible for managing pharmacovigilance and product complaints and for formulating and implementing any related strategies, both Parties will cooperate with each other in order to fulfill all regulatory requirements concerning pharmacovigilance and risk management plans and product complaint reporting in all countries in which any Licensed Product is being developed, manufactured, or commercialized anywhere in the Territory. Without limitation to the foregoing, the Parties shall execute a Safety Data Exchange Agreement (“SDEA”) setting forth the specific procedures to be used by the Parties to coordinate the investigation and exchange of reports of adverse events/adverse drug reactions and Licensed Product complaints to ensure timely communication to Regulatory Authorities and compliance with Laws.

7.5 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to a Licensed Product in the Field, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit to the extent it relates to the Development, Manufacture or Commercialization of a Licensed Product for use in the Field under this Agreement. Following receipt of the inspection or audit observations of the Regulatory Authority (a copy of which the receiving Party will promptly provide to the other Party), the Party in receipt of the observations will prepare any appropriate responses; provided that the other Party, to the extent practicable, shall have the right to review and comment on such responses to the extent they cover or may be reasonably expected to adversely impact the Licensed Products in the Field in the Territory, and the Party that received the observations shall consider in good faith the comments made by such other Party. In the event the Parties disagree concerning the form or content of a response, the Party that received the observations will decide the appropriate form and content of the response. Without limiting the foregoing, each Party (and its Third Party subcontractors) shall notify the other Party within forty-eight (48) hours of receipt of a notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities used or proposed to be used for the Manufacture of Licensed Products for use in the Field under this Agreement; provided that such notification shall be given no later than twenty-four (24) hours prior to any such Regulatory Authority audit or inspection.

7.6 Recalls and Other Corrective Actions. Decisions with respect to any recall, market withdrawal or other corrective action related to any Licensed Product in the Field in the Territory shall be made only upon mutual agreement of the Parties, which agreement shall not be unreasonably withheld or delayed; provided, however, that nothing herein shall prohibit either

Party from initiating or conducting any recall or other corrective action mandated by a Governmental Authority or Law. The Party that determines that a recall or market withdrawal of a Licensed Product in the Field in the Territory may be required shall, within twenty-four (24) hours, notify the other Party and, without limitation of and subject to the proviso in the immediately preceding sentence, the Parties shall decide whether such a recall or market withdrawal is required. The Parties shall cooperate with respect to any actions taken or public statements made in connection with any such recall or market withdrawal. Expenses associated with such recalls will be treated as Other Shared Expenses.

## **ARTICLE VIII MANUFACTURING AND SUPPLY**

8.1 Manufacture and Supply of Clinical Supply Requirements of Formulated Bulk Product. Until such time as Commercial Supply Requirements are being Manufactured, Regeneron will use Commercially Reasonable Efforts to provide an adequate and timely supply of Formulated Bulk Product for Clinical Supply Requirements of Licensed Products in the Field in the Territory in accordance with the Manufacturing Plan. Regeneron may use its Manufacturing facilities or, subject to Sanofi's prior written approval, such approval not to be unreasonably withheld or delayed, Sanofi or Third Parties to Manufacture such Formulated Bulk Product. If an entity other than Regeneron is to be used to Manufacture Formulated Bulk Product for Clinical Supply Requirements, preference shall be given to Sanofi or an Affiliate of Sanofi that is qualified to Manufacture the applicable Licensed Product in accordance with applicable Good Practices and where the estimated Manufacturing Cost is comparable to that of Third Party Manufacturers. The Formulated Bulk Product Manufactured by or on behalf of Regeneron for Clinical Supply Requirements will be billed to Sanofi by Regeneron at the Manufacturing Cost per Part I of Schedule 1 as a Development Cost. To the extent that Regeneron maintains manufacturing capacity available for the Manufacture of Clinical Supply Requirements, the cost of maintaining such capacity shall be included as a Development Cost to the extent it is not included as a Manufacturing Cost.

8.2 Finished Product Supply of Clinical Supply Requirements. Regeneron will timely identify, and enter into an agreement with, a Third Party or Third Parties or Sanofi (or use its own facilities, if Regeneron has such capabilities) to perform the filling, packaging, labeling and testing of the Formulated Bulk Product and supply Finished Product for Clinical Supply Requirements for Licensed Products for use under this Agreement. If an entity other than Regeneron is to be used to perform filling, packaging, labeling or testing services related to Finished Product for Clinical Supply Requirements, preference shall be given to Sanofi or an Affiliate of Sanofi that is qualified to perform such services in accordance with applicable Good Practices and where the estimated Manufacturing Cost is comparable to that of Third Parties. Such Finished Product for Clinical Supply Requirements Manufactured on behalf of Regeneron will be billed to Sanofi at the Manufacturing Cost as a Development Cost, in accordance with Part I of Schedule 1.

8.3 Manufacture and Supply of Commercial Supply Requirements.

(a) The Parties, through the JMC and JSC, will determine whether a Party, or a Third Party on behalf of a Party, will be responsible for Manufacturing and

supplying Commercial Supply Requirements of Formulated Bulk Product and/or Finished Product for each Licensed Product for use under this Agreement. The JMC shall use all reasonable efforts to make such determination no later than \*\*\*\*\* . Such a notice (a “Manufacturing Notice”) shall be irrevocable and shall be treated as a firm commitment to supply such Formulated Bulk Product or Finished Product, as the case may be. Preference will be given to having a Party or both Parties, rather than Third Parties, Manufacture and supply Commercial Supply Requirements, provided that the Party is qualified to Manufacture such Licensed Product in accordance with applicable Good Practices and on terms mutually acceptable to the Parties. If both Parties desire to Manufacture and supply such Commercial Supply Requirements, \*\*\*\*\* . If one Party desires to Manufacture and supply \*\*\*\*\* . If the Parties can not agree on terms under which either or both Parties will Manufacture and supply Commercial Supply Requirements of a Licensed Product, the JMC shall arrange for a Third Party to Manufacture and supply such Commercial Supply Requirements.

(b) Once Manufacture of Commercial Supply Requirements of a Licensed Product begins, or is scheduled to begin, Manufacture of Clinical Supply Requirements of such Licensed Product shall be coordinated with Manufacture of Commercial Supply Requirements of such Licensed Product. Formulated Bulk Product and/or Finished Product Manufactured by or on behalf of a Party for Commercial Supply Requirements, and for Clinical Supply Requirements that are Manufactured in coordination with the Commercial Supply Requirements, will be billed at the Manufacturing Cost described in Part II of Schedule 1 as a Commercial Supply Cost and Clinical Supply Cost, respectively. If a Party has commercial scale capacity available in anticipation of beginning to Manufacture Commercial Supply Requirements, the JMC shall decide if such Party shall Manufacture any Clinical Supply Requirements even before it begins to Manufacture Commercial Supply Requirements.

(c) Any Third Party manufacturer of Commercial Supply Requirements or Clinical Supply Requirements will be required to enter into a separate confidentiality agreement with Regeneron prior to the transfer of the manufacturing operations from Regeneron to such Third Party. All of Regeneron’s costs and expenses associated with the transfer of the manufacturing operations and related Know-How to the Third Party manufacturer (or Sanofi, to the extent that Sanofi manufactures all or part of the Commercial Supply Requirements or Clinical Supply Requirements) will be billed as a Development Cost.

8.4 Supply Agreement. The Parties shall enter into one or more clinical supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements, which shall contain terms consistent with this Agreement. At least \*\*\*\*\* of a Licensed Product, the Parties shall enter into separate commercial supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements and Commercial Supply Requirements after the First Commercial Sale, which shall contain terms consistent with this Agreement. Each supply agreement will include as an annex thereto a customary quality

agreement containing terms and conditions regarding quality assurance and Good Practices and provide for terms for forecasting, ordering, delivery, payment and supply consistent with the terms of this Agreement.

8.5 Process Development and Manufacturing Plans. The Parties, through the JMC, will develop and update as necessary, for each Licensed Product, a Manufacturing Plan. The JMC shall be responsible for deciding on process and technology selection, on process improvements and all related process development activities which impact manufacturing. The JMC shall also be responsible for all decisions relating to Manufacturing Formulated Bulk Product for Clinical Supply Requirements of Licensed Products. Each Manufacturing Plan shall set forth the supply requirements of a Licensed Product over an ensuing period of at \*\*\*\*\*. The Manufacturing Plan will include arrangements for the Manufacture of back-up Formulated Bulk Product for Licensed Product requirements at a Party or a Third Party back-up Manufacturing facility. The Manufacturing Plan (including each annual update thereto) shall be prepared by the JMC and approved by the JSC at least two (2) months prior to the end of the then current Contract Year, except that the initial Manufacturing Plan covering at least initial expected Clinical Supply Requirements for a Licensed Product, to the extent not included in the Initial Development Plan, shall be approved by the JSC within the initial Global Development Plan. The Parties shall design Manufacturing Plans to ensure an adequate supply of Licensed Product and shall use Commercially Reasonable Efforts to perform their responsibilities in accordance with the approved Manufacturing Plans.

8.6 Manufacturing Shortfall. Each Party is required to provide prompt written notice to the other Party if it reasonably determines that it will not, despite its using Commercially Reasonable Efforts, be able to supply the agreed upon demand forecast for the Licensed Products set forth in the Manufacturing Plan. Upon such notification, the matter will be referred to the JMC and JSC to determine what, if any (and identify and establish, as quickly as possible, if applicable) alternative supply source of Licensed Product (including the other Party) should be utilized.

8.7 Manufacturing Compliance. Each Party will use diligent efforts to Manufacture the Formulated Bulk Product and Finished Product supplied under this Article VIII or, as applicable, to ensure that the same is Manufactured by Third Parties in conformity with Good Practices and applicable Laws. Each Party will timely notify and seek the approval of the other Party, which approval shall not be unreasonably withheld or delayed, for any Manufacturing changes for the Formulated Bulk Product or Finished Product that are reasonably likely to have an adverse impact on (a) the quality of the Licensed Products supplied under this Agreement or (b) the regulatory status of the Licensed Products in the Territory, including requirements to support or maintain any Approvals. Each Party shall have the right to conduct inspections and audits of the other Party's facilities involved in the Manufacture of Licensed Products in the Field pursuant to this Agreement at reasonable times and on reasonable prior notice on terms to be agreed upon by the Parties. Moreover, each Party will use diligent efforts to negotiate agreements that would allow the other Party to audit the facilities of Third Party contractors (including Sanofi, if applicable) involved in the Manufacture of Licensed Products for use in the Field under this Agreement.

**ARTICLE IX  
PERIODIC REPORTS; PAYMENTS**

9.1 Development Costs. Sanofi shall be responsible for paying one hundred percent (100%) of the total Development Costs for each Licensed Product incurred by or on behalf of Sanofi, Regeneron and their respective Affiliates, except that Shared Phase 3 Trial Costs will be shared eighty percent (80%) by Sanofi and twenty percent (20%) by Regeneron.  
\*\*\*\*\*

9.2 Milestone Payments. In addition to the other payments contemplated herein, Sanofi shall be obligated to pay the non-refundable, non-creditable milestone payments listed in Schedule 3 to Regeneron upon the occurrence of the applicable milestone event. Sanofi shall have thirty (30) Business Days after the achievement of any such milestones to pay the corresponding amount to Regeneron, in each case, which shall not be reduced by any withholding or similar taxes.

9.3 Royalties. Any royalty amounts payable pursuant to Section 2.6(d) and 5.6 of this Agreement shall be paid to the applicable Party for the period of time, as determined on an Opt-Out Product-by-Opt-Out Product and country-by-country basis, commencing on the first commercial sale of such Opt-Out Product and \*\*\*\*\* (the "Royalty Term"). During the Royalty Term, the paying Party shall deliver to the other Party with each royalty payment a report detailing in reasonable detail the information necessary to calculate the royalty payments due under this Section 9.3 for such calendar quarter, including the following information, specified on an Opt-Out Product-by-Opt-Out Product and country-by-country basis: (a) total gross invoiced amount from sales of each such Opt-Out Product by the paying Party, its Affiliates and sublicensees; (b) all relevant deductions from gross invoiced amounts to calculate Net Sales; (c) Net Sales; and (d) royalties payable.

9.4 Sharing of Profits from Licensed Products. Commencing on the Effective Date and continuing during the Term, the Parties shall share the U.S. Profit Split in the United States, and (ii) the Rest of World Profit Split in the Rest of World Countries, in each case, as described in Schedule 2.

9.5 Periodic Reports. Sanofi and Regeneron shall each prepare and deliver to the other Party the periodic reports specified below:

(a) Each Party shall deliver electronically the reports required to be delivered by it pursuant to Section 5.4;

(b) Within twenty (20) days following the end of each month, commencing with the month in which First Commercial Sale occurs, Sanofi shall deliver electronically to Regeneron a monthly detailed Net Sales report with monthly and year-to-date sales for each Licensed Product in the Field in the Territory by country in United States Dollars;

(c) Within forty-five (45) days following the end of each Quarter, commencing with the Quarter in which First Commercial Sale occurs, Sanofi shall

deliver electronically to Regeneron a written report setting forth, on a country-by-country basis in the Territory for such Quarter (i) the Net Sales of each Licensed Product in local currency and in United States Dollars, (ii) Licensed Product quantities sold in the Field by dosage form and unit size and (iii) gross Licensed Product sales in the Field and an accounting of the deductions from gross sales permitted by the definition of Net Sales;

(d) Within forty-five (45) days following the end of each Quarter, each Party that has incurred any Other Shared Expenses or Shared Commercial Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Other Shared Expenses and/or Shared Commercial Expenses incurred by such Party in such Quarter on a country-by-country and Licensed Product-by-Licensed Product basis, including whether any such expenses are also included in the reports delivered pursuant to clause (e) below;

(e) Within forty-five (45) days after the end of each Quarter, commencing with the Quarter in which First Commercial Sale in a Reporting Country/Region occurs (or such earlier agreed upon calendar Quarter, if appropriate), Sanofi shall provide to Regeneron, in electronic form, for each Reporting Country/Region, and Regeneron shall provide to Sanofi, in electronic form, for each Co-Commercialization Country, a report summarizing in reasonable detail the marketing, detailing, selling and promotional activities undertaken by a Party (or its Affiliates) during the previous Quarter in such Reporting/Country Region and/or Co-Commercialization Country; and

(f) Within sixty (60) days following the end of each Quarter, Sanofi shall deliver electronically to Regeneron a Consolidated Payment Report in respect of such Quarter, combining the information reported by each Party pursuant to this Article IX and showing its calculations in accordance with Schedule 2 of the amount of any payments to be made by the Parties hereunder for such Quarterly period as contemplated by Section 9.5 (including, as applicable, showing the calculation of the U.S. Profit Split and Rest of World Profit Split) and, if applicable, providing for the netting of such payments.

All reports referred to in this Section 9.5 shall be in such form, format and level of detail as may be approved by the JFC. Unless otherwise agreed by the JCC, the financial data in the reports will include calculations in local currency and United States Dollars.

9.6 Funds Flow. The Parties shall make Quarterly True-Up payments as set forth in Schedule 2. If Sanofi is the Party owing the Quarterly True-Up payment based on the calculations in the applicable Consolidated Payment Report, it shall, subject to Section 9.12, make such payment to Regeneron within fifteen (15) days after its delivery to Regeneron of such Consolidated Payment Report. If Regeneron is the Party owing the Quarterly True-Up payment based on the calculations in the applicable Consolidated Payment Report, it shall, subject to Section 9.12, make such payment to Sanofi within fifteen (15) days after its receipt of such Consolidated Payment Report from Sanofi. Notwithstanding the foregoing, no later than fifty-five (55) days after the end of each Quarter, Sanofi shall pay Regeneron fifty percent (50%) of the amount of royalties or other amounts payable under any License (to the extent attributable to

the Manufacture, Development and/or Commercialization of Licensed Products under the Plans for the Territory) to which Regeneron is a party on account of the Commercialization of Licensed Products in the Field in the Territory and provide such supporting documentation required by such License, as the case may be.

9.7 Invoices and Documentation. The JFC shall approve the form of any necessary documentation relating to any payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder.

9.8 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars using the average of the buying and selling exchange rates for conversion of the applicable foreign currency into United States Dollars, using the spot rates (the "Closing Mid-Point Rates" found in the "Dollar spot forward against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties) from the last Business Day of the preceding month.

9.9 Late Payments. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. All late payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in *The Wall Street Journal* (Eastern Edition) effective for the date on which the payment was due, plus \*\*\*\*\* (such sum being referred to as the "Default Interest Rate").

9.10 Taxes. Except as set forth in Section 9.2, any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to the other Party; provided, however, that the withholding Party shall promptly furnish to the other Party proper evidence or other reasonable documentation of the taxes so paid. Each Party shall cooperate with the other and furnish to the other Party appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable). Without limiting the foregoing, each Party agrees to make all lawful and reasonable efforts to minimize any such taxes, assessments and fees and will claim on the other Party's behalf the benefit of any available treaty on the avoidance of double taxation that applies to any payments hereunder to such other Party.

9.11 Adjustments to FTE Rates. Notwithstanding anything herein to the contrary, upon the request of either Party, the Parties shall meet to review the accuracy of an applicable FTE rate in any country (e.g., Sales Force FTE Rate, Medical Post-Approval FTE Rate, Development FTE Rate, etc.). The Parties agree to share reasonable supporting documents

and materials in connection with an assessment of the applicable FTE rate and to determine in good faith whether to adjust the rate(s) in any country.

9.12 Resolution of Payment Disputes. In the event there is a dispute relating to any of the payment obligations or reports under this Article IX, the Party with the dispute shall have its representative on the JFC provide the other Party's representative on the JFC with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties, through the JFC, will seek to resolve the dispute as promptly as possible, but no later than ten (10) days after such written notice is received. In the event that no resolution is reached by the JFC, the matter shall be referred to the JSC in accordance with Section 3.11(a). Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any reasonably disputed amount shall not be deemed to have been triggered until such dispute is resolved hereunder, provided that all amounts that are not in dispute shall be paid in accordance with the provisions of this Agreement.

## **ARTICLE X DISPUTE RESOLUTION**

10.1 Resolution of Disputes. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement and to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

10.2 Governance Disputes. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in Article III ("Governance Disputes") shall be resolved pursuant to Article III and, to the extent such matters constitute Technical Development Matters, a dispute referred to in Section 14.2(b) or a Budget Dispute, Section 10.4, except to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 10.3 shall apply. For the purposes of this Agreement, the term "Technical Development Matter" shall mean any dispute concerning a Party's refusal to approve a clinical trial proposed pursuant to Section 2.6(b).

10.3 Legal Disputes. The Parties agree that, subject to Sections 10.5 and 16.2, they shall use all reasonable efforts, through their participation in the JSC in the first instance, to resolve any Legal Dispute arising after the Effective Date by good faith negotiation and discussion. In the event that the JSC is unable to resolve any such Legal Dispute within five (5) Business Days of receipt by a Party of notice of such Legal Dispute, either Party may submit the Legal Dispute to the Executive Officers for resolution. In the event the Executive Officers are unable to resolve any such Legal Dispute within the time period set forth in Section 3.11(b), the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 20.1 and Section 20.15.

### 10.4 Expert Panel.

(a) In the event of a dispute between the Parties concerning a Technical Development Matter, any Budget Dispute or a dispute referred to in Section

14.2(b) that cannot be resolved by the Executive Officers pursuant to Section 3.11(b) (other than a Legal Dispute), either Party may by written notice to the other Party require the specific issue in dispute to be submitted to a panel of experts (“Expert Panel”) in accordance with this Section 10.4 (for the avoidance of doubt, it is understood that, subject to Section 10.4(e), in the case of a Budget Dispute first submitted to the Expert Panel, the specific issue shall be limited to the overall commercial reasonableness of the Disputed Budget). Such notice shall contain a statement of the issue forming the basis of the dispute, the position of the moving Party as to the proper resolution of that issue and the basis for such position. Within fifteen (15) days after receipt of such notice, the responding Party shall submit to the moving Party a statement of its conception of the specific issue in question, its position as to the proper resolution of that issue and the basis for such position.

(b) Within fifteen (15) days of the responding Party’s response, each Party shall appoint to the Expert Panel an individual who (i) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue (or, in the case of a dispute regarding an audit as referred to in Section 14.2(b), expertise in accounting and auditing with respect to the development and commercialization of pharmaceutical products), (ii) is not a current or former director, employee or consultant of such Party or any of its Affiliates, or otherwise has not received compensation or other payments from such Party (or its Affiliates) for the past five (5) years and (iii) has no known personal financial interest or benefit in the outcome or resolution of the dispute, and the appointing Party shall give the other Party written notice of such appointment; provided that for such appointment to be effective and for such individual to serve on the Expert Panel, such individual must deliver to the other Party a certificate confirming that such individual satisfies the criteria set forth in clauses (i) through (iii) above, disclosing any potential conflict or bias and certifying that, as a member of the Expert Panel, such individual is able to render an independent decision.

(c) Within fifteen (15) days of the appointment of the second (2nd) expert, the two (2) appointed experts shall agree on an additional expert who meets the same criteria as described above, and shall appoint such expert as chair of the Expert Panel. If the Party-appointed experts fail to timely agree on a third (3rd) expert, then upon the written request of either Party, each Party-appointed expert shall, within ten (10) days of such request, nominate one expert candidate and the CPR Institute for Dispute Resolution shall, within ten (10) days of receiving the names of the Parties’ respective nominees, select one of those experts to serve as the chair of the Expert Panel. Each expert shall agree, prior to his or her appointment, to render a decision as soon as practicable after the appointment of the full Expert Panel.

(d) Within seven (7) days of the appointment of the third (3rd) expert, the Expert Panel shall hold a preliminary meeting or teleconference with the Parties or their representatives and shall designate a time and place for a hearing of the Parties on the dispute and the procedures to be utilized at the hearing. The Parties may agree in writing to waive the hearing and have the Expert Panel reach a decision on the basis of written submissions alone. The Expert Panel may order the Parties to produce any documents or

documents or information which are relevant to the dispute. All such documents or information shall be provided to the other Party and the Expert Panel as expeditiously as possible but no later than one (1) week prior to the hearing (if any), along with the names of all witnesses who will testify at the hearing and a brief summary of their testimony. The hearing shall be held in New York, NY, unless otherwise agreed by the Parties, and shall take place as soon as possible but no more than forty-five (45) days after the appointment of the third expert, unless the Parties otherwise agree in writing or the Expert Panel agrees to extend such time period for good cause shown. The hearing shall last no more than one (1) day, unless otherwise agreed by the Parties or the Expert Panel agrees to extend such time period for good cause shown. After the conclusion of all testimony (or if no hearing is held after all submissions have been received from the Parties), at a time designated by the Expert Panel no later than seven (7) days after the close of the hearing or the receipt of all submissions, each Party shall simultaneously submit to the Expert Panel and exchange with the other Party its final proposed resolution (which, in the case of a Budget Dispute first submitted to the Expert Panel shall be a Party's proposed resolution that the Disputed Budget either is or is not overall commercially reasonable).

(e) In rendering the final decision with respect to a Budget Dispute first submitted to the Expert Panel, the Expert Panel shall be limited to determining the overall commercial reasonableness of the Disputed Budget. If the Expert Panel determines that such Disputed Budget is overall commercially reasonable, then such Budget Dispute shall be deemed finally resolved and such resolution shall be binding on the Parties. However, if the Expert Panel determines that such Disputed Budget is not overall commercially reasonable, then the Expert Panel shall, within fifteen (15) days after such determination, render a final decision as to what modifications could be made to such Disputed Budget in order for it to be overall commercially reasonable (a "Budget Modification Decision"). In connection with reaching a Budget Modification Decision, the Expert Panel shall order the Parties to produce any documents or other information which are relevant to such final decision, and the Parties shall submit such documents or other information, together with their respective proposed resolutions which shall consist of their respective proposed modifications to the Disputed Budget in order for it to be overall commercially reasonable, at least seven days prior to the date a Budget Modification Decision is required to be rendered as provided above. In rendering the final decision (which, for other than a Budget Modification Decision, shall be rendered no later than fifteen (15) days after receipt by the Expert Panel of the Parties' respective proposed resolutions, and for a Budget Modification Decision, shall be rendered no later than seven days after receipt by the Expert Panel of the Parties' respective proposed resolutions), the Expert Panel shall be limited to choosing a resolution proposed by a Party without modification; provided, however, that in no event shall the Expert Panel render a decision that is inconsistent with the Collaboration Purpose and the Parties' intentions as set forth in this Agreement. The agreement of two (2) of the three (3) experts shall be sufficient to render a decision and the Parties shall abide by such decision.

(f) The decision of the Expert Panel shall be final and binding on the Parties and may be entered and enforced in any court having jurisdiction. Each Party

shall bear the cost of its appointee to the Expert Panel and the Parties shall share equally the costs of the third expert.

10.5 No Waiver. Nothing in this Article X or elsewhere in this Agreement shall prohibit either Party from seeking and obtaining immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions or inaction of the other.

## ARTICLE XI TRADEMARKS AND CORPORATE LOGOS

11.1 Corporate Names. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.

11.2 Selection of Product Trademarks. For each Licensed Product, the JCC shall select one Product Trademark for use in the Field throughout the Territory, unless such Product Trademark is prohibited by law in any country in the Territory or the JCC determines that a different Product Trademark should be used in particular countries or Regions to maximize the commercial potential of such Licensed Product. Once a Product Trademark has been selected by the JCC, the Parties shall enter into an agreement or, in the alternative, shall amend this Agreement as the Parties may agree, in order to address the Parties' respective rights and obligations with respect to such Product Trademark. Each Licensed Product in the Field shall be promoted and sold in the Territory under the applicable Product Trademark(s), trade dress and packaging approved by the JCC.

11.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, and subject to Sections 11.4 and 11.5, Sanofi (or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s), together with all associated domain names and all goodwill related thereto in all countries in the Territory.

11.4 Prosecution and Maintenance of Product Trademark(s). Sanofi will use Commercially Reasonable Efforts to prosecute and maintain the Product Trademark(s) in all countries in the Territory. Notwithstanding the foregoing, in the event Sanofi elects not to prosecute or maintain any Product Trademark(s) in any country in the Territory, Sanofi shall provide reasonable prior written notice to Regeneron of its intention not to prosecute or maintain any such Product Trademark in such country in the Territory, and Regeneron shall have the right to do so on behalf of Sanofi for use with Licensed Products, subject to consultation and cooperation with Sanofi. All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of Product Trademarks as provided in this Section 11.4 shall be shared by the Parties as part of Shared Commercial Expenses.

11.5 License to the Product Trademark(s). Sanofi hereby grants to Regeneron a co-exclusive license (non-exclusive only with respect to Regeneron) to use the Product Trademark(s) for the Licensed Products solely for the purposes of Regeneron's Development, Manufacturing, and, if applicable, Co-Promotion of Licensed Products, or other Regeneron Commercialization activities with respect to Licensed Products if agreed to by Sanofi or set forth

in any Plans, subject to the terms and conditions of this Agreement. Consistent with Section 4.4 of this Agreement, neither Party shall license (or in the case of Regeneron, sublicense) rights to use, or otherwise transfer ownership of the Product Trademark(s) without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed. Sanofi shall only utilize the Product Trademark(s) on approved Promotional Materials, on the Licensed Products as needed and on or other approved product-related materials for the Licensed Products in the Field in the Territory for the purposes contemplated herein, and all use by Sanofi or its Affiliates or Sublicensees of the Product Trademark(s) shall be in accordance with (a) rules established by the JCC and (b) quality standards established by the JCC which are reasonably necessary in order to preserve the validity and enforceability of the Product Trademark(s). Each Party agrees that at no time during the Term will it or any of its Affiliates attempt to use or register any trademarks, trade dress, service marks, trade names or domain names confusingly similar to the Product Trademark(s) in relation to a product that is a Licensed Product, or take any other action which damages or dilutes the rights to, or goodwill associated with, the Product Trademark(s). Upon request by either Party, the other Party shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required for the purpose of recording with any Governmental Authority the license, or a recordable version thereof, referred to above in this Section 11.5.

11.6 Use of Corporate Names. Sanofi (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include Regeneron's name with equal prominence on materials related to each Licensed Product in the Field (including, without limitation, package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with such Licensed Product), unless to do so would be prohibited under applicable Laws; provided, however, in the case of multi-product materials that refer to a Licensed Product in the Field as well as other pharmaceutical products, the prominence of Regeneron's name shall be commensurate with the relative prominence of the Licensed Product in such materials. Each Party grants to the other Party (and its Affiliates) the right, free of charge, to use its name and logo on package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with the applicable Licensed Product in the Field in the Territory during the Term and thereafter with respect to Promotional Materials, package inserts, packaging, labeling, trade packaging and samples, only for the time period and solely to the extent necessary to exhaust the existing inventory of Licensed Product (including packaging materials for such Licensed Product) and Promotional Materials containing such name or logo. During the Term, each Party shall submit samples of each such package inserts, packaging, trade packaging, etc. to such other Party for its prior approval, which approval shall not be unreasonably withheld or delayed, at least thirty (30) days before dissemination of such materials. Failure of the receiving Party to object within such thirty (30) day period shall constitute approval of the submitting Party's package inserts, packaging, trade packaging, etc.

## **ARTICLE XII NEWLY CREATED INVENTIONS AND KNOW-HOW**

### 12.1 Ownership of Newly Created Intellectual Property.

(a) Subject to Section 12.1(e), each Party (and each Party's respective Affiliates) shall exclusively own all intellectual property (including, without limitation,

Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created in connection with the Collaboration solely by such Party, its Affiliates, employees, agents and consultants (“Sole Inventions”). Sole Inventions made solely by Sanofi, its Affiliates, employees, agents and consultants are referred to herein as “Sanofi Sole Inventions”. Sole Inventions made solely by Regeneron, its Affiliates, employees, agents and consultants are referred to herein as “Regeneron Sole Inventions”. The Parties agree that nothing in this Agreement, and no use by a Party of the other Party’s Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party’s Intellectual Property, other than the license rights expressly granted hereunder. Any remuneration payable under applicable law to an inventor and costs associated with determining such remuneration shall be treated as Other Shared Expenses.

(b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Collaboration during the Term that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Sanofi or its Affiliate (or for which ownership vests in Sanofi or its Affiliate by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron or its Affiliate (or for which ownership vests in Regeneron or its Affiliate by operation of Law), on the other hand, on the basis of each Party (or its Affiliate) having an undivided interest in the whole (“Joint Inventions”).

(c) Notwithstanding the foregoing in Section 12.1(b), (i) for purposes of determining whether a patentable invention is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, (ii) for purposes of determining whether a copyrighted work is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.

(d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under the Collaboration during the Term vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.

(e) Subject to the other terms and conditions of this Agreement (other than Section 12.1(a)), to the extent permitted under any relevant Third Party agreement, each Party agrees that all Know-How, other than Excluded Know-How Rights, discovered, invented, authored or otherwise created by it (or its Affiliate) after the

Effective Date directly in connection with the performance of the research and clinical activities approved by the JDC, in each case, as included in the Global Development Plans shall be Joint Inventions. Each Party agrees to execute all necessary documentation to reflect the foregoing. As used above, the term “Excluded Know-How Rights” shall mean any Know-How claiming or covering composition (including any formulation) of a Licensed Product, including, for the avoidance of doubt, any manufacturing and/or cell line related intellectual property. For further clarity, nothing in this Section 12.1(e) shall be construed to grant either Party any rights to Patents or Know-How of the other Party discovered, invented, authored or otherwise created by it outside the performance of the research activities approved by the JDC and/or the clinical development activities approved by the JDC, in each case, as included in Global Development Plans.

(f) The Parties hereby agree that each Party’s use of the Joint Inventions is governed by the terms and conditions of this Agreement shall be governed as follows: each Party’s interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement); provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as may be expressly set forth in Article IV, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee’s written agreement to be bound by the terms of this Section 12.1(e) and (iii) nothing in this Article XII shall relieve a Party or its Affiliates of their obligations under Article XVI with respect to confidential Party Information provided by the other Party or such other Party’s Affiliates. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld. Neither Party hereto shall have the obligation to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Collaboration. The provisions governing Joint Inventions set forth in this Section 12.1(e) shall survive the expiration or termination of this Agreement.

#### 12.2 Prosecution and Maintenance of Patent Rights.

(a) Regeneron shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights in the Territory. Regeneron shall undertake such activities using outside counsel reasonably acceptable to Sanofi except that all provisionals, the priority application based thereon and the corresponding PCT may be prepared and filed by Regeneron’s in-house counsel. Regeneron shall confer with and keep Sanofi reasonably informed regarding the status of such activities. In addition, Regeneron shall have the following obligations with respect to the filing, prosecution and maintenance of Regeneron Patent Rights: (i) Regeneron shall provide to Sanofi for review and comment a substantially completed draft of any

priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Regeneron and incorporate any reasonable comment from Sanofi within such thirty (30) day period unless Regeneron reasonably believes that such comments will adversely affect the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) Regeneron shall provide Sanofi promptly with copies of all material communications received from or filed in patent offices in the Territory with respect to such filings; (iii) Regeneron shall consult with Sanofi promptly following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications, provided, however, applications shall be filed in at least \*\*\*\*\* (the “Patent Jurisdictions”) unless otherwise agreed in writing; and (iv) Regeneron shall consult with Sanofi a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Regeneron desires to abandon any Patent included in the Regeneron Patent Rights in the Territory, Regeneron shall provide reasonable prior written notice to Sanofi of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Regeneron Patent with the applicable patent office) and Sanofi shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof, in Regeneron’s name or Sanofi’s name at Sanofi’s sole discretion, unless, with respect to any such Patent Applications that are unpublished, Regeneron notifies Sanofi that Regeneron would prefer to maintain the subject matter of such Patent Application as a trade secret and Sanofi agrees in writing.

(b) Sanofi shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Sanofi Patent Rights in the Territory and shall confer with and keep Regeneron reasonably informed regarding the status of such activities. In addition, Sanofi shall have the following obligations with respect to the filing, prosecution and maintenance of Sanofi Patent Rights: (i) Sanofi shall provide to Regeneron for review and comment a copy of a substantially completed draft of any priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Sanofi and incorporate any reasonable comment from Regeneron unless Sanofi reasonably believes that such comments will adversely affect the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) Sanofi shall provide Regeneron promptly with copies of all material communications received from or filed in patent offices with respect to such filings; (iii) Sanofi shall consult with Regeneron promptly following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications, provided, however, applications shall be filed in at least the Patent Jurisdictions unless otherwise agreed in writing; and (iv) Sanofi shall

consult with Regeneron a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Sanofi desires to abandon any Patent included in the Sanofi Patent Rights in the Territory, Sanofi shall provide reasonable prior written notice to Regeneron of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Sanofi Patent with the applicable patent office) and Regeneron shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Sanofi's name, unless, with respect to any such Patent Applications that are unpublished, Sanofi notifies Regeneron that Sanofi would prefer to maintain the subject matter of such Patent Application as a trade secret and Regeneron agrees in writing.

(c) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of the Controlling Party. The Controlling Party shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners through outside counsel reasonably acceptable to the non-Controlling Party, except that the Controlling Party may prepare and file all provisional applications, priority applications based thereon and the corresponding PCTs using in-house counsel. The Controlling Party shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents under any such Joint Patent Rights: (i) the Controlling Party shall provide the non-Controlling Party with notice and a copy of a substantially completed draft of any priority Patent Application at least thirty (30) days prior to the filing of any such priority Patent Application by the Controlling Party and incorporate any reasonable comment provided by the non-Controlling Party within such thirty (30) day period (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period; (ii) the Controlling Party shall notify the non-Controlling Party prior to the filing of a Patent Application by the Controlling Party; (iii) the Controlling Party shall consult with the non-Controlling Party promptly following the filing of the priority Patent Application to mutually determine in which countries it shall file convention Patent Applications provided, however, applications shall be filed in at least the Patent Jurisdictions unless otherwise agreed in writing; (iv) the Controlling Party shall provide the non-Controlling Party promptly with copies of all material communications received from or filed in patent offices with respect to such filings and the Parties use all reasonable efforts to reach agreement in a timely manner with respect to all material responses and amendments; and (v) the Controlling Party shall provide the non-Controlling Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office (including but not limited to substantially narrowing or canceling any claim without reserving the

right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the non-Controlling Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that the Controlling Party materially breaches the foregoing obligations and such breach is not cured within thirty (30) days of a written notice from the non-Controlling Party to the Controlling Party describing such breach, or in the event that the Controlling Party fails to undertake the filing of a Patent Application within the earlier of (i) ninety (90) days of a written request by the non-Controlling Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the non-Controlling Party may assume the Controlling Party's responsibility for filing, prosecution and maintenance of any such Joint Patent Right, and will thereafter be deemed the Controlling Party for purposes hereof. Notwithstanding the foregoing, the Controlling Party may withdraw from or abandon any Patent or Patent Application relating to any Joint Patent Rights on thirty (30) days' prior written notice to the other Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the non-Controlling Party a free-of-charge option to assume the prosecution or maintenance thereof.

(d) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Patents and Patent Applications pursuant to this Section 12.2, including, without limitation, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Joint Patent Rights that such Party has elected not to pursue as provided for in Section 12.2(c). The JCC, with the approval of the JSC, will determine which of the Sanofi Patent Rights, Regeneron Patent Rights and Joint Patent Rights for which to seek an extension of term and the applicable Party will file for said patent term extension.

(e) All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Sanofi Patent Rights, Regeneron Patent Rights and Joint Patent Rights in the Territory for use in the Field, and any extensions thereof, shall be treated as Other Shared Expenses.

### 12.3 Interference, Opposition and Reissue.

(a) Each Party will notify the other within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition or reexamination relating to Regeneron Patent Rights, Sanofi Patent Rights or Joint Patent Rights in the Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. The Parties will reasonably consult with one another in an effort to agree with respect to decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms,

provided that if such agreement cannot be reached promptly, such decisions will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Sanofi, (ii) with respect to Sanofi Patent Rights, by Sanofi in consultation with Regeneron and (iii) with respect to Joint Patent Rights, jointly by the Parties.

(b) All Out-of-Pocket Costs incurred in connection with any interference, opposition, reissue or reexamination proceeding relating to the Regeneron Patent Rights, Sanofi Patent Rights and/or Joint Patent Rights in the Territory for use in the Field shall be treated as Other Shared Expenses.

### **ARTICLE XIII INTELLECTUAL PROPERTY LITIGATION AND LICENSES**

#### **13.1 Third Party Infringement Suits.**

(a) In the event that either Party or any of its Affiliates becomes aware of an actual, potential or suspected infringement of a Sanofi Patent Right, a Regeneron Patent Right, a Joint Patent Right, Product Trademark or any other intellectual property right jointly owned or licensed under this Agreement, by a Third Party's activities in the Field in the Territory, the Party that became aware of the infringement shall promptly notify the other Party in writing of this claim or assertion and shall provide such other Party with all available evidence supporting such known, potential or suspected infringement or unauthorized use. As soon as reasonably practicable after the receipt of such notice, the Parties shall cause the JSC to meet and consider the appropriate course of action with respect to such infringement. The Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning prosecution and/or settlement of any such claim.

(b) With respect to any such actual, suspected or potential infringement by virtue of a generic or potential generic competitor's activities in the Field in the Territory, including but not limited to, any ANDA filing, Paragraph IV Certification (or the equivalent for biologics) or other actual or potential infringement by a generic or potential generic competitor anywhere in the Territory, the Parties will consult and cooperate fully to determine a course of action. Final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made by Sanofi with active assistance from and in consultation with Regeneron. Regeneron will provide reasonable assistance to Sanofi in prosecuting any suit, and if required by Law, will join in the suit. Although Sanofi has the right to select counsel of its own choice, it shall first consult with Regeneron and consider in good faith the recommendations of Regeneron. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall first be used to pay reasonable costs, including attorneys' fees, relating to such legal proceedings and then shared equally by the Parties or according to the U.S. Profit Split and Rest of World Profit Split if and as applicable.

(c) With respect to all other such actual, potential or suspected infringement by virtue of a Third Party's activities in the Field in the Territory, the Parties will consult and cooperate fully in an effort to determine a mutually agreeable course of action, provided if such agreement cannot be reached promptly, final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Sanofi, (ii) with respect to Sanofi Patent Rights, by Sanofi in consultation with Regeneron, and (iii) with respect to Joint Patent Rights, jointly by the Parties. Any disagreement between the Parties concerning the enforcement of Joint Patent Rights shall be referred to the Executive Officers for resolution. The Party initiating the litigations shall be referred to as the "Lead Litigation Party." The non-Lead Litigation Party will provide reasonable assistance to the Lead Litigation Party in prosecuting any suit, and if required by Law, will join in the suit. Although the Lead Litigation Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of the other Party. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall first be used to pay reasonable costs, including attorneys' fees, relating to such legal proceedings and then shared equally by the Parties.

(d) All Out-of-Pocket Costs incurred in connection with any litigation under Section 13.1(b) or (c) related to activities in the Field in the Territory shall be treated as Other Shared Expenses.

(e) For the avoidance of doubt, neither Party will enter into any settlement of any suit referenced in this Section 13.1 that materially affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory without the other Party's prior written consent. Furthermore, no Party shall enter into any Third Party intellectual property license requiring the payment of royalties or other amounts based on the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory under this Agreement without the other Party's prior written consent.

13.2 Patent Marking. Each Party shall comply with the patent marking statutes in each country in which a Licensed Product in the Field is made, offered for sale, sold or imported by such Party, its Affiliates and/or Sublicensees.

### 13.3 Third Party Infringement Claims; New Licenses.

(a) If either Party or its Affiliates shall learn of an allegation that the Development, Manufacture or Commercialization of any Licensed Product in the Field in the Territory under this Agreement infringes or otherwise violates the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this allegation. As soon as reasonably practicable after the receipt of such notice and at all times thereafter, the Parties shall meet and consider the appropriate course of action with respect to such allegation of infringement. In any such instance, each Party shall have the right to defend any action naming it using its own

counsel; however, the Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning a potential defense and/or settlement of any such claim. The rights and obligations in this Section 13.3 shall apply even if only one Party defends any claimed infringement action commenced by a Third Party in the Territory claiming that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes or otherwise violates any intellectual property rights of any Third Party.

(b) Except as otherwise set forth in this Agreement, all Out-of-Pocket Costs (except for the expenses of the non-controlling Party's counsel, if only one Party defends a claim) incurred in connection with any litigation referred to in this Section 13.3 shall be treated as Other Shared Expenses.

(c) \*\*\*\*\*

(d) License fees, royalties and other payments under Licenses to the extent attributable to, and based on, the discovery, Development and Manufacture of Commercial Supply Requirements or the Commercialization of Licensed Products in the Field in the Territory shall be treated as Other Shared Expenses.

(e) \*\*\*\*\*

**ARTICLE XIV  
BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS**

14.1 Books and Records. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with GAAP or IAS/IFRS) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 14.2, to visit and inspect, during regular business hours and under the guidance of officers of the Party being inspected, and to examine the books of record and account of such Party or such Affiliate to the extent relating to this Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate to the extent relating to this Agreement with, and be advised as to the same by, its and their officers and independent accountants.

14.2 Audits and Adjustments.

(a) Each Party shall have the right (at its own cost), upon no less than thirty (30) days advance written notice and at such reasonable times and intervals and to such reasonable extent as the investigating Party shall request, not more than once during

any Contract Year, to have the books and records of the other Party and its Affiliates to the extent relating to this Agreement for the preceding two (2) years audited by an independent “Big Four” (or equivalent) accounting firm of its choosing under reasonable appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days. Unless otherwise mutually agreed by the Parties, any disputes regarding the results of any such audit shall be subject to dispute resolution in accordance with Article X. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than seven and one-half percent (7.5%), the audited Party shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the auditing party in all other cases). Such accountants shall not reveal to the Party seeking verification the details of its review, except for such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article XVI.

(c) If any examination or audit of the records described above discloses an under- or over-payment of amounts due hereunder, then unless the result of the audit is to be contested pursuant to Section 14.2(b) above, the Party owing any money hereunder shall pay the same (plus interest thereon at the Default Interest Rate from the date of such underpayment through the date of payment of the amount required to be paid pursuant to this Section 14.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section.

14.3 GAAP/IAS/IFRS. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with, at a Party’s election, GAAP or IAS/IFRS.

## **ARTICLE XV REPRESENTATIONS, WARRANTIES AND COVENANTS**

15.1 Due Organization, Valid Existence and Due Authorization; Financial Capability. Each Party hereby represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate (or, in the case of Sanofi Amerique, partnership) power and authority and has taken all corporate (or, in the case of Sanofi Amerique, partnership) action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other agreement by which it is bound or any requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in

accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting, the licenses granted to the other under Article IV hereof; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf. Each Party hereby represents and warrants to the other Party that such Party has, and will continue to have, sufficient liquid assets to promptly and timely pay and perform all of the payments and obligations required by such Party or its Affiliates to be paid and performed by them hereunder.

15.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any Governmental Authority or arbitrator that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

15.3 Additional Regeneron Representations, Warranties and Covenants. Regeneron additionally represents and warrants to Sanofi that, as of the Effective Date:

(a) Regeneron owns all right, title and interest in and to all Regeneron Patent Rights in existence as of the Effective Date;

(b) Regeneron has the right and authority to grant the rights granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted any rights that would be inconsistent with or in conflict with or in derogation of the rights granted herein;

(c) there is no pending litigation that alleges that any of Regeneron's activities relating to the Regeneron Intellectual Property have violated, or would violate, the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation);

(d) to Regeneron's knowledge, no litigation has been otherwise threatened which alleges that any of its activities relating to the Regeneron Intellectual Property have violated or would violate, any intellectual property rights of any Third Party;

(e) the conception, development and reduction to practice of any Regeneron Intellectual Property existing as of the Effective Date has not constituted or involved the misappropriation of trade secrets or other rights of any Person;

(f) to Regeneron's knowledge, the issued Patents included in the Regeneron Intellectual Property existing as of the Effective Date are not invalid or unenforceable, in whole or part;

(g) Regeneron has not received any written notice of any threatened claims or litigation seeking to invalidate or otherwise challenge the Regeneron Patent Rights or Regeneron's rights therein, and, to Regeneron's knowledge, none of the Regeneron Patent Rights are subject to any pending re-examination, opposition, interference or litigation proceedings; and

(h) Regeneron has enforceable written agreements with all of its employees and contractors who may participate in the conduct of the Collaboration or receive Confidential Information hereunder assigning to Regeneron ownership of all intellectual property rights created in the course of their employment or provision of services, as applicable.

15.4 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY LICENSED PRODUCT IN THE FIELD. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

15.5 Mutual Covenants. Each Party hereby covenants to the other Party as of the Effective Date as follows: (a) it will not during the Term grant any right or license to any Third Party in the Territory which would be inconsistent with or in conflict with or in derogation of the rights granted to the other Party under this Agreement, and will not take any action that would materially conflict with or adversely affect its obligations to the other Party under this Agreement; (b) neither Party will use the Patent Rights or Know-How of the other Party outside the scope of the licenses and rights granted to it under this Agreement; and (c) in the course of the Development or Commercialization of a Licensed Product in the Field under this Agreement, it will not knowingly use and will not have knowingly used an employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority.

## **ARTICLE XVI CONFIDENTIALITY**

### 16.1 Confidential Information.

(a) Each of Sanofi and Regeneron acknowledges (subject to the further provisions of this Article XVI and the provisions of Article XIX) that all Party Information provided to it (or its Affiliate) or otherwise made available to it by the other Party or its respective Affiliates pursuant to this Agreement (or, in the case of Sanofi, Party Information provided to it under the Confidentiality Agreements is confidential and proprietary to such other Party. Furthermore, each of Sanofi and Regeneron acknowledges (subject to the further provisions of this Article XVI) that all New

Information is confidential and proprietary to both Parties. Subject to the further provisions of this Article XVI, each of Sanofi and Regeneron agrees to (i) maintain such Party Information of the other Party (or its Affiliates) and all New Information in confidence during the Term and for a period of ten (10) years thereafter and (ii) use such Party Information of the other Party (or its Affiliate) and New Information solely for the purpose of exercising its rights and performing its obligations hereunder. Each of Sanofi and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any such Party Information of the other Party (or its Affiliate) or New Information to any Third Party except (A) to its employees, agents, consultants or any other Person under its authorization; provided such employees, agents, consultants or Persons are subject in writing to substantially the same confidentiality obligations as the Parties, (B) as approved by both Parties hereunder or (C) as set forth elsewhere in this Agreement.

(b) Notwithstanding anything provided above, the restrictions provided in this Article XVI shall not apply to information that was or is (and such information shall not be considered confidential or proprietary under this Agreement) (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the receiving Party or its Affiliate or any Person to whom the receiving Party or its Affiliate provided such information; (ii) already in the possession of the receiving Party or its Affiliate at the time of disclosure by the disclosing Party, other than under an obligation of confidentiality; (iii) disclosed to the receiving Party or its Affiliate on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information; (iv) similar in nature to the purported Party Information or New Information but has been independently created, as evidenced by written or electronic documentation, without any aid, application or use of the Party Information or New Information; (v) necessary to file, prosecute or defend Patents and Patent Applications for which the Party has the right to assume filing, prosecution, defense or maintenance pursuant to this Agreement; or (vi) required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded), or court order to be disclosed, provided that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information or to request that the receiving Party seek confidential treatment for such information, if applicable, and provided, further, that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information which is required by Governmental Authority, applicable Law (including the rules or regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded) or court order to be disclosed. Moreover, either Party may use Party Information and New Information to enforce the terms of this Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information.

(c) Notwithstanding anything provided above or elsewhere in this Agreement, Regeneron and its Affiliates shall have the right to use and disclose any New Information directly related to any Licensed Product (including the Manufacture or use thereof) to Governmental Authorities or Regulatory Authorities as required by Law.

(d) Notwithstanding anything provided above or elsewhere in this Agreement, Sanofi and its Affiliates shall have the right to use and disclose any New Information directly related to any Licensed Product (including the Manufacture or use thereof) to Governmental Authorities or Regulatory Authorities as required by Law.

16.2 Injunctive Relief. The Parties hereby acknowledge and agree that the rights of the Parties hereunder are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

16.3 Publication of New Information. During the Term, if either Sanofi or Regeneron (the “Publishing Party”) desires to disclose any New Information in scientific journals, publications or scientific presentations, the Publishing Party shall provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation relating to the New Information prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it or the Licensed Product as a result of the publication or disclosure (such recommendation of changes to include a description of the specific material adverse effect) to which the Publishing Party shall give due consideration. Disputes concerning publication shall be resolved by the JDC (other than Legal Disputes).

16.4 Disclosures Concerning this Agreement. The Parties will mutually agree upon the contents of their respective press releases with respect to the execution of this Agreement and any Ancillary Agreement which shall be issued simultaneously by both Parties on the Effective Date. Sanofi and Regeneron agree not to (and to ensure that their respective Affiliates do not ) issue any other press releases or public announcements concerning this Agreement, any Ancillary Agreement or any actions or activities contemplated hereunder or thereunder without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party’s (or its parent entity’s) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable

cooperation to assist the other Party to protect such information and shall limit the disclosure to that information which is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement, any Ancillary Agreement or any actions or activities contemplated hereunder or thereunder which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding the Collaboration. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article XVI without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. The Parties, through the Committees, shall establish mechanisms and procedures to ensure that there are coordinated timely corporate communications relating to the Licensed Products in the Field. Sanofi acknowledges that Regeneron as a publicly traded company may be legally obligated to make timely disclosures of material events relating to Licensed Products. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement and each Ancillary Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

## **ARTICLE XVII INDEMNITY**

### **17.1 Indemnity and Insurance.**

(a) Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees, licensees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and costs or amounts paid to settle (collectively, "Damages"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Regeneron Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by or of Sanofi, its Affiliates or their respective directors, officers, employees, agents or Sublicensees, including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad

faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee; or

(ii) material breach by Sanofi of the terms of, or the inaccuracy when made of any representation or warranty made by it in, this Agreement.

(b) Regeneron will defend, indemnify and hold harmless Sanofi, its Affiliates and their respective officers, directors, employees, Sublicensees and agents ("Sanofi Indemnitees") from and against all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Sanofi Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by or of Regeneron, its Affiliates or their respective directors, officers, employees, licensees or agents including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts, or omissions or violations of Law committed by Sanofi or any other Sanofi Indemnitee; or

(ii) material breach by Regeneron of the terms of, or the inaccuracy when made of any representation or warranty made by it in, this Agreement.

(c) In the event of any Third Party claim alleging that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes a Patent Right of a Third Party for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other Party for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.

(d) In the event of any Third Party product liability claim alleging that the Development or Commercialization of any Licensed Product in the Field causes damages for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.

(e) Each of Regeneron and Sanofi will use Commercially Reasonable Efforts to procure and maintain during the Term and for a minimum period of five (5) years thereafter and for an otherwise longer period as may be required by applicable Law in countries where the project is conducted, product liability insurance in an amount not less than \*\*\*\*\* in the annual aggregate. Such insurance shall insure against liability on the part of Regeneron and Sanofi and any of its Affiliates, due to injury, disability or death of any person or persons, or property damage arising from services performed under this Agreement.

(f) Notwithstanding anything to the contrary in this Section 17.1, neither Party shall be responsible to indemnify the other Party (or the Regeneron Indemnitees or Sanofi Indemnitees, as the case may be) from Third Party claims resulting from, and to the extent allocable to, the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Third Parties contracted to Manufacture any part of the Clinical Supply Requirements or Commercial Supply Requirements pursuant to Article VIII; provided, however, that nothing in this Section 17.1(f) limits either Party's indemnification obligations to the extent any Third Party claims arise from the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed directly by the Party that is responsible for contracting with such Third Party Manufacturer(s) pursuant to Article VIII.

17.2 Indemnity Procedure. The Party entitled to indemnification under this Article XVII (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within five (5) Business Days of becoming aware of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder. For the avoidance of doubt, the indemnification procedures in this Section 17.2 shall not apply to claims for which each Party indemnifies the other Party for fifty percent (50%) of all Damages, under the terms of Section 17.1(c).

(a) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) such compromise or settlement does not (A) include any admission of legal wrongdoing by the Indemnified Party, (B) require any payment by the Indemnified Party that is not indemnified hereunder or (C) result in the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably withheld or delayed); provided that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such

litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld or delayed.

(b) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party.

(c) The amount of any Damages for which indemnification is provided under this Article XVII will be reduced by the insurance proceeds received, and any other amount recovered if any, by the Indemnified Party in respect of any such Damages.

(d) If an Indemnified Party receives an indemnification payment pursuant to this Article XVII and subsequently receives insurance proceeds from its insurer with respect to the Damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this Article XVII and (ii) the amount necessary to fully and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this Article XVII.

#### **ARTICLE XVIII FORCE MAJEURE**

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

#### **ARTICLE XIX TERM AND TERMINATION**

##### 19.1 Term/Expiration of Term.

(a) The “Term” of this Agreement shall commence on the Effective Date and, unless this Agreement is earlier terminated in its entirety in accordance with this Article XIX, shall expire upon the later to occur of (i) the expiration of the Discovery Program, and (ii) such time as neither Party, nor either Party’s Affiliates or Sublicensees, is Developing or Commercializing any Licensed Product in the Field in the Territory under this Agreement and such cessation of Development and Commercialization activities is acknowledged by both Parties in writing to be permanent.

(b) Upon expiration of the Term pursuant to Section 19.1(a) above, except as set forth in this Agreement, all licenses and rights with respect to Licensed Products shall automatically terminate and revert to the granting Party.

#### 19.2 Termination Without Cause.

(a) By Sanofi. (i) Sanofi may terminate this Agreement in its entirety, but only after the expiration or earlier termination of the Discovery Program in accordance with the terms of the Discovery Agreement, or may terminate this Agreement in the entire Territory for a particular Licensed Product or particular Licensed Products in the Field, in any such case on twelve (12) months’ prior written notice to Regeneron. Except as otherwise provided below in this Section 19.2(a), in the event of such termination by Sanofi of this Agreement in its entirety or with respect to one or more Licensed Product(s) pursuant to this Section 19.2, this Agreement (including, without limitation, all payment obligations hereunder) shall continue in full force and effect through the notice period set forth above (the “Sanofi Termination Notice Period”) and the terms of Schedule 4 (including the grant of rights and licenses set forth in paragraph 2 thereof) shall automatically apply. Except as set forth in this Section 19.2(a) or Schedule 4, during the Sanofi Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize Licensed Products (including the Opt-Out Product(s)) in the Field in accordance with Plans. During the Sanofi Termination Notice Period, to the extent set forth or requested in one or more written notices from Regeneron to Sanofi hereunder and in any event upon the expiration of the Sanofi Termination Notice Period, whether or not any such notice is given by Regeneron, (i) the licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Opt-Out Product(s) shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the Sanofi Termination Notice Period), (ii) the licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Opt-Out Product(s) shall terminate, and (iii) Sanofi will promptly take the actions required by Schedule 4 and Regeneron will reasonably cooperate with Sanofi (for avoidance of doubt, such cooperation shall not require Regeneron to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Regeneron) to facilitate Regeneron’s (or its nominee’s) expeditious assumption during the Sanofi Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of the Opt-Out Product(s) in the Field in the Territory. In addition, during the Sanofi Termination Notice Period, neither Party will, without the prior written consent of the other Party’s representatives on the applicable Committee, propose or implement any amendment or

change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Sanofi Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

(ii) In addition to Sanofi's termination rights set forth in Section 19.2(a)(i), from and after the twelfth (12<sup>th</sup>) anniversary of the First Commercial Sale of a Licensed Product in a country, Sanofi may, upon twenty-four (24) months' prior written notice to Regeneron, terminate this Agreement with respect to such Licensed Product in such country. If Sanofi exercises such right, the provisions of Section 19.2(a)(i) (except that the Sanofi Termination Notice Period referred to therein shall be twenty-four (24) months rather than twelve (12) months), and Sections 19.7(a) and 19.8 shall apply with respect to such Terminated Licensed Product in such country.

(b) By Regeneron. Regeneron may terminate this Agreement in its entirety, but only after the expiration or earlier termination of the Discovery Program in accordance with its terms, or may terminate this Agreement in the entire Territory for a particular Licensed Product or particular Licensed Products in the Field, in any such case, on twelve (12) months' prior written notice to Sanofi. Except as otherwise provided below in this Section 19.2(b), in the event of such termination by Regeneron of this Agreement in its entirety or with respect to one or more Licensed Product(s) pursuant to this Section 19.2(b), this Agreement (including, without limitation, all payment obligations hereunder) shall continue in full force and effect through the notice period set forth above (the "Regeneron Termination Notice Period") and the terms of Schedule 5 (including the grant of rights and licenses set forth in paragraph 2 thereof) shall automatically apply. Except as set forth in this Section 19.2(b) or Schedule 5, during the Regeneron Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize Licensed Products (including the Opt-Out Product(s)) in the Field in accordance with Plans. During the Regeneron Termination Notice Period, to the extent set forth or requested in one or more written notices from Sanofi to Regeneron hereunder and in any event upon the expiration of the Regeneron Termination Notice Period, whether or not any such notice is given by Sanofi, (i) the licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Opt-Out Product(s) shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the Regeneron Termination Notice Period), (ii) the licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Opt-Out Product(s) shall terminate, and (iii) Regeneron will promptly take the actions required by Schedule 5 and Sanofi will reasonably cooperate with Regeneron (for avoidance of doubt, such cooperation shall not require Sanofi to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Sanofi) to facilitate Sanofi's (or its nominee's) expeditious assumption during the Regeneron Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of the Opt-Out Product(s) in the Field in the Territory. In addition, during the Regeneron Termination

Notice Period, neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any amendment or change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Regeneron Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

19.3 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 19.3, this Agreement shall be terminable by a Party in its entirety or for a particular Licensed Product or particular Licensed Products in the Field in the entire Territory, upon written notice to the other Party, if such other Party commits a material breach of its obligations under this Agreement with respect to such Licensed Product(s) as to which such notice of termination is given (or all Licensed Products if such notice of termination is with respect to this Agreement is in its entirety). Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such ninety (90) day period, such longer period not to exceed one hundred eighty (180) days so long as the breaching party is using Commercially Reasonable Efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such one hundred eighty (180) day period or such time as the breaching party ceases to use Commercially Reasonable Efforts to cure such breach). Notwithstanding the foregoing, in the case of breach of a payment obligation hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall instead be thirty (30) days (and the immediately preceding parenthetical clause in the immediately preceding sentence shall not apply). For purposes of this Section 19.3, the term "material breach" shall mean an intentional, continuing (and uncured within the time period described above) material breach by a Party, as determined by a court of competent jurisdiction.

19.4 Termination for Insolvency. Either Party shall have the right to terminate this Agreement in its entirety, by and effective immediately, upon written notice to the other Party, if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, (b) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within ninety (90) days after the filing thereof or (c) if the other Party shall make a general assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties agree

that all intellectual property rights licensed hereunder, including, without limitation, any patents or patent applications in any country of a party covered by the license grants under this Agreement, are part of the “intellectual property” as defined under Section 101(52) of the Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

19.5 Termination for Breach of Standstill or Lock-Up. Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have breached their obligations under any of Sections 3, 4 or 5 of the Investor Agreement (to the extent such sections of the Investor Agreement is then in effect). Furthermore, Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have (a) breached their obligations under Section 20.16 of the Aventis Collaboration Agreement, to the extent that such Section 20.16 remains in effect after the Effective Date, or (b) breached its obligations under Section 5.3 of the Aventis Stock Purchase Agreement, to the extent that such Section 5.3 remains in effect after the Effective Date. Any such breach of the Investor Agreement, the Aventis Stock Purchase Agreement or the Aventis Collaboration Agreement, as the case may be, shall be treated as a breach of this Agreement. Notwithstanding the foregoing and for the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of (i) a de minimus breach of Section 3.1(a) of the Investor Agreement (to the extent such Section 3.1(a) is in effect after the Effective Date) or of Section 20.16(a) of the Aventis Collaboration Agreement (to the extent such Section 20.16(a) remains in effect after the Effective Date) or (ii) an inadvertent breach of Section 3.1(g) of the Investor Agreement (to the extent such Section 3.1(g) is in effect after the Effective Date) or an inadvertent breach of Section 20.16(g) of the Aventis Collaboration Agreement (to the extent such Section 20.16(g) remains in effect after the Effective Date), arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of such Section 20.16 or of paragraphs (a) through (e) of Section 3.1 of the Investor Agreement, as applicable.

19.6 Termination of Discovery Agreement.

(a) By Regeneron. Regeneron may terminate this Agreement in its entirety, effective upon written notice to Sanofi, if the Discovery Agreement has been terminated by Regeneron pursuant to Section 12.2, 12.3 or 12.5 thereof.

(b) By Sanofi. Sanofi may terminate this Agreement in its entirety effective upon written notice to Regeneron, if the Discovery Agreement has been terminated by Sanofi pursuant to Section 12.2 or 12.3 thereof.

(c) Automatic. This Agreement shall automatically terminate in its entirety if, at the time the Discovery Agreement terminates for any reason pursuant to Article 12 thereof, Sanofi has not exercised its Opt-In Right pursuant to Section 5.3 of the Discovery Agreement with respect to any Product Candidate.

19.7 Effect of Termination.

(a) Except as provided in Section 19.2(b), and in Section 19.7(b) below, upon termination of this Agreement with respect to all Licensed Products in the Field, or for a particular Licensed Product or particular Licensed Products in the Field in the Territory or, if applicable pursuant to Section 19.2(a)(ii), in one or more countries, the provisions of Schedule 4 shall apply (including during any applicable Termination Notice Period) with respect to the Terminated Licensed Product(s), and except to the extent required by Sanofi to fulfill its obligations pursuant to Schedule 4, (i) all licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate, and revert to Regeneron, (ii) all licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate and (iii) the license from Sanofi and its Affiliates to Regeneron referred to in Schedule 4 shall automatically come into full force and effect with respect to the Terminated Licensed Product(s). If Regeneron terminates this Agreement pursuant to Section 19.3, 19.4 or 19.5, or pursuant to Section 19.6(a) then Sanofi shall pay to Regeneron, in addition to any other amount payable by Sanofi to Regeneron under this Agreement, under Law, or pursuant to any contractual remedies available to Regeneron, an amount equal to one hundred percent (100%) of the Development Costs incurred by Regeneron under the Global Development Plan during the period commencing on the effective date of such termination of this Agreement pursuant to any of such Sections and ending on the twelve (12) month anniversary of such date.

(b) Upon termination of this Agreement by Regeneron pursuant to Section 19.2(b) or by Sanofi pursuant to Section 19.3 or 19.4, in its entirety, or for a particular Licensed Product or particular Licensed Products in the Field, the provisions of Schedule 5 shall apply (including during any applicable Termination Notice Period) with respect to the Terminated Licensed Product(s) and, except to the extent required by Regeneron to fulfill its obligations pursuant to Schedule 5, (i) all licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate, and revert to Sanofi, (ii) all licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate and (iii) the license from Regeneron referred to in Schedule 5 shall come into full force and effect with respect to the Terminated Licensed Product(s)

19.8 Survival of Obligations. Except as otherwise provided in this Article XIX, or Schedule 4 or Schedule 5, upon expiration, or upon termination of this Agreement with respect to all Licensed Products in the Field, or for a particular Licensed Product or particular Licensed Products in the Field in the Territory or, if applicable pursuant to Section 19.2(a)(ii), in one or more countries, the rights and obligations of the Parties hereunder with respect to the Terminated Licensed Product(s), in the applicable country or countries if such termination is pursuant to Section 19.2(a)(ii), shall terminate, and this Agreement shall cease to be of further force or effect to the extent of such termination, provided that notwithstanding any expiration or termination of this Agreement:

(a) neither Sanofi nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of a Plan (even if such costs and expenses arise following termination or expiration, as the case may be), except that Regeneron's obligations with respect to the Global Development Balance payments provided for in Schedule 2 shall automatically terminate and the Global Development Balance shall equal zero;

(b) subject to the provisions of this Article XIX, including Schedule 4 and Schedule 5 to the extent applicable, the obligations of the Parties with respect to the protection and nondisclosure of Party Information and New Information in accordance with Article XVI, as well as other provisions (including, without limitation, Sections 7.4, 9.8, 9.9, 9.12, 10.3 and 10.4, the second sentence of Section 12.1(e) and Articles XII (with respect to Joint Inventions), XVI, XVII, XIX and XX) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable; and

(c) such expiration or termination and this Article XIX shall be without prejudice to any rights or remedies a party may have for breach of this Agreement.

## **ARTICLE XX MISCELLANEOUS**

20.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Except as set forth in Article X, the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

20.2 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

20.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 6 attached hereto and shall be (a) delivered personally, (b) sent via a reputable

nationwide overnight courier service, or (c) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, one (2) Business Days after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.

20.4 Entire Agreement. This Agreement, together with the Discovery Agreement and, solely to the extent referred to herein, the Ancillary Agreements contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof, provided that the last sentence of Section 1.41 of the Discovery Agreement shall apply with respect to any conflict or inconsistency between this Agreement and the Discovery Agreement.

20.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Sanofi and Regeneron.

20.6 Interpretation. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; and (d) the words “herein” or “hereunder” relate to this Agreement.

20.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction (“Modified Clause”), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

20.8 Registration and Filing of the Agreement. To the extent that a Party concludes in good faith that it is or may be required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.4. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.

20.9 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Sanofi or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by

Sanofi or (b) the prior written consent of Sanofi in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

20.10 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Sanofi Indemnitees to the extent provided in the last sentence of Section 20.13.

20.11 Affiliates. Each Party may, and to the extent it is in the best interests of the Licensed Products in the Field in the Territory shall, perform its obligations hereunder through one or more of its Affiliates. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party the prompt and timely performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Sanofi Amerique guarantees to Regeneron the prompt and timely payment of amounts payable by Sanofi to Regeneron hereunder once those amounts have become legally due and payable. Without limiting the foregoing, no Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. If an Affiliate of a Party will engage in the Development, Manufacture or Commercialization of a Licensed Product under this Agreement, then such Party shall enter into a separate agreement with such Affiliate pursuant to which the obligations of such Party hereunder shall be binding on such Affiliate and which shall provide that the other Party is a third-party beneficiary of such agreement entitled to enforce such agreement and this Agreement against such Affiliate. Each Party represents and warrants to the other Party that it has licensed or will license from its Affiliates the Patents and Know-How owned by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement.

20.12 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

20.13 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, Article XVII is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Sanofi Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.

20.14 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as provided for in this Agreement. Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

20.15 Limitation of Damages. IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 20.15 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD-PARTY CLAIMS .

20.16 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the Development, Manufacture or Commercialization of any Licensed Product to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

20.17 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party.

**[Remainder of page intentionally left blank; signature page follows]**

IN WITNESS WHEREOF, Sanofi, Sanofi Amerique and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMACEUTICALS INC.

By: /s/ Karen Linehan  
Name: Karen Linehan  
Title: Authorized Signatory

By: /s/ Robin White  
Name: Robin White  
Title: Authorized Signatory

SANOFI-AVENTIS AMERIQUE DU NORD  
(solely for purposes of Section 15.1, 15.2 and  
20.11).

By: /s/ Jean-Luc Renard  
Name: Jean-Luc Renard  
Title: Authorized Signatory

By: /s/ Karen Linehan  
Name: Karen Linehan  
Title: Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By: /s/ Leonard Schleifer  
Name: Leonard Schleifer  
Title: President & CEO

---

EXHIBIT A  
Royalties For Opt-Out Products

Stage of Development at Opt-Out

\*\*\*\*\*

\*\*\*\*\*

Royalties on Net Sales

\*\*\*\*\*

\*\*\*\*\*

EXHIBIT B

Summary Outline of Initial Development Plan For REGN88 (IL-6RmAb)

\*\*\*\*\*

SCHEDULE 1

Manufacturing Cost

\*\*\*\*\*

SCHEDULE 2

Quarterly True-Up

At the end of each Quarter, the Parties will calculate the net payment one Party shall be required to make to the other Party (the "Quarterly True-Up") equal to (a) the U.S. Profit Split for such Quarter payable to Regeneron (as set forth in Part I), plus (b) the Rest of World Profit Split for such Quarter payable to Regeneron (as set forth in Part II), minus (c) the Development Compensation Payment for such Quarter payable to Sanofi (as set forth in Part III), plus or minus (d) the Regeneron Reimbursement Amount for such Quarter payable to either Regeneron or Sanofi (as set forth in Part IV).

In the event that the Quarterly True-Up is an amount greater than zero, such amount shall be payable by Sanofi to Regeneron in accordance with the terms set forth in Article 9. In the event that the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Sanofi in accordance with the terms set forth in Article 9. An example of the Quarterly True-Up is shown in Part V.

I. U.S. PROFIT SPLIT

The "U.S. Profit Split" shall mean fifty percent (50%) of U.S. Profits in a Quarter. "U.S. Profits" in a Quarter shall mean aggregate Net Sales of all Licensed Products in the U.S. in the Quarter less the sum of (a) aggregate COGS in the U.S. in the Quarter, (b) aggregate Shared Commercial Expenses incurred by both Parties and allocable to the U.S. in the Quarter, and (c) aggregate Other Shared Expenses incurred by both Parties and allocable to, the U.S. in the Quarter.

An example of a calculation of the U.S. Profit Split in a Quarter would be:

\*\*\*\*\*

## II. REST OF WORLD PROFIT SPLIT

The Parties intend to share profits from Net Sales of Licensed Products in the Rest of World (or ROW) in each Contract Year (the “Rest of World Profit Split,” defined below) based on the aggregate amount of such Net Sales in accordance with the Target ROW Profit Split (defined below). Since the full calculation cannot be done until aggregate Net Sales for the full Contract Year are known, each Quarter, the Parties will calculate an estimated profit split for the Quarter based on Net Sales for the Quarter in ROW and the Applicable ROW Percentages (defined below). Following the end of each Contract Year, the Parties will true-up the quarterly estimates of the Rest of World Profit Split to the Target ROW Profit Split through the ROW Profit Split Annual True-Up calculation (defined below).

The “Target ROW Profit Split” for any Contract Year shall mean a profit split whereby ROW Profits from ROW Net Sales of all Licensed Products up to \*\*\*\*\* in the Contract Year are split 65% Sanofi/35% Regeneron, and ROW Profits from ROW Net Sales of all Licensed Products from \*\*\*\*\* up to \$750 million in the Contract Year are split 60% Sanofi/40% Regeneron, and ROW Profits from ROW Net Sales of all Licensed Products greater than \$750 million in the Contract Year are split 55% Sanofi/45% Regeneron, with all profit splits calculated using the assumption that the ratio of ROW Profits to ROW Net Sales is the same on each dollar of ROW Net Sales in the Contract Year.

The “Rest of World Profit Split” (or “ROW Profit Split”) for a Quarter shall mean \*\*\*\*\*

The “Applicable ROW Percentages” for the Quarter for each of Sanofi and Regeneron shall mean the percentages to be used to calculate each Party’s Rest of World Profit Split for the Quarter, as illustrated in the example below. At the end of each Contract Year, as part of the calculation of the fourth Quarter Rest of World Profit Split, a “ROW Profit Split Annual True-Up” shall also be calculated to make each Party’s Rest of World Profit Split for the Contract Year equal to the Target ROW Profit Split. Calculation of the Applicable ROW Percentages and Rest of World Profit Splits for a Quarter and ROW Profit Split Annual True-Up for a Contract Year are illustrated in the example below.

\*\*\*\*\*

Notwithstanding the method of calculation shown above, in any Quarter (or for any full Contract Year) in which the ROW Profits are negative, the Applicable ROW Percentages for such Quarter

(or for such Contract Year after calculation of the ROW Profit Split Annual True-Up) shall be fifty-five percent (55%) for Sanofi and forty-five percent (45%) for Regeneron.

An example of a calculation of the Rest of World Profit Split in a Quarter would be:

	Aggregate	Sanofi	Regeneron
Net Sales in the ROW	*****	*****	*****
COGS	*****	*****	*****
Shared Commercial Expenses	*****	*****	*****
Other Shared Expenses	*****	*****	*****
<b>ROW Profits</b>	<b>*****</b>	<b>*****</b>	<b>*****</b>
Applicable ROW Percentages		***	***
<b>ROW Profit Split</b>		<b>***</b>	<b>***</b>

### III. DEVELOPMENT COMPENSATION PAYMENT

The “Regeneron Profit Split” in a Quarter shall mean the sum of (a) the U.S. Profit Split for such Quarter payable to Regeneron plus (b) the Rest of World Profit Split for such Quarter payable to Regeneron.

The “Development Balance” as of the end of a Quarter shall mean \*\*\*\*\*

If both the Development Balance as of the end of a Quarter is greater than zero and the Regeneron Profit Split for the Quarter is greater than zero, the “Development Compensation Payment” for such Quarter shall equal the lower of (a) \*\*\*\*\* and (b) the Development Balance. Otherwise, the Development Compensation Payment for the Quarter shall equal zero.

An example of a calculation of the Development Compensation Payment in a Quarter would be:

Development Balance at the end of the Quarter	***
U.S. Profit Split payable to Regeneron	***
Rest of World Profit Split payable to Regeneron	***
Regeneron Profit Split	***
*****	***
Development Compensation Payment	**

For the avoidance of doubt, the Development Costs for and Opt-Out Product until the time such Opt-Out Product becomes an Opt-Out Product are included in the calculation of the Development Balance.

#### IV. REGENERON REIMBURSEMENT AMOUNT

The “Regeneron Reimbursement Amount” for a Quarter shall mean \*\*\*\*\*

An example of a calculation of the Regeneron Reimbursement Amount in a Quarter would be:

Regeneron Shared Commercial Expenses in the U.S.	****
Regeneron Shared Commercial Expenses in ROW	****
Regeneron Other Shared Expenses in the U.S.	****
Regeneron Other Shared Expenses in ROW	****
Regeneron Development Costs under a Global Development Plan	****
Shared Phase 3 Trial Costs Balance	****
<hr/>	
Regeneron Reimbursement Amount	****

V. EXAMPLE OF QUARTERLY TRUE-UP

An example of a calculation of the Quarterly True-Up in a Quarter would be:

U.S. Profit Split Payable to Regeneron	***
ROW Profit Split Payable to Regeneron	***
Development Compensation Payment	***
Regeneron Reimbursement Amount	****

---

Quarterly True-Up \*\*\*

In this example, Sanofi would pay Regeneron \*\*\* in accordance with the terms set forth in Article 9.

SCHEDULE 3  
Sales Milestones

<u>Aggregate annual Net Sales</u> <u>of all Licensed Products</u> <u>in Rest of World Countries</u>	<u>Sales Milestone</u>
US\$1 billion	*****
*****	*****
*****	*****
*****	*****
*****	*****

For purposes of clarification, each of the foregoing milestone payments shall be made only once and only upon the first occurrence of each milestone. Aggregate annual Net Sales of Licensed Products shall be determined based on the aggregate Net Sales of all Licensed Products in Rest of World Countries in any rolling twelve (12) month period.

## SCHEDULE 4

### Termination Arrangements

The rights and obligations set forth in this Schedule 4 shall apply only to the extent of the applicable termination of this Agreement, and accordingly such rights and obligations shall apply only with respect to the applicable Terminated Licensed Product(s) as to which, and, if applicable pursuant to Section 19.2(a)(ii), only in the country or countries in which, this Agreement has been terminated.

1. Sanofi shall promptly collect and return, and cause its Affiliates and Sublicensees to collect and return, to Regeneron or, at Regeneron's request, destroy, all documents containing New Information or Party Information directly related to any Terminated Licensed Product(s), and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any such New Information or Party Information with respect to any Terminated Licensed Product(s). In addition, at Regeneron's request, Sanofi shall collect and transfer to Regeneron any remaining inventory of Promotional Materials, sales training materials, samples, and product inventory. Notwithstanding the foregoing, Sanofi may retain copies of any Party Information or New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Regeneron and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than any royalties due for any Royalty Products under the Discovery Agreement and any amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or Collaboration by Sanofi), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Sanofi Intellectual Property existing at the time notice of termination was given or at the effective date of termination solely for the purpose of Developing, Manufacturing and Commercializing Terminated Licensed Product(s) in the Field in the Territory (and solely to the extent such Sanofi Intellectual Property has, as of the date notice of termination was given, actually been incorporated into such Licensed Product(s) or otherwise claims or covers its use), with all other rights to such Sanofi Intellectual Property retained by Sanofi).

3. Sanofi shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture, and Commercialization of the Terminated Licensed Product(s) in the Field in the Territory. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:

(a) Sanofi shall transfer and assign to Regeneron (or its nominee) all Marketing Approvals, Pricing Approvals, and other regulatory filings (including Registration Filings) made or obtained by Sanofi or its Affiliates or any of its Sublicensees to the extent specifically relating to the Terminated Licensed Product(s).

(b) Sanofi shall assign and transfer to Regeneron (or its nominee) Sanofi's entire right, title and interest in and to all Product Trademarks for any Terminated Licensed and Promotional Materials relating to the Terminated Licensed Product(s); provided that nothing herein is intended to convey any rights in or to Sanofi's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Sanofi shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory) of all information (including any New Information) in its possession or under its control to the extent directly relating to the Terminated Licensed Product(s) in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Sanofi, or such other format as may be reasonably requested by Regeneron.

(d) Sanofi shall use Commercially Reasonable Efforts to assign to Regeneron any applicable sublicenses to the extent related to the Terminated Licensed Product(s) and/or contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory, as reasonably requested by Regeneron.

(e) Without limitation of Sanofi's other obligations under this Schedule 4, to the extent Sanofi or its Affiliate is Manufacturing (in whole or in part) the Terminated Licensed Product(s) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Sanofi (or its Affiliate) will perform such Manufacturing responsibilities and supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of such Terminated Licensed Product(s), and Regeneron shall purchase such Terminated Licensed Product(s), at the same price, and on such other terms and conditions on which Sanofi was supplying, or in the absence of termination would have been required to supply, such Terminated Licensed Product(s), through the second anniversary of the effective date of termination of this Agreement with respect to such Terminated Licensed Product(s) or such shorter period if Regeneron notifies Sanofi that Regeneron is able to Manufacture or have Manufactured such Terminated Licensed Product(s) on comparable financial terms.

4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the development, manufacture, and commercialization of the Terminated Licensed Product(s) in the Field hereunder to Regeneron (or its sublicensee or Third Party designee) as soon as is reasonably possible.

5. For the avoidance of doubt, except as expressly provided in the Discovery Agreement or this Agreement, Regeneron shall not be required to provide Sanofi any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 4; provided, however, that Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Sanofi may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights.

## SCHEDULE 5

### Termination Arrangements

The rights and obligations set forth in this Schedule 5 shall apply only to the extent of the applicable termination of this Agreement, and accordingly such rights and obligations shall apply only with respect to the applicable Terminated Licensed Product(s) as to which this Agreement has been terminated.

1. Regeneron shall promptly collect and return, and cause its Affiliates and sublicensees to collect and return, to Sanofi or, at Sanofi's request, destroy, all documents containing New Information or Party Information of Sanofi and its Affiliates directly related to any Opt-Out Products, and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any such New Information or Party Information with respect to the Terminated Licensed Product(s). In addition, at Sanofi's request, Regeneron shall collect and transfer to Sanofi any remaining inventory of Promotional Materials, sales training materials, product samples and product inventory. Notwithstanding the foregoing, Regeneron may retain copies of any Party Information or New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Sanofi and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than for amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or Collaboration by Regeneron), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Regeneron Intellectual Property existing at the time notice of termination was given or at the effective date of termination solely for the purpose of Developing, Manufacturing, and Commercializing the Terminated Licensed Product(s) in the Field in the Territory (and solely to the extent such Regeneron Intellectual Property has, as of the date notice of termination was given, actually been incorporated into such Licensed Product(s) or otherwise claims or covers its use), with all other rights to such Regeneron Intellectual Property retained by Regeneron.

3. Regeneron shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Sanofi to enable Sanofi (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture and Commercialization of the Terminated Licensed Product(s) in the Field in the Territory. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:

(a) Regeneron shall transfer and assign to Sanofi (or its nominee) all Marketing Approvals, Pricing Approvals and other regulatory filings (including Registration Filings) made or obtained by Regeneron or its Affiliates or any of its sublicensees to the extent specifically relating to the Terminated Licensed Product(s).

(b) Regeneron shall assign and transfer to Sanofi (or its nominee) Regeneron's entire right, title and interest in and to all Product Trademarks for the Terminated Licensed Product(s) and Promotional Materials relating to the Terminated Licensed Product(s); provided that nothing herein is intended to convey any rights in or to Regeneron's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Regeneron shall provide to Sanofi (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory) of all information (including any New Information) in its possession or under its control to the extent directly relating to the Terminated Licensed Product(s) in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Regeneron, or such other format as may be reasonably requested by Sanofi.

(d) Regeneron shall use Commercially Reasonable Efforts to assign to Sanofi any applicable sublicenses to the extent related to the Terminated Licensed Product(s) and/or contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory, as reasonably requested by Sanofi.

(e) Without limitation of Regeneron's other obligations under this Schedule 5, to the extent Regeneron or its Affiliate is Manufacturing (in whole or in part) the Terminated Licensed Product(s) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Regeneron (or its Affiliate) will perform such Manufacturing responsibilities and supply Sanofi with Clinical Supply Requirements and/or Commercial Supply Requirements of such Terminated Licensed Product(s), and Sanofi shall purchase such Terminated Licensed Product(s), at the same price, and on such other terms and conditions on which Regeneron was supplying, or in the absence of termination would have been required to supply, such Terminated Licensed Product(s), through the second anniversary of the effective date of termination of this Agreement with respect to such Terminated Licensed Product(s) or such shorter period if Sanofi notifies Regeneron that Sanofi is able to Manufacture or have Manufactured such Terminated Licensed Product(s) on comparable financial terms.

4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture and Commercialization of the Terminated Licensed Product(s) in the Field hereunder to Sanofi (or its Sublicensee or Third Party designee) as soon as is reasonably possible.

5. For the avoidance of doubt, Sanofi shall not be required to provide Regeneron any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 5; provided, however, that Sanofi shall be solely responsible for paying any royalties, fees or other consideration that Regeneron may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Sanofi of such licenses or other rights.

SCHEDULE 6

Notices

- (a) If to Sanofi or Sanofi Amerique:

Aventis Pharmaceuticals Inc  
200 Crossing Boulevard  
Bridgewater  
New Jersey 08807  
USA  
Attention: President R&D  
Copy: General Counsel

With a copy to:

sanofi-aventis  
174 Avenue de France  
Paris, France 75017  
Attention: General Counsel

- (b) If to Regeneron:

Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591  
U.S.A.  
Attention: President Copy: General Counsel

With a copy to:

Skadden, Arps, Slate, Meagher & Flom LLP  
One Beacon Street, 31<sup>st</sup> Floor  
Boston, Massachusetts 02108  
Attention: Kent A. Coit

**STOCK PURCHASE AGREEMENT**

**By and Among**

**SANOFI-AVENTIS AMÉRIQUE DU NORD,  
SANOFI-AVENTIS US LLC**

**AND**

**REGENERON PHARMACEUTICALS, INC.**

**Dated as of November 28, 2007**

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## TABLE OF CONTENTS

	<u>Page</u>
1. DEFINITIONS	1
1.1 Defined Terms	1
1.2 Additional Defined Terms	4
2. PURCHASE AND SALE OF COMMON STOCK	4
3. CLOSING DATE; DELIVERIES	5
3.1 Closing Date	5
3.2 Deliveries	5
4. REPRESENTATIONS AND WARRANTIES OF THE COMPANY	6
4.1 Organization, Good Standing and Qualification	6
4.2 Capitalization and Voting Rights	6
4.3 Subsidiaries	7
4.4 Authorization	7
4.5 No Defaults	7
4.6 No Conflicts	7
4.7 No Governmental Authority or Third Party Consents	8
4.8 Valid Issuance of Shares	8
4.9 Litigation	8
4.10 Licenses and Other Rights; Compliance with Laws	8
4.11 Company SEC Documents; Financial Statements; Nasdaq Stock Market	8
4.12 Absence of Certain Changes	9
4.13 Internal Controls; Disclosure Controls and Procedures	9
4.14 Intellectual Property	10
4.15 Offering	10
4.16 No Integration	10
4.17 Brokers' or Finders' Fees	10
4.18 Not Investment Company	10
5. REPRESENTATIONS AND WARRANTIES OF THE INVESTOR	10
5.1 Organization; Good Standing	10
5.2 Authorization	11

5.3 No Conflicts	11
5.4 No Governmental Authority or Third Party Consents	11
5.5 Purchase Entirely for Own Account	11
5.6 Disclosure of Information	12
5.7 Investment Experience and Accredited Investor Status	12
5.8 Acquiring Person	12
5.9 Restricted Securities	12
5.10 Legends	12
5.11 Financial Assurances	13
6. COVENANTS OF THE COMPANY	13
6.1 Conduct of the Business Pending Closing	13
6.2 Use of Proceeds	13
7. INVESTOR'S CONDITIONS TO CLOSING	13
7.1 Representations and Warranties	13
7.2 Covenants	14
7.3 Investor Agreement	14
7.4 Discovery Agreement; Sanofi License and Collaboration Agreement	14
7.5 No Material Adverse Effect	14
8. COMPANY'S CONDITIONS TO CLOSING	14
8.1 Representations and Warranties	14
8.2 Covenants	14
8.3 Investor Agreement	14
8.4 Discovery Agreement; Sanofi License and Collaboration Agreement	14
9. MUTUAL CONDITIONS TO CLOSING	15
9.1 HSR Act and Other Qualifications	15
9.2 Absence of Litigation	15
9.3 No Prohibition	15
10. TERMINATION	15
10.1 Ability to Terminate	15
10.2 Effect of Termination	16
11. ADDITIONAL COVENANTS AND AGREEMENTS	17
11.1 Legending of Existing Shares	17
11.2 Amendment of Aventis Agreement	17

11.3 Market Listing	18
11.4 Notification under the HSR Act	18
11.5 Assistance and Cooperation	18
11.6 Effect of Waiver of Condition to Closing	19
12. MISCELLANEOUS	19
12.1 Governing Law; Submission to Jurisdiction	19
12.2 Waiver	19
12.3 Notices	20
12.4 Entire Agreement	20
12.5 Amendments	20
12.6 Headings; Nouns and Pronouns; Section References	20
12.7 Severability	20
12.8 Assignment	20
12.9 Successors and Assigns	21
12.10 Counterparts	21
12.11 Third Party Beneficiaries	21
12.12 No Strict Construction	21
12.13 Survival of Warranties	21
12.14 Remedies	21
12.15 Expenses	21
Exhibit A – Form of Cross Receipt	
Exhibit B – Form of Investor Agreement	
Exhibit C – Conduct of the Business Pending Closing	
Exhibit D – Notices	

STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this “Agreement”), dated as of November 28, 2007, by and among sanofi-aventis Amérique du Nord (the “Investor”), a *société en nom collectif* organized under the laws of France and wholly owned by sanofi-aventis, a company organized under the laws of France (“sanofi-aventis”), with its principal headquarters at 174, avenue de France, 75013 Paris, France, sanofi-aventis US LLC (solely for purposes of Sections 5.11, 8.2, 8.3, 11.2 and 12.13), a Delaware limited liability company indirectly wholly owned by the Investor (“Sanofi US”) and the successor in interest to Aventis Pharmaceuticals Inc., a Delaware corporation indirectly wholly owned by the Investor (“Aventis”), with respect to the Aventis Collaboration Agreement, with its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 00807, and Regeneron Pharmaceuticals, Inc. (the “Company”), a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value \$0.001 per share, of the Company (the “Common Stock”).

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor, Sanofi US and the Company agree as follows:

**1. Definitions.**

**1.1 Defined Terms.** When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

“Affiliate” shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The parties acknowledge that in the case of certain entities organized under the Laws of certain countries outside of the United States, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For the purposes of this Agreement, in no event shall the Investor or any of its Affiliates be deemed Affiliates of the

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Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

“Agreement” shall have the meaning set forth in the Preamble, including all Exhibits attached hereto.

“Aventis Collaboration Agreement” shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between Sanofi US (as successor in interest to Aventis) and the Company, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth Amendment, dated as of January 31, 2006, Section 11.2 of this Agreement, and as further amended from time to time.

“Business Day” shall mean a day on which commercial banking institutions in New York, New York are open for business.

“Collaboration Agreements” means, collectively, the Aventis Collaboration Agreement, the Discovery Agreement and the Sanofi License and Collaboration Agreement.

“Cross Receipt” shall mean an executed document signed by each of the Company and the Investor, in substantially the form of Exhibit A attached hereto.

“Discovery Agreement” shall mean that certain Discovery and Preclinical Development Agreement between the Company and Aventis dated as of the date hereof, as the same may be amended from time to time.

“Effect” shall have the meaning set forth in the definition of “Material Adverse Effect.”

“Governmental Authority” shall mean any court, agency, authority, department or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.

“Intellectual Property” shall mean shall mean trademarks, trade names, trade dress, service marks, copyrights, and similar rights (including registrations and applications to register or renew the registration of any of the foregoing), patents and patent applications, trade secrets, and any other similar intellectual property rights.

“Intellectual Property License” shall mean any license, permit, authorization, approval, contract or consent granted, issued by or with any Person relating to the use of Intellectual Property.

“Investor Agreement” shall mean that certain Investor Agreement among sanofi-aventis, Sanofi US, Aventis, the Investor and the Company, to be dated as of the Closing Date, in substantially the form of Exhibit B attached hereto, as the same may be amended from time to time.

“Law” or “Laws” shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

“Material Adverse Effect” shall mean any change, event or occurrence (each, an “Effect”) that, individually or when taken together with all other Effects, has (i) a material adverse effect on the business, financial condition, results of operations or prospects of the Company and its subsidiaries, taken as a whole, or (ii) a material adverse effect on the Company’s ability to perform its obligations, or consummate the Transaction, in accordance with the terms of this Agreement, except in the case of (i) or (ii) to the extent that any such Effect results from or arises out of: (A) changes in conditions in the United States or global economy or capital or financial markets generally, including changes in interest or exchange rates, (B) changes in general legal, regulatory, political, economic or business conditions or changes in generally accepted accounting principles in the United States or interpretations thereof that, in each case, generally affect the biotechnology or biopharmaceutical industries, (C) the announcement, pendency or performance of this Agreement, the Discovery Agreement or the Sanofi License and Collaboration Agreement, or the consummation of the Transaction or the identity of the Investor, (D) any change in the trading prices or trading volume of the Common Stock (it being understood that the facts giving rise to or contributing to any such change may be deemed to constitute, or be taken into account when determining whether there has been or will be, a Material Adverse Effect, except to the extent any of such facts is an Effect referred in clauses (A) through (J) of this definition), (E) acts of war, sabotage or terrorism, or any escalation or worsening of any such acts of war, sabotage or terrorism, (F) earthquakes, hurricanes, floods or other natural disasters, (G) any action taken by the Company contemplated by this Agreement or in accordance with any of the Collaboration Agreements or with the Investor’s written consent, (H) any breach, violation or non-performance by the Investor or any of its Affiliates under any of the Collaboration Agreements, or (I) shareholder litigation arising out of or in connection with the execution, delivery or performance of the Transaction Agreements, the Discovery Agreement or the Sanofi License and Collaboration Agreement; provided, that with respect to clauses (A), (B), (E) and (F) such Effect does not have a materially disproportionate and adverse effect on the Company relative to most other comparable companies and their respective subsidiaries, taken as a whole, in the biotechnology or biopharmaceutical industries.

“Organizational Documents” shall mean (i) the Restated Certificate of Incorporation of the Company as of June 21, 1991, as amended through the date of this Agreement and (ii) the By-Laws of the Company, as amended through the date of this Agreement.

“Person” shall mean any individual, partnership, limited liability company, firm, corporation, trust, unincorporated organization, government or any department or agency thereof or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

“Sanofi License and Collaboration Agreement” shall mean that certain License and Collaboration Agreement between the Company, the Investor and Aventis dated as of the date hereof.

“Third Party” shall mean any Person (other than a Governmental Authority) other than the Investor, the Company or any Affiliate of the Investor or the Company.

“Transaction” means the issuance and sale of the Shares by the Company, and the purchase of the Shares by the Investor, in accordance with the terms hereof.

“Transaction Agreements” shall mean this Agreement and the Investor Agreement.

**1.2 Additional Defined Terms.** In addition to the terms defined in Section 1.1, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

<u>Defined Term</u>	<u>Section</u>
Aggregate Purchase Price	Section 2
Aventis	Preamble
Class A Stock	Section 4.2(a).
Closing	Section 3.1
Closing Date	Section 3.1
Common Stock	Preamble
Company	Preamble
Company SEC Documents	Section 4.11(a)
Exchange Act	Section 4.11(a)
Final Termination Date	Section 10.1(b)
HSR Act	Section 4.7
Investor	Preamble
LAS	Section 4.7
Modified Clause	Section 12.7
Permits	Section 4.10
Original Termination Date	Section 10.1(b)
Sanofi US	Preamble
sanofi-aventis	Preamble
SEC	Section 4.7
Securities Act	Section 4.11(a)
Share Amount	Section 2
Shares	Section 2

**2. Purchase and Sale of Common Stock.** Subject to the terms and conditions of this Agreement, at the Closing, the Company shall issue and sell to the Investor, free and clear of all liens, other than any liens arising as a result of any action by the Investor, and the Investor shall purchase from the Company, a number of shares of Common Stock equal to the Share Amount (the “Shares”), for an aggregate purchase price of US \$312,000,000.00. (the “Aggregate Purchase Price”). The “Share Amount” shall equal 12,000,000; provided, however, that in the event of any stock dividend, stock split, combination of shares, recapitalization or other similar change in the capital structure of the Company after the date hereof and on or prior to the Closing which affects or relates to the Common Stock, the Share Amount shall be adjusted proportionately.

### 3. Closing Date; Deliveries.

**3.1 Closing Date.** Subject to the satisfaction or waiver of all the conditions to the Closing set forth in Sections 7, 8 and 9 hereof, the closing of the purchase and sale of the Shares hereunder (the “Closing”) shall be held on the third (3<sup>rd</sup>) Business Day after the satisfaction of the conditions to Closing set forth in Sections 7, 8 and 9 (other than those conditions that by their nature are to be satisfied at the Closing), at 10:00 a.m. New York City time, at the offices of Skadden, Arps, Slate, Meagher & Flom LLP, 4 Times Square, New York, New York 10036, or at such other time, date and location as the parties may agree in writing. The date the Closing occurs is hereinafter referred to as the “Closing Date.”

#### 3.2 Deliveries.

**(a) Deliveries by the Company.** At the Closing, the Company shall deliver to the Investor a stock certificate, registered in the name of the Investor, representing the Shares, and the Company shall instruct its transfer agent to register such issuance at the time of such issuance. The Company shall also deliver at the Closing: (i) a duly executed Cross Receipt; (ii) a certificate in form and substance reasonably satisfactory to the Investor and duly executed on behalf of the Company by an authorized executive officer of the Company, certifying that the conditions to Closing set forth in Sections 7 and 9.3(b) of this Agreement have been fulfilled; (iii) a duly executed Investor Agreement; and (iv) a certificate of the secretary of the Company dated as of the Closing Date certifying (A) that attached thereto is a true and complete copy of the By-Laws of the Company as in effect on the Closing Date; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board of Directors of the Company authorizing the execution, delivery and performance of the Transaction Agreements and the Transaction and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby as of the Closing Date; (C) that attached thereto is a true and complete copy of the Company’s Restated Certificate of Incorporation as in effect on the Closing Date; and (D) as to the incumbency and specimen signature of any officer of the Company executing a Transaction Agreement on behalf of the Company.

**(b) Deliveries by the Investor.** At the Closing, the Investor shall deliver to the Company the Aggregate Purchase Price by wire transfer of immediately available United States funds to an account designated by the Company. The Company shall notify the Investor in writing of the wiring instructions for such account not less than three (3) Business Days before the Closing Date. The Investor shall also deliver, or cause to be delivered, at the Closing: (i) a duly executed Cross Receipt; (ii) a certificate in form and substance reasonably satisfactory to the Company duly executed by an authorized executive officer of the Investor certifying that the conditions to Closing set forth in Section 8 of this Agreement have been fulfilled; (iii) an Investor Agreement, duly executed by sanofi-aventis, Sanofi US, Aventis and the Investor; and (iv) a certificate of the secretaries of sanofi-aventis, Sanofi US, Aventis and the Investor dated as of the Closing Date certifying (A) that attached thereto are true and complete copies of any and all organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents) of each of sanofi-aventis, Sanofi US, Aventis and the Investor, as applicable, as in effect on the Closing Date; and (B) as to the incumbency and specimen signature of any officer executing a Transaction Agreement on behalf of sanofi-aventis, Sanofi US, Aventis or the Investor, as applicable.

**4. Representations and Warranties of the Company.** The Company hereby represents and warrants to the Investor that:

**4.1 Organization, Good Standing and Qualification.**

(a) The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of New York. The Company has all requisite corporate power and corporate authority to own, lease and operate its properties and assets, to carry on its business as now conducted, and as proposed to be conducted as described in the Company SEC Documents, to enter into the Transaction Agreements to issue and sell the Shares and to carry out the other transactions contemplated by the Transaction Agreements.

(b) The Company is qualified to transact business and is in good standing in each jurisdiction in which the character of the properties owned, leased or operated by the Company or the nature of the business conducted by the Company makes such qualification necessary, except where the failure to be so qualified would not have a Material Adverse Effect.

**4.2 Capitalization and Voting Rights.**

(a) The authorized capital of the Company as of the date hereof consists of: (i) 160,000,000 shares of Common Stock of which, as of the date of this Agreement, (w) 63,932,731 shares are issued and outstanding, (x) 2,260,266 shares are reserved for issuance upon conversion of the Company's Class A Stock, par value \$0.001 per share (the "Class A Stock"), each share of Class A Stock being convertible into one (1) share of Common Stock, (y) 18,843,943 shares are reserved for issuance pursuant to the Company's 2000 Long-Term Incentive Plan, of which 15,244,146 shares are issuable upon the exercise of stock options outstanding on the date hereof, and (z) 6,611,300 shares are reserved for issuance upon conversion of the Company's 5<sup>1/2</sup>% Convertible Senior Subordinated Notes due 2008; (ii) 40,000,000 shares of Class A Stock of which, as of the date of this Agreement, 2,260,266 shares are issued and outstanding and 44,246 shares are reserved for issuance pursuant to the Company's 1989 Executive Stock Purchase Plan; and (iii) 30,000,000 shares of preferred stock, par value \$0.01 per share, of which no shares are issued and outstanding as of the date of this Agreement. All of the issued and outstanding shares of Common Stock and Class A Stock (A) have been duly authorized and validly issued, (B) are fully paid and non-assessable and (C) were issued in compliance with all applicable federal and state securities Laws and not in violation of any preemptive rights.

(b) All of the authorized shares of Common Stock are entitled to one (1) vote per share. All of the authorized shares of Class A Stock are entitled to ten (10) votes per share.

(c) Except as described or referred to in Section 4.2(a) above, as of the date hereof, there are not: (i) any outstanding equity securities, options, warrants, rights (including conversion or preemptive rights) or other agreements pursuant to which the Company is or may become obligated to issue, sell or repurchase any shares of its capital stock or any other securities of the Company or (ii) except as set forth in the Investor Agreement, any restrictions on the transfer of capital stock of the Company other than pursuant to state and federal securities Laws.

(d) Except as provided in the Investor Agreement, the Company is not a party to or subject to any agreement or understanding relating to the voting of shares of capital stock of the Company or the giving of written consents by a stockholder or director of the Company.

**4.3 Subsidiaries.** The Company does not have any subsidiaries required to be disclosed in an exhibit to its Annual Report on Form 10-K pursuant to Item 601(b)(21) of Regulation S-K.

**4.4 Authorization.**

(a) All requisite corporate action on the part of the Company, its directors and stockholders required by applicable Law or, assuming the accuracy of the Investor's representation in Section 5.8, The NASDAQ Stock Market LLC for the authorization, execution and delivery by the Company of the Transaction Agreements and the performance of all obligations of the Company hereunder and thereunder, including the authorization, issuance and delivery of the Shares, has been taken.

(b) This Agreement has been, and upon the execution and delivery of the Investor Agreement by the Company at the Closing, the Investor Agreement will be, duly executed and delivered by the Company, and upon the due execution and delivery of this Agreement by the Investor and Sanofi US, this Agreement will constitute, and upon the due execution and delivery of the Investor Agreement by sanofi-aventis, Sanofi US, Aventis and the Investor, the Investor Agreement will constitute, valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms (except as such enforceability may be limited by (i) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights and (ii) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).

**4.5 No Defaults.** The Company is not in default under or in violation of (a) its Organizational Documents, (b) any provision of applicable Law or any ruling, writ, injunction, order, Permit, judgment or decree of any Governmental Authority or (c) any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound, except, in the case of subsections (b) and (c), as would not have a Material Adverse Effect. To the knowledge of the Company, there exists no condition, event or act which after notice, lapse of time, or both, would constitute a default or violation by the Company under any of the foregoing, except, in the case of subsections (b) and (c), as would not have a Material Adverse Effect.

**4.6 No Conflicts.** The execution, delivery and performance of the Transaction Agreements and compliance with the provisions thereof by the Company do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound or (c)

violate or conflict with any of the provisions of the Company's Organizational Documents, except, in the case of subsections (a) and (b), as would not have a Material Adverse Effect.

**4.7 No Governmental Authority or Third Party Consents.** No consent, approval, authorization or other order of, or filing with, or notice to, any Governmental Authority or other Third Party is required to be obtained or made by the Company in connection with the authorization, execution and delivery by the Company of any of the Transaction Agreements or with the authorization, issue and sale by the Company of the Shares, except (i) such filings as may be required to be made with the Securities and Exchange Commission (the "SEC") and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws, (ii) as required pursuant to the Hart-Scott-Rodino Antitrust Improvements Act, as amended (the "HSR Act") and (iii) with respect to the Shares, the filing with The NASDAQ Stock Market LLC of, and the absence of unresolved issues with respect to, a Notification Form: Listing of Additional Shares (the "LAS").

**4.8 Valid Issuance of Shares.** When issued, sold and delivered at the Closing in accordance with the terms hereof for the Aggregate Purchase Price, the Shares shall be duly authorized, validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal or other similar rights, other than as arising pursuant to the Transaction Agreements, as a result of any action by the Investor or under federal or state securities Laws.

**4.9 Litigation.** Except as set forth in the Company SEC Documents filed prior to the date of this Agreement, there is no action, suit, proceeding or investigation pending (of which the Company has received notice or otherwise has knowledge) or, to the Company's knowledge, threatened, against the Company or which the Company intends to initiate which has had or is reasonably likely to have a Material Adverse Effect.

**4.10 Licenses and Other Rights; Compliance with Laws.** The Company has all franchises, permits, licenses and other rights and privileges ("Permits") necessary to permit it to own its properties and to conduct its business as presently conducted and is in compliance thereunder, except where the failure to be in compliance does not and would not have a Material Adverse Effect. To the Company's knowledge, it has not taken any action that would interfere with the Company's ability to renew all such Permit(s), except where the failure to renew such Permit(s) would not have a Material Adverse Effect. The Company is and has been in compliance with all Laws applicable to its business, properties and assets, and to the products and services sold by it, except where the failure to be in compliance does not and would not have a Material Adverse Effect.

**4.11 Company SEC Documents; Financial Statements; Nasdaq Stock Market.**

(a) Since December 31, 2006, the Company has timely filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein), and any required amendments to any of the foregoing, with the SEC (the "Company SEC Documents"). As of their respective filing dates, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of

1934, as amended (the “Exchange Act”), and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents, and no Company SEC Documents when filed, declared effective or mailed, as applicable, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) The financial statements of the Company included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and in its quarterly reports on Form 10-Q for the quarterly periods ended September 30, 2007, June 30, 2007, and March 31, 2007 comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto, have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended. Except (i) as set forth in the Company SEC Documents or (ii) for liabilities incurred in the ordinary course of business subsequent to the date of the most recent balance sheet contained in the Company SEC Documents, the Company has no liabilities, whether absolute or accrued, contingent or otherwise, other than those that would not, individually or in the aggregate, have a Material Adverse Effect.

(c) As of the date of this Agreement, the Common Stock is listed on The Nasdaq Global Market, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from The Nasdaq Global Market. As of the date of this Agreement, the Company has not received any notification that, and has no knowledge that, the SEC or The NASDAQ Stock Market LLC is contemplating terminating such listing or registration.

**4.12 Absence of Certain Changes.** Except as disclosed in the Company SEC Documents, since December 31, 2006, there has not occurred any event that has caused or would reasonably be expected to cause a Material Adverse Effect.

**4.13 Internal Controls; Disclosure Controls and Procedures.** The Company maintains internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. The Company has implemented the “disclosure controls and procedures” (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) required in order for the Chief Executive Officer and Chief Financial Officer of the Company to engage in the review and evaluation process mandated by the Exchange Act, and is in compliance with such disclosure controls and procedures in all material respects. Each of the Chief Executive Officer and the Chief Financial Officer of the Company (or each former Chief Executive Officer of the Company and each former Chief Financial Officer of the Company, as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 with respect to all reports, schedules, forms, statements and other documents required to be filed by the Company with the SEC.

**4.14 Intellectual Property.** The Intellectual Property that is owned by the Company is owned free from any liens or restrictions, and all of the Company's material Intellectual Property Licenses are in full force and effect in accordance with their terms, and are free of any liens or restrictions, except (a) where the failure to be free from such liens or restrictions would not have a Material Adverse Effect or (b) as set forth in any such Intellectual Property License. Except as set forth in the Company SEC Documents, there is no legal claim or demand of any Person pertaining to, or any proceeding which is pending (of which the Company has received notice or otherwise has knowledge) or, to the knowledge of the Company, threatened, (i) challenging the right of the Company in respect of any Company Intellectual Property, or (ii) that claims that any default exists under any Intellectual Property License, except, in the case of (i) and (ii) above, where any such claim, demand or proceeding would not have a Material Adverse Effect.

**4.15 Offering.** Subject to the accuracy of the Investor's representations set forth in Sections 5.5, 5.6, 5.7, 5.9 and 5.10, the offer, sale and issuance of the Shares to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements. Neither the Company nor any Person acting on its behalf will take any action that would cause the loss of such exemption.

**4.16 No Integration.** The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act) which is or will be integrated with the Shares sold pursuant to this Agreement in a manner that would require the registration of the Shares under the Securities Act.

**4.17 Brokers' or Finders' Fees.** No broker, finder, investment banker or other Person is entitled to any brokerage, finder's or other fee or commission from the Company in connection with the transactions contemplated by the Transaction Agreements.

**4.18 Not Investment Company.** The Company is not, and solely after receipt of the Aggregate Purchase Price and application of such proceeds in substantially the manner described under "Use of Proceeds" in the Company's prospectus supplement filed November 15, 2006 with the SEC, will not be, an "investment company" as defined in the Investment Company Act of 1940, as amended.

**5. Representations and Warranties of the Investor.** The Investor hereby represents and warrants to the Company as set forth in Sections 5.1 through 5.10 (on behalf of itself, Sanofi US, Aventis and sanofi-aventis), and the Investor and Sanofi US hereby jointly and severally represent and warrant to the Company as set forth in Section 5.11, that:

**5.1 Organization; Good Standing.** The Investor is a partnership duly organized, validly existing and in good standing under the laws of France. Sanofi US is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware. Aventis is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. sanofi-aventis is a company duly organized, validly existing and in good standing under the laws of France. Each of the Investor and Sanofi US has, and Aventis and sanofi-aventis will have, all requisite power and authority to enter into the

Transaction Agreements to which it is or will be a party, in the case of the Investor to purchase the Shares and, in the case of the Investor, Sanofi US, Aventis and sanofi-aventis, to perform its respective obligations under and to carry out the other transactions contemplated by the Transaction Agreements to which it is or will be a party.

**5.2 Authorization.** All requisite action on the part of the Investor, Sanofi US, Aventis, sanofi-aventis and their respective directors and stockholders, required by applicable Law for the authorization, execution and delivery by the Investor, Sanofi US, Aventis and sanofi-aventis of the Transaction Agreements to which they are a party, and the performance of all of their respective obligations thereunder, including the subscription for and purchase of the Shares, has been taken or, in the case of Aventis and sanofi-aventis, will be taken prior to the Closing. This Agreement, and upon the execution and delivery of the Investor Agreement at the Closing by the Investor, Sanofi US, Aventis and sanofi-aventis, the Investor Agreement will be, duly executed and delivered by, as applicable, the Investor, Sanofi US, Aventis and sanofi-aventis and upon the due execution and delivery thereof by the Company, will constitute valid and legally binding obligations of, as applicable, the Investor, Sanofi US, Aventis and sanofi-aventis, enforceable against, as applicable, the Investor, Sanofi US, Aventis and sanofi-aventis in accordance with their respective terms (except as such enforceability may be limited by (a) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights and (b) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).

**5.3 No Conflicts.** The execution, delivery and performance of the Transaction Agreements and compliance with the provisions thereof by the Investor, Sanofi US, Aventis and sanofi-aventis, do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Investor, Sanofi US, Aventis or sanofi-aventis or any of their respective assets, are bound, or (c) violate or conflict with any of the provisions of the Investor's, Sanofi US', Aventis' or sanofi-aventis' organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents), except as would not impair or adversely affect the ability of the Investor, Sanofi US, Aventis or sanofi-aventis, as applicable, to consummate the Transactions and perform their respective obligations under the Transaction Agreements and except, in the case of subsections (a) and (b) as would not have a material adverse effect on the Investor, Sanofi US, Aventis or sanofi-aventis.

**5.4 No Governmental Authority or Third Party Consents.** No consent, approval, authorization or other order of any Governmental Authority or other Third Party is required to be obtained by the Investor, Sanofi US, Aventis or sanofi-aventis in connection with the authorization, execution and delivery of any of the Transaction Agreements or with the subscription for and purchase of the Shares, except as required pursuant to the HSR Act.

**5.5 Purchase Entirely for Own Account.** The Shares shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the

resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation or otherwise distributing the Shares. The Investor does not have and will not have as of the Closing any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participation to a Person any of the Shares.

**5.6 Disclosure of Information.** The Investor has received all the information from the Company and its management that the Investor considers necessary or appropriate for deciding whether to purchase the Shares hereunder. The Investor further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the Company, its financial condition, results of operations and prospects and the terms and conditions of the offering of the Shares sufficient to enable it to evaluate its investment.

**5.7 Investment Experience and Accredited Investor Status.** The Investor is an “accredited investor” (as defined in Regulation D under the Securities Act). The Investor has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder.

**5.8 Acquiring Person.** As of the date of this Agreement and immediately prior to the Closing, (a) sanofi-aventis together with its Affiliates, beneficially own and will beneficially own (as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership) 2,799,552 shares of Common Stock, and (b) neither sanofi-aventis nor any of its Affiliates beneficially owns, or will beneficially own (as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership), any other securities of the Company.

**5.9 Restricted Securities.** The Investor understands that the Shares, when issued, shall be “restricted securities” under the federal securities Laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such Laws the Shares may be resold without registration under the Securities Act only in certain limited circumstances. In this connection, the Investor represents that it is familiar with Rule 144 of the Securities Act, as presently in effect.

**5.10 Legends.** The Investor understands that the certificates representing the Shares shall bear the following legends:

(a) “These securities have not been registered under the Securities Act of 1933. They may not be sold, offered for sale, pledged or hypothecated in the absence of a registration statement in effect with respect to the securities under the Securities Act or an opinion of counsel (which counsel shall be reasonably satisfactory to Regeneron Pharmaceuticals, Inc.) that such registration is not required or unless sold pursuant to Rule 144 of the Securities Act.”;

(b) any legend required by applicable state securities Laws; and

(c) “The securities represented by this certificate are subject to and shall be transferable only upon the terms and conditions of an Investor Agreement dated as of [ ], 2007,

by and among Regeneron Pharmaceuticals, Inc. and the other parties signatory thereto, a copy of which is on file with the Secretary of Regeneron Pharmaceuticals, Inc.”

**5.11 Financial Assurances.** As of the date hereof and as of the Closing Date, the Investor has and will have access to cash in an amount sufficient to pay to the Company the Aggregate Purchase Price.

## **6. Covenants of the Company.**

**6.1 Conduct of the Business Pending Closing.** During the period from the date hereof until the Closing, except as (a) set forth on Exhibit C attached hereto, (b) consented to in writing by the Investor (which consent shall not be unreasonably withheld, conditioned or delayed) or (c) otherwise contemplated by this Agreement or any of the Collaboration Agreements, the Company shall (i) operate its business only in the ordinary course, (ii) maintain its existence under applicable Law, (iii) use commercially reasonable efforts to maintain and enforce its material Intellectual Property, (iv) pay all applicable material taxes when due and payable and (v) (A) not declare, set aside or pay any dividend or make any other distribution or payment (whether in cash, stock or property or any combination thereof) in respect of its capital stock, (B) not make any other actual, constructive or deemed distribution in respect of any shares of its capital stock or otherwise make any payments to stockholders in their capacity as such and (C) not redeem, repurchase or otherwise acquire any securities of the Company or any of its subsidiaries.

**6.2 Use of Proceeds.** From and after the Closing Date, the Company shall use the Aggregate Purchase Price in substantially the manner described under “Use of Proceeds” in the Company’s prospectus supplement filed November 15, 2006 with the SEC.

**7. Investor’s Conditions to Closing.** The Investor’s obligation to purchase the Shares at the Closing is subject to the fulfillment as of such Closing of the following conditions (unless waived in writing by the Investor):

**7.1 Representations and Warranties.** (a) The representations and warranties made by the Company in Section 4 hereof shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of such Closing Date; (b) the representations and warranties made by the Company in Article 8 of the Discovery Agreement (other than Section 8.1(a) thereof) shall be true and correct as of the date of the Discovery Agreement and as of the Closing Date as though made on and as of such Closing Date; and (c) the representations and warranties made by the Company in Article XV of the Sanofi License and Collaboration Agreement (other than Section 15.1(a) thereof) shall be true and correct as of the date of the Sanofi License and Collaboration Agreement and as of the Closing Date as though made on and as of such Closing Date, except in the case of subsections (a), (b) and (c) to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 7.1, all such representations and warranties of the Company (other than Sections 4.1(a), 4.2, 4.3, 4.4(a) and 4.8 of this Agreement, Section 8.1(b) of the Discovery Agreement and Section 15.1(b) of the Sanofi License and Collaboration Agreement) shall be deemed to be true and correct for purposes of this Section 7.1 unless the

failure or failures of such representations and warranties to be so true and correct, without regard to any “material,” “materiality” or “Material Adverse Effect” qualifiers set forth therein (other than any reference to “material” in Sections 4.11(a) and 4.11(b)), individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.

**7.2 Covenants.** All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.

**7.3 Investor Agreement.** The Company shall have duly executed and delivered to the Investor, pursuant to Section 3.2(a) of this Agreement, the Investor Agreement, and (subject to execution by sanofi-aventis, Sanofi US, Aventis and the Investor) such agreement shall be in full force and effect.

**7.4 Discovery Agreement; Sanofi License and Collaboration Agreement.** The Company shall have duly executed and delivered to the Investor the Discovery Agreement and the Sanofi License and Collaboration Agreement, and there shall have been no termination of either of the Discovery Agreement or the Sanofi License and Collaboration Agreement that, as of the Closing, is effective.

**7.5 No Material Adverse Effect.** From and after the date of this Agreement until the Closing Date, there shall have occurred no event that has caused or would reasonably be expected to cause a Material Adverse Effect.

**8. Company’s Conditions to Closing.** The Company’s obligation to issue and sell the Shares at the Closing is subject to the fulfillment as of such Closing of the following conditions (unless waived in writing by the Company):

**8.1 Representations and Warranties.** The representations and warranties made by the Investor (on its own behalf and on behalf of Sanofi US, Aventis and sanofi-aventis) and by Sanofi US (a) in Section 5 hereof (other than Sections 5.4 and 5.6 hereof) shall be true and correct and (b) in Sections 5.4 and 5.6 hereof shall be true and correct in all material respects, in each case as of the date of this Agreement and as of the Closing Date as though made on and as of such Closing Date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date).

**8.2 Covenants.** All covenants and agreements contained in this Agreement to be performed or complied with by the Investor or Sanofi US as applicable, on or prior to the Closing Date shall have been performed or complied with in all material respects.

**8.3 Investor Agreement.** sanofi-aventis, Sanofi US, Aventis and Investor shall have duly executed and delivered to the Company, pursuant to Section 4.2(b) of this Agreement, the Investor Agreement, and (subject to execution by the Company) such agreement shall be in full force and effect.

**8.4 Discovery Agreement; Sanofi License and Collaboration Agreement.** Sanofi US, Aventis and the Investor, as applicable, shall have duly executed and delivered to the

Company the Discovery Agreement and the Sanofi License and Collaboration Agreement, and there shall have been no termination of either of the Discovery Agreement or the Sanofi License and Collaboration Agreement that, as of the Closing, is effective. The Company shall have received from Aventis the payment required by Section 4.1 of the Discovery Agreement.

**9. Mutual Conditions to Closing.** The obligations of the Investor and the Company to consummate the Closing is subject to the fulfillment as of the Closing Date of the following conditions:

**9.1 HSR Act and Other Qualifications.** The filings required under the HSR Act in connection with this Agreement shall have been made and the required waiting period shall have expired or been terminated as of the Closing Date, and all other authorizations, consents, waivers, permits, approvals, qualifications and registrations to be obtained or effected with any Governmental Authority, including, without limitation, necessary blue sky permits and qualifications required by any state for the offer and sale to the Investor of the Shares, shall have been duly obtained and shall be in effect as of the Closing Date.

**9.2 Absence of Litigation.** There shall be no action, suit, proceeding or investigation by a Governmental Authority pending or currently threatened in writing against the Company, the Investor, Sanofi US, Aventis or sanofi-aventis which questions the validity of any of the Transaction Agreements, the right of the Company, the Investor, Sanofi US, Aventis or sanofi-aventis to enter into any Transaction Agreement or to consummate the transactions contemplated hereby or thereby or which, if determined adversely, would impose substantial monetary damages on the Company, the Investor, Sanofi US, Aventis or sanofi-aventis as a result of the consummation of the transactions contemplated by any Transaction Agreement.

**9.3 No Prohibition.** (a) No provision of any applicable Law and no judgment, injunction (preliminary or permanent), order or decree that prohibits, makes illegal or enjoins the consummation of the Transaction shall be in effect; and (b) there shall be no unresolved issues with The NASDAQ Stock Market LLC with respect to the LAS.

## **10. Termination.**

**10.1 Ability to Terminate.** This Agreement may be terminated at any time prior to the Closing by:

(a) mutual written consent of the Company and the Investor;

(b) either the Company or the Investor, upon written notice to the other no earlier than three (3) Business Days after January 31, 2008 (the "Original Termination Date"), if the Original Termination Date cannot be or has not been validly extended pursuant to this Section 10.1(b), and if the Transaction shall not have been consummated by the Original Termination Date; provided, however, that the Original Termination Date may be extended to March 31, 2008 (the "Final Termination Date") by either the Company or the Investor, upon written notice to the other on or within two (2) Business Days after the Original Termination Date, if the Transaction shall not have been consummated by the Original Termination Date solely as the result of a failure to satisfy the condition set forth in Section 9.1 as of the Original Termination Date; provided further, however, that the right to terminate this Agreement under

this Section 10.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Original Termination Date or the Final Termination Date, as applicable;

(c) either the Company or the Investor, upon written notice to the other, if any of the mutual conditions to the Closing set forth in Section 9 shall have become incapable of fulfillment by the Original Termination Date or, if the Original Termination Date has been validly extended pursuant to Section 10.1(b), the Final Termination Date, and shall not have been waived in writing by the other party; provided, however, that the right to terminate this Agreement under this Section 10.1(c) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Original Termination Date or the Final Termination Date, as applicable;

(d) the Company, upon written notice to the Investor, so long as the Company is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 7.1 or 7.2, as applicable, could not be satisfied by the Closing Date, (i) upon a breach of any covenant or agreement on the part of the Investor set forth in this Agreement, or (ii) if any representation or warranty of the Investor or Sanofi US shall have been or become untrue, in each case such that any of the conditions set forth in Section 8.1, 8.2, 8.3 or 8.4, as applicable, could not be satisfied by the Closing Date;

(e) the Company, upon written notice to the Investor, if the Investor or any of its Affiliates has breached Section 20.16 of the Aventis Collaboration Agreement (for avoidance of doubt, the Company shall not have the right to terminate this Agreement as a result of a de minimis breach of Section 20.16(a) of the Aventis Collaboration Agreement or an inadvertent breach of Section 20.16(g) of the Aventis Collaboration Agreement arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of Section 20.16 of the Aventis Collaboration Agreement); provided that any action taken in connection with the Transaction shall not be deemed to be a violation of Section 20.16 of the Aventis Collaboration Agreement; and

(f) the Investor, upon written notice to the Company, so long as the Investor and Sanofi US are not then in breach of their representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 8.1 or 8.2, as applicable, could not be satisfied by the Closing Date, upon a breach of any covenant or agreement on the part of the Company set forth in this Agreement, or if any representation or warranty of the Company shall have been or become untrue, in each case such that any of the conditions set forth in Section 7.1, 7.2, 7.3 or 7.4, as applicable, could not be satisfied by the Closing Date.

**10.2 Effect of Termination.** In the event of the termination of this Agreement pursuant to Section 10.1 hereof, (a) this Agreement (except for this Section 10.2 and Article XII (other than Section 12.13), and any definitions set forth in this Agreement and used in such sections) shall forthwith become void and have no effect, without any liability on the part of any

party hereto or its Affiliates, and (b) all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other Person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; provided, however, that nothing contained in this Section 10.2 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

## **11. Additional Covenants and Agreements.**

**11.1 Legending of Existing Shares.** At the Closing, the Investor shall cause Aventis to deliver to the Company the certificate(s) representing 2,799,552 shares of Common Stock issued to Aventis, and the Company shall (or shall cause its transfer agent to) promptly cancel such certificate and issue to Aventis a replacement certificate representing 2,799,552 shares of Common Stock and containing the legends set forth in Section 5.10 hereof.

**11.2 Amendment of Aventis Agreement.** Effective as of the date of this Agreement, the Investor hereby acknowledges and agrees that it shall be bound by (and shall cause its Affiliates to comply with) the restrictions applicable to Sanofi US (as successor to Aventis) under Section 20.16 of the Aventis Collaboration Agreement, and the Investor, Sanofi US and the Company acknowledge and agree that for purposes of Section 19.5 of the Aventis Collaboration Agreement, references to "Aventis" in such section include the Investor and its other Affiliates. The Investor, Sanofi US and the Company agree that, subject to clause (c) below, effective as of the date of this Agreement:

(a) The first clause of Section 20.16 of the Aventis Collaboration Agreement is hereby amended and restated in its entirety to read:

"From and after the Effective Date until the later of (A) the fifth (5<sup>th</sup>) anniversary of the expiration or earlier termination of the Term and (B) the fifth (5<sup>th</sup>) anniversary of the expiration or earlier termination of the "Term" (as such term is defined in the License and Collaboration Agreement among the Company, sanofi-aventis Amérique du Nord and Aventis dated as of November 28, 2007), neither Aventis nor any of its Affiliates (for purposes of this Section 20.16, Aventis, together with such Affiliates, being referred to as the "Investor") shall:"

(b) Section 20.16(a) of the Aventis Collaboration Agreement is hereby amended and restated in its entirety to read:

"(a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Capital Stock and/or Common Stock Equivalents, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Capital Stock and/or Common Stock Equivalents, if after giving effect to such acquisition (and assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents beneficially owned by the Investor), the Investor would beneficially own (as defined in Rule 13d-3 under the Securities Exchange Act) more than the Standstill Limit; provided, however, that notwithstanding the provisions of this Section 20.16, if the number of shares constituting Shares of Then Outstanding Capital Stock is reduced or if

the aggregate ownership of the Investor is increased as a result of a recapitalization of Regeneron, the Investor shall not be required to dispose of any of its holdings of Shares of Then Outstanding Capital Stock even though such action resulted in Investor's ownership totaling more than the Standstill Limit; as used in this Section 20.16(a):

(i) "Common Stock Equivalents" shall mean any options, warrants or other securities or rights convertible into or exercisable or exchangeable for, whether directly or following conversion into or exercise or exchange for other options, warrants or other securities or rights, shares of Class A Stock or Common Stock; and

(ii) "Standstill Limit" shall mean (i) from November 28, 2007 until December 31, 2011, the lesser of (A) twenty-one percent (21%) of the Shares of Then Outstanding Capital Stock, in the case of this clause (A) only, calculated on a fully diluted basis assuming the full conversion into, or exercise or exchange for, shares of Common Stock of all Common Stock Equivalents outstanding (as such Common Stock Equivalents outstanding are calculated from Regeneron's most recent Form 10-Q or Form 10-K, as applicable, filed with the SEC), and (B) twenty-five percent (25%) of the Shares of Then Outstanding Capital Stock, and (ii) from and after January 1, 2012, thirty percent (30%) of the Shares of Then Outstanding Capital Stock;"

(c) Notwithstanding the foregoing, if this Agreement is terminated in accordance with Section 10 hereof, the amendments to Section 20.16 of the Aventis Collaboration Agreement set forth above shall be of no further force or effect, and the provisions of Section 20.16 of the Aventis Collaboration Agreement in effect immediately prior to the execution and delivery of this Agreement shall again be in full force and effect.

**11.3 Market Listing.** From the date hereof through the Closing Date, Company shall use all reasonable efforts to (a) maintain the listing and trading of the Common Stock on The NASDAQ Global Market and (b) effect the listing of the Shares on The NASDAQ Global Market, including submitting a notice of listing of additional shares with respect to the Shares to The NASDAQ Stock Market LLC no later than fifteen (15) calendar days prior to the Closing Date.

**11.4 Notification under the HSR Act.** The parties shall, as soon as practicable, and, in any event, no later than ten (10) days after the date of this Agreement, file or cause to be filed with the Federal Trade Commission and the Department of Justice the notifications required to be filed under the HSR Act and the rules and regulations promulgated thereunder with respect to the transactions contemplated by this Agreement. The parties will use all reasonable efforts to respond on a timely basis to any requests for additional information made by either of such agencies.

**11.5 Assistance and Cooperation.** Prior to the Closing, upon the terms and subject to the conditions set forth in this Agreement, each of the parties agrees to use all reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement, including using all reasonable efforts to accomplish the following: (a) taking all

reasonable acts necessary to cause the conditions precedent set forth in Sections 7, 8 and 9 to be satisfied (including, in the case of the Company, promptly notifying the Investor of any notice from The NASDAQ Stock Market LLC with respect to the LAS); (b) obtaining all necessary actions or non-actions, waivers, consents, approvals, orders and authorizations from Governmental Authorities and the making of all necessary registrations, declarations and filings (including registrations, declarations and filings with Governmental Authorities, if any) and taking all reasonable steps as may be necessary to avoid any suit, claim, action, investigation or proceeding by any Governmental Authority; (c) obtaining all necessary consents, approvals or waivers from Third Parties; and (d) defending any suits, claims, actions, investigations or proceedings, whether judicial or administrative, challenging this Agreement or the consummation of the transactions contemplated hereby, including seeking to have any stay or temporary restraining order entered by any court or other Governmental Authority vacated or reversed. In addition, each of the Company and the Investor will promptly take any and all steps necessary to obtain any consent or to vacate or lift any order, writ, judgment, injunction, decree, stipulation, determination or award entered by or with any Governmental Authority relating to antitrust matters that would have the effect of making any of the transactions contemplated by this Agreement illegal or otherwise prohibiting or materially delaying their consummation. Notwithstanding anything to the contrary in this Section 11.5, nothing in this Section 11.5 will require the Investor to dispose of or hold separate any portion of its business or assets if such action, in the reasonable business judgment of the Investor, would impair, or be reasonably expected to impair, in any significant manner (i) the benefits to the Investor of the transactions contemplated by this Agreement, the Discovery Agreement or the Collaboration Agreements or (ii) the business, financial condition, results of operations or prospects of the Investor and its subsidiaries, taken as a whole.

**11.6 Effect of Waiver of Condition to Closing.** In the event that, as of the Closing, the Investor waives the condition regarding a Material Adverse Effect set forth in Section 7.5 of this Agreement, the Investor shall be deemed to have waived any right of recourse against the Company for, and agreed not to sue the Company in respect of, any and all events or inaccuracies in any representations or warranties of the Company (a) that, as of the Closing, have caused or would reasonably be expected to cause such Material Adverse Effect and (b) of which the Investor had notice in writing from the Company immediately prior to the Closing.

## **12. Miscellaneous.**

**12.1 Governing Law; Submission to Jurisdiction.** This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. The parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

**12.2 Waiver.** Waiver by a party of a breach hereunder by the other party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such party. No waiver

shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

**12.3 Notices.** All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit D attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either party may change its address by giving notice to the other party in the manner provided above.

**12.4 Entire Agreement.** This Agreement and the Investor Agreement (once executed), contain the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.

**12.5 Amendments.** No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the Investor and the Company.

**12.6 Headings; Nouns and Pronouns; Section References.** Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

**12.7 Severability.** If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction (“Modified Clause”), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

**12.8 Assignment.** Neither this Agreement nor any of the rights or obligations hereunder may be assigned by either the Investor or the Company without (a) the prior written

consent of Company in the case of any assignment by the Investor or (b) the prior written consent of the Investor in the case of an assignment by the Company.

**12.9 Successors and Assigns.** This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

**12.10 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

**12.11 Third Party Beneficiaries.** None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.

**12.12 No Strict Construction.** This Agreement has been prepared jointly and will not be construed against either party.

**12.13 Survival of Warranties.** The representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing for eighteen (18) months, except for (a) the representations and warranties set forth in Sections 4.1, 4.2, 4.4, 4.8, 4.15, 4.16, 4.17, 4.18, 5.1, 5.2, 5.5, 5.7, 5.8, 5.9 and 5.10, which shall survive forever and (b) the representation and warranty of the Investor and Sanofi US in Section 5.11, which shall not survive the Closing. The parties hereby acknowledge and agree that the rights of the parties hereunder are special, unique and of extraordinary character, and that if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or the Investor as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged party at law or in equity, such damaged party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

**12.14 Remedies.** The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

**12.15 Expenses.** Each party shall pay its own fees and expenses in connection with the preparation, negotiation, execution and delivery of the Transaction Agreements.

*(Signature Page Follows)*

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

**SANOFI-AVENTIS AMÉRIQUE DU NORD**

By: /s/ Jean-Luc Renard  
Name: Jean-Luc Renard  
Title: Authorized Signatory

By: /s/ Karen Linehan  
Name: Karen Linehan  
Title: Authorized Signatory

**SANOFI-AVENTIS US LLC  
(Solely for purposes of  
Sections 5.11, 8.2, 8.3, 11.2 and 12.13)**

By: /s/ Karen Linehan  
Name: Karen Linehan  
Title: Authorized Signatory

By: /s/ Robin White  
Name: Robin White  
Title: Authorized Signatory

**REGENERON PHARMACEUTICALS, INC.**

By: /s/ Leonard Schleifer  
Name: Leonard S. Schleifer, M.D., Ph.D.  
Title: President & CEO

*Signature Page to Stock Purchase Agreement,*

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**EXHIBIT A**  
**FORM OF CROSS RECEIPT**

**CROSS RECEIPT**

Regeneron Pharmaceuticals, Inc. hereby acknowledges receipt from sanofi-aventis Amérique du Nord on [\_\_\_\_\_], 2007 of US\$312,000,000.00, representing the purchase price for 12,000,000 shares of Common Stock, par value \$0.001 per share, of Regeneron Pharmaceuticals, Inc., pursuant to that certain Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amérique du Nord, sanofi-aventis US LLC and Regeneron Pharmaceuticals, Inc.

REGENERON PHARMACEUTICALS, INC.

By: \_\_\_\_\_  
Name:  
Title:

sanofi-aventis Amérique du Nord hereby acknowledges receipt from Regeneron Pharmaceuticals, Inc. on [\_\_\_\_\_], 2007 of 12,000,000 shares of Common Stock, par value \$0.001 per share, of Regeneron Pharmaceuticals, Inc., delivered pursuant to that certain Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amérique du Nord, sanofi-aventis US LLC and Regeneron Pharmaceuticals, Inc.

SANOFI-AVENTIS AMÉRIQUE DU NORD

By: \_\_\_\_\_  
Name:  
Title:

By: \_\_\_\_\_  
Name:  
Title:

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**EXHIBIT B**  
**FORM OF INVESTOR AGREEMENT**

[See the Investor Agreement, dated as of December 20, 2007, filed as Exhibit 10.21]

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## **EXHIBIT C**

### **CONDUCT OF THE BUSINESS PENDING CLOSING**

The Company may refinance its 5<sup>1/2</sup>% Convertible Senior Subordinated Notes due 2008.

The Company, in its sole discretion, shall be entitled to make equity-based or phantom equity incentive and other compensation awards, pursuant to equity-based or phantom equity incentive and other compensation plans in effect on the date of this Agreement.

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**EXHIBIT D**  
**NOTICES**

(a) If to the Investor or Sanofi US:

sanofi-aventis  
174, avenue de France  
75013 Paris  
France  
Attention: General Counsel

with a copy to:

Jones Day  
222 East 41<sup>st</sup> Street  
New York, New York 10017  
Attention: Jere R. Thomson

(b) If to the Company:

Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591  
U.S.A.  
Attention: President  
Copy: General Counsel

with a copy to:

Skadden, Arps, Slate, Meagher & Flom LLP  
One Beacon Street, 31<sup>st</sup> Floor  
Boston, MA 02108  
Attention: Kent A. Coit

**INVESTOR AGREEMENT**  
**By and Among**  
**SANOFI-AVENTIS,**  
**SANOFI-AVENTIS US LLC,**  
**AVENTIS PHARMACEUTICALS INC.,**  
**SANOFI-AVENTIS AMÉRIQUE DU NORD**  
**AND**  
**REGENERON PHARMACEUTICALS, INC.**  
**Dated as of December 20, 2007**

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## TABLE OF CONTENTS

	<u>Page</u>
1. DEFINITIONS	1
2. REGISTRATION RIGHTS	7
2.1 Required Registration	7
2.2 Underwritten Required Registration Required; Priority in Underwritten Offering	9
2.3 Priority in Required Registration	9
2.4 Revocation of Required Registration	10
2.5 Effective Required Registrations	10
2.6 Continuous Effectiveness of Registration Statement	11
2.7 Obligations of the Company	11
2.8 Furnish Information	14
2.9 Expenses	14
2.10 Indemnification	14
2.11 SEC Reports	16
2.12 Assignment of Registration Rights	16
3. RESTRICTIONS ON BENEFICIAL OWNERSHIP	17
3.1 Standstill	17
3.2 Amendment to Aventis Collaboration Agreement	18
4. RESTRICTIONS ON DISPOSITIONS	18
4.1 Lock-Up	18
4.2 Limitations Following Lock-Up Term	19
4.3 Certain Tender Offers	20
4.4 Offering Lock-Up	20
5. VOTING AGREEMENT	20
5.1 Voting of Securities	20
5.2 Certain Extraordinary Matters	21
5.3 Quorum	21
6. TERMINATION OF CERTAIN RIGHTS AND OBLIGATIONS	22
6.1 Termination of Registration Rights	22
6.2 Termination of Standstill Agreement	22
6.3 Termination of Restrictions on Dispositions	23
6.4 Termination of Voting Agreement	23
6.5 Effect of Termination	23
7. MISCELLANEOUS	23
7.1 Governing Law; Submission to Jurisdiction	23
7.2 Waiver	23
7.3 Notices	24

	<u>Page</u>
7.4 Entire Agreement	24
7.5 Amendments	24
7.6 Headings; Nouns and Pronouns; Section References	24
7.7 Severability	24
7.8 Assignment	25
7.9 Successors and Assigns	25
7.10 Counterparts	25
7.11 Third Party Beneficiaries	25
7.12 No Strict Construction	25
7.13 Remedies	25
7.14 Specific Performance	25
7.15 No Conflicting Agreements	25
Exhibit A – Form of Irrevocable Proxy	
Exhibit B – Notices	

## INVESTOR AGREEMENT

**THIS INVESTOR AGREEMENT** (this “Agreement”) is made as of December 20, 2007, by and among sanofi-aventis, a company organized under the laws of France, with its principal headquarters at 174, avenue de France, 75013 Paris, France (“sanofi-aventis”), sanofi-aventis US LLC, a Delaware limited liability company indirectly wholly owned by sanofi-aventis (“Sanofi US”) and the successor-in-interest to Aventis Pharmaceuticals Inc. (“Aventis”) with respect to the Aventis Collaboration Agreement, with its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 00807, Aventis, a Delaware corporation and an indirect wholly owned subsidiary of the Investor with its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 00807, sanofi-aventis Amérique du Nord, a *société en nom collectif* organized under the laws of France wholly owned by sanofi-aventis with its principal headquarters at 174, avenue de France, 75013 Paris, France (the “Investor”, and, together with sanofi-aventis, Sanofi US and Aventis, the “Purchaser Parties”), and Regeneron Pharmaceuticals, Inc. (the “Company”), a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

WHEREAS, the Stock Purchase Agreement, dated as of November 28, 2007, by and among the Investor, sanofi-aventis US and the Company (the “Purchase Agreement”) provides for the issuance and sale by the Company to the Investor, and the purchase by the Investor, of a number of shares of the Company’s common stock, par value \$0.001 per share (the “Common Stock”), equal to the Share Amount (as defined in the Purchase Agreement) (the “Purchased Shares”); and

WHEREAS, as a condition to consummating the transactions contemplated by the Purchase Agreement, the Purchaser Parties and the Company have agreed upon certain rights and restrictions as set forth herein with respect to the Purchased Shares and other securities of the Company beneficially owned by the Purchaser Parties and their respective Affiliates, and it is a condition to the closing under the Purchase Agreement that this Agreement be executed and delivered by the Purchaser Parties and the Company.

NOW, THEREFORE, in consideration of the premises and mutual agreements hereinafter set forth, and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

**1. Definitions.** As used in this Agreement, the following terms shall have the following meanings:

(a) “Acquisition Proposal” shall have the meaning set forth in Section 3.1(c).

(b) “Affiliate” shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent

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(50%) of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The parties acknowledge that in the case of certain entities organized under the Laws of certain countries outside the United States, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For the purposes of this Agreement, in no event shall the Investor or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

(c) “Agreement” shall have the meaning set forth in the Preamble to this Agreement, including all Exhibits attached hereto.

(d) “Aventis” shall have the meaning set forth in the Preamble to this Agreement.

(e) “Aventis Collaboration Agreement” shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between Sanofi US and the Company, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth Amendment, dated as of January 31, 2006, and Section 11.2 of the Purchase Agreement, as the same may be further amended from time to time.

(f) “Aventis Stock Purchase Agreement” shall mean the Stock Purchase Agreement, dated as of September 5, 2003, by and between Aventis and the Company.

(g) “beneficial owner,” “beneficially owns,” “beneficial ownership” and terms of similar import used in this Agreement shall, with respect to a Person, have the meaning set forth in Rule 13d-3 under the Exchange Act (i) assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents beneficially owned by such Person and (ii) determined without regard for the number of days in which such Person has the right to acquire such beneficial ownership.

(h) “Business Day” shall mean a day on which commercial banking institutions in New York, New York are open for business.

(i) “Change of Control” shall mean, with respect to the Company, any of the following events: (i) any Person is or becomes the beneficial owner (except that a Person shall be deemed to have beneficial ownership of all shares that any such Person has the right to acquire, whether such right which may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all Shares of Then Outstanding Common Stock; (ii) the Company consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into the Company, 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) a majority 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 becomes the beneficial owner, directly or indirectly, of a majority of the total voting power of all Shares of Then Outstanding Common Stock or (iii) the Company conveys, transfers or leases all or substantially all of its assets to any Person other than a wholly owned Affiliate of the Company.

(j) “Class A Stock” shall mean the Class A Stock, par value \$0.001 per share, of the Company.

(k) “Closing Date” shall have the meaning set forth in the Purchase Agreement.

(l) “Common Stock” shall have the meaning set forth in the Preamble to this Agreement.

(m) “Common Stock Equivalents” shall mean any options, warrants or other securities (including Class A Stock) or rights convertible into or exercisable or exchangeable for, whether directly or following conversion into or exercise or exchange for other options, warrants or other securities or rights, shares of Common Stock.

(n) “Company” shall have the meaning set forth in the Preamble to this Agreement.

(o) “Demand Request” shall have the meaning set forth in Section 2.1.

(p) “Disposition” or “Dispose of” shall mean any (i) offer, pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Class A Stock or Common Stock, or any Common Stock Equivalents, including, without limitation, any “short sale” or similar arrangement, or (ii) swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Class A Stock or Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

(q) “Exchange Act” shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC promulgated thereunder.

(r) “Extraordinary Matter” shall have the meaning set forth in Section 5.2.

(s) “Filing Date” shall mean (i) with respect to any Registration Statement to be filed on Form S-1 (or any applicable successor form), ninety (90) days after receipt by the Company of a Demand Request for such Registration Statement and (ii) with respect to any Registration Statement to be filed on Form S-3 (or any applicable successor form), forty-five (45) days after receipt by the Company of a Demand Request for such Registration Statement.

(t) “Governmental Authority” shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.

(u) “Holders” shall mean (but, in each case, only for so long as such Person remains an Affiliate of sanofi-aventis) the Investor, Aventis and any Permitted Transferee thereof, if any, in accordance with Section 2.12.

(v) “Initiating Holder” shall have the meaning set forth in Section 2.2.

(w) “Interference” shall have the meaning set forth in Section 2.5.

(x) “Investor” shall have the meaning set forth in the Preamble to this Agreement.

(y) “Law” or “Laws” shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

(z) “Lock-Up Term” shall have the meaning set forth in Section 4.1.

(aa) “Modified Clause” shall have the meaning set forth in Section 7.7. (bb) “Offeror” shall have the meaning set forth in Section 3.1(c).

(cc) “Other Holders” shall mean any Person having rights to participate in a registration of the Company’s securities.

(dd) “Permitted Transferee” shall mean a controlled Affiliate of sanofi-aventis that is wholly owned, directly or indirectly, by sanofi-aventis; it being understood that for purposes of this definition “wholly owned” shall mean an Affiliate in which sanofi-aventis owns, directly or indirectly, at least ninety-nine percent (99%) of the outstanding capital stock of such Affiliate.

(ee) “Person” shall mean any individual, partnership, firm, corporation, association, trust, unincorporated organization, government or any department or agency thereof or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

(ff) “Prospectus” shall mean the prospectus forming a part of any Registration Statement, as supplemented by any and all prospectus supplements and as amended by any and all amendments (including post-effective amendments) and including all material incorporated by reference or explicitly deemed to be incorporated by reference in such prospectus.

(gg) “Purchase Agreement” shall have the meaning set forth in the Preamble to this Agreement, and shall include all Exhibits attached thereto.

(hh) “Purchased Shares” shall have the meaning set forth in the Preamble to this Agreement, and shall be adjusted for (i) any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the Purchased Shares.

(ii) “Purchaser Parties” shall have the meaning set forth in the Preamble to this Agreement.

(jj) “registers,” “registered,” and “registration” refer to a registration effected by preparing and filing a Registration Statement or similar document in compliance with the Securities Act, and the declaration or ordering of effectiveness of such Registration Statement or document by the SEC.

(kk) “Registrable Securities” shall mean (i) the Purchased Shares and any shares of Common Stock owned of record by Aventis as of the date of this Agreement, together with any shares of Common Stock issued in respect thereof as a result of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the shares of Common Stock described in clause (i) of this definition, excluding in all cases, however, (A) any Registrable Securities if and after they have been transferred to a Permitted Transferee in a transaction in connection with which registration rights granted hereunder are not assigned, (B) any Registrable Securities sold to or through a broker or dealer or underwriter in a public distribution or a public securities transaction or (C) Registrable Securities eligible for resale pursuant to Rule 144(k) under the Securities Act.

(ll) “Registration Expenses” shall mean all expenses incurred by the Company in connection with any Required Registration pursuant to Section 2.1 or the Company’s compliance with Section 2.7 (excluding clauses (m), (n) and (r) thereof), including, without limitation, all registration and filing fees, fees and expenses of compliance with securities or blue sky Laws (including reasonable fees and disbursements of counsel in connection with blue sky qualifications of any Registrable Securities), expenses of printing (i) certificates for any Registrable Securities in a form eligible for deposit with the Depository Trust Company or (ii) Prospectuses if the printing of Prospectuses is requested by Holders, messenger and delivery expenses, fees and disbursements of counsel for the Company and its independent certified public accountants (including the expenses of any management review, cold comfort letters or any special audits required by or incident to such performance and compliance), Securities Act liability insurance (if the Company elects to obtain such insurance), the reasonable fees and expenses of any special experts retained by the Company in connection with such registration, fees and expenses of other Persons retained by the Company and the reasonable fees and expenses of one (1) counsel for the Holders of Registrable Securities in each Required Registration, selected by the Holders of a majority of the Registrable Securities to be included in such Required Registration. In addition, the Company will pay its internal expenses (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), the expense of any annual audit and the fees and expenses incurred in connection with the listing of the Purchased Shares to be registered on each securities exchange,

if any, on which equity securities issued by the Company are then listed or the quotation of such securities on any national securities exchange on which equity securities issued by the Company are then quoted.

(mm) “Registration Rights Term” shall have the meaning set forth in Section 2.1.

(nn) “Registration Statement” shall mean any registration statement of the Company under the Securities Act that covers any of the Registrable Securities pursuant to the provisions of this Agreement, including the related Prospectus, all amendments and supplements to such registration statement (including post-effective amendments), and all exhibits and all materials incorporated by reference or explicitly deemed to be incorporated by reference in such Registration Statement.

(oo) “Required Period” with respect to a Required Registration shall mean the earlier of (i) the date on which all Registrable Securities covered by such Required Registration are sold pursuant thereto and (ii) one-hundred twenty (120) days following the first day of effectiveness of the Registration Statement for such Required Registration, in each case subject to extension as set forth herein; provided, however, that in no event will the Required Period expire prior to the expiration of the applicable period referred to in Section 4(3) of the Securities Act and Rule 174 promulgated thereunder.

(pp) “Required Registration” shall have the meaning set forth in Section 2.1.

(qq) “Sanofi License and Collaboration Agreement” shall mean that certain License and Collaboration Agreement between the Company, the Investor and Aventis dated as of November 28, 2007, as the same may be amended from time to time.

(rr) “sanofi-aventis” shall have the meaning set forth in the Preamble to this Agreement.

(ss) “Sanofi US” shall have the meaning set forth in the Preamble to this Agreement.

(tt) “SEC” shall mean the United States Securities and Exchange Commission.

(uu) “Securities Act” shall mean the Securities Act of 1933, as amended, and the rules and regulations of the SEC promulgated thereunder.

(vv) “Selling Expenses” shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities pursuant to this Agreement.

(ww) “Shares of Then Outstanding Common Stock” shall mean, at any time, the issued and outstanding shares of Class A Stock and Common Stock at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend, or reclassification of Class A Stock or Common Stock distributable, on a pro rata basis, to all holders of Class A Stock and Common Stock, as applicable.

(xx) “Standstill Limit” shall mean (i) from the Closing Date until the fourth (4<sup>th</sup>) anniversary of the Closing Date, the lesser of (A) twenty-one percent (21%) of the Shares of Then Outstanding Common Stock, in the case of this clause (A) only, calculated on a fully diluted basis assuming the full conversion into, or exercise or exchange for, shares of Common Stock of all Common Stock Equivalents outstanding (as such Common Stock Equivalents outstanding are calculated from the Company’s most recent Form 10-Q or Form 10-K, as applicable, filed with the SEC), and (B) twenty-five percent (25%) of the Shares of Then Outstanding Common Stock, and (ii) from the fourth (4<sup>th</sup>) anniversary of the Closing Date until the expiration of the Standstill Term, thirty percent (30%) of the Shares of Then Outstanding Common Stock.

(yy) “Standstill Parties” shall have the meaning set forth in Section 3.1. (zz) “Standstill Term” shall have the meaning set forth in Section 3.1.

(aaa) “Third Party” shall mean any Person other than the Purchaser Parties, the Company or any of their respective Affiliates.

(bbb) “Underwritten Registration” or “Underwritten Offering” shall mean a registration in which Registrable Securities are sold to an underwriter for reoffering to the public.

(ccc) “Violation” shall have the meaning set forth in Section 2.10(a).

## **2. Registration Rights.**

**2.1 Required Registration.** If, at any time after the expiration of the Lock-Up Term but no later than the tenth (10<sup>th</sup>) anniversary of such expiration (the “Registration Rights Term”), the Company receives from any Holder or Holders a written request or requests (each, a “Demand Request”) that the Company file a Registration Statement under the Securities Act to effect the registration (a “Required Registration”) of Registrable Securities, the Company shall use all reasonable efforts to file a Registration Statement covering such Holders’ Registrable Securities as soon as practicable (and by the applicable Filing Date) and shall use all reasonable efforts to, as soon as practicable thereafter, effect the registration of the Registrable Securities to permit or facilitate the sale and distribution in an Underwritten Offering of all or such portion of such Holder’s or Holders’ Registrable Securities as are specified in such Demand Request, subject however, to the conditions and limitations set forth herein; provided, however, that the Company shall not be obligated to effect any registration of Registrable Securities upon receipt of a Demand Request pursuant to this Section 2.1 if:

(i) the Company has already completed three (3) Required Registrations;

(ii) (A) in the event that the market value of all Registrable Securities outstanding is equal to or greater than \$50,000,000, the market value of the Registrable Securities proposed to be included in the registration, based on the average closing price during the ten (10) consecutive trading days period prior to the making of the Demand Request, is less than \$50,000,000 or (B) in the event that the market value of all Registrable Securities outstanding is less than

\$50,000,000, (i) less than all such Registrable Securities are proposed to be included in the registration, or (ii) the market value of all such Registrable Securities is less than \$25,000,000;

(iii) the Company shall furnish to the Holders a certificate signed by an authorized officer of the Company stating that (A) within ninety (90) days of receipt of the Demand Request under this Section 2.1, the Company shall file a registration statement for the public offering of securities for the account of the Company (other than a registration of securities (x) issuable pursuant to an employee stock option, stock purchase or similar plan, (y) issuable pursuant to a merger, exchange offer or a transaction of the type specified in Rule 145(a) under the Securities Act or (z) in which the only securities being registered are securities issuable upon conversion of debt securities which are also being registered), or (B) the Company is engaged in a material transaction or has an undisclosed material corporate development, in either case, which would be required to be disclosed in the Registration Statement, and in the good faith judgment of the Company's Board of Directors, such disclosure would be seriously detrimental to the Company and its stockholders at such time (in which case, the Company shall disclose the matter as promptly as reasonably practicable and thereafter file the Registration Statement, and each Holder agrees not to disclose any information about such material transaction to Third Parties until such disclosure has occurred or such information has entered the public domain other than through breach of this provision by such Holder), provided, however, that the Company shall have the right to only defer the filing of the Registration Statement pursuant to this subsection once in any twelve (12) month period and, such deferral may not exceed a period of more than one-hundred twenty (120) days after receipt of a Demand Request;

(iv) the Company has, within the twelve (12) month period preceding the date of the Demand Request, already effected one (1) Required Registration for any Holder pursuant to this Section 2.1; or

(v) at any time during the period between the Company's receipt of the Demand Request and the completion of the Required Registration, any Holder is in breach of or has failed to cause its Affiliates to comply with the obligations and restrictions of Sections 3, 4 or 5 of this Agreement, and such breach or failure is ongoing and has not been remedied; it being understood that (A) a one-time, inadvertent and de minimis breach of Section 4 shall not be deemed to be a breach of the obligations and restrictions under Section 4 for purposes of this Section 2.1(v) and (B) a de minimis breach of Section 3.1(a) hereof, or an inadvertent breach of Section 3.1(g) hereof arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of Section 3.1, shall not be deemed to be a breach of the obligations and restrictions under Section 3.1 for purposes of this Section 2.1(v).

**2.2 Underwritten Required Registration Required; Priority in Underwritten Offering.** The underwriter for any Underwritten Offering requested pursuant to Section 2.1 shall be selected by a majority in interest of the Holders initiating the Required Registration hereunder (such Holder(s) initiating the registration request, the “Initiating Holders”) and shall be acceptable to the Company. The right of any Holder to include its Registrable Securities in the Underwritten Offering shall be conditioned upon such Holder’s participation in such Underwritten Offering and the inclusion of such Holder’s Registrable Securities to the extent provided herein. All Holders requesting the inclusion of their Registrable Securities in such Underwritten Offering shall (together with the Company as provided in Section 2.7(h)) enter into an underwriting agreement in customary form with the underwriter or underwriters selected for such Underwritten Offering. Notwithstanding any other provision of this Section 2, if the managing underwriter for the Underwritten Offering determines in good faith that marketing factors require a limitation of the number of shares of Registrable Securities to be included in such Underwritten Offering, then the Company shall so advise all Holders which requested inclusion of their Registrable Securities in such Underwritten Offering, and the number of shares of Registrable Securities that may be included in such Underwritten Offering shall be allocated among the Holders in proportion (as nearly as practicable) to the amount of Registrable Securities of the Company owned by each Holder; provided, however, that the number of shares of Registrable Securities to be included in such Underwritten Offering shall not be reduced unless all other securities are first entirely excluded from such Underwritten Offering. In the event the Company advises the Holders of its intent to decrease the total number of Registrable Securities that may be included by the Holders in such Required Registration such that the number of Registrable Securities included in such Required Registration would be less than seventy-five percent (75%) of all Registrable Securities which the Holders requested be included in such Required Registration, then Holders representing a majority of the Registrable Securities requested to be included in such Required Registration will have the right to withdraw, on behalf of all Holders of all Registrable Securities requested to be so included, such Required Registration, in which case, such Required Registration will not count as a Required Registration for the purposes of Section 2.1(i), and the Company shall bear all Registration Expenses in connection therewith; provided, that, the right to withdraw a registration and have it not count as a Required Registration may only be exercised once by the Holders (taken collectively).

**2.3 Priority in Required Registration.** With respect to any Required Registration of Registrable Securities requested pursuant to Section 2.1, the Company may also (i) propose to sell shares of Common Stock on its own behalf and (ii) provide written notice of such Required Registration to Other Holders and permit all such Other Holders who request to be included in the Required Registration to include any or all Company securities held by such Other Holders in such Required Registration on the same terms and conditions as the Registrable Securities. Notwithstanding the foregoing, if the managing underwriter or underwriters of the Underwritten Offering to which any Required Registration relates advise the Company and the Holders of Registrable Securities that, in its good faith determination, the total amount of securities that such Holders, Other Holders, and the Company intend to include in such Required Registration is in an amount in the aggregate which would adversely affect the success of such Underwritten Offering, then such Required Registration shall include (i) first, all Registrable Securities of the Holders allocated, if the amount is less than all the Registrable Securities requested to be sold, *pro rata* on the basis of the total number of Registrable Securities held by such Holders; and (ii) second, as many other securities proposed to be included in the Required Registration by the

Company and any Other Holders, allocated *pro rata* among the Company and such Other Holders, on the basis of the amount of securities requested to be included therein by the Company and each such Other Holder so that the total amount of securities to be included in such Underwritten Offering is the full amount that, in the written opinion of such managing underwriter, can be sold without materially and adversely affecting the success of such Underwritten Offering.

**2.4 Revocation of Required Registration.** With respect to one (1) Required Registration only, the Holders of at least a majority of the Registrable Securities to be included in a Registration Statement with respect to such Required Registration may, at any time prior to the effective date of such Registration Statement, on behalf of all Holders of all Registrable Securities requested to be included therein, revoke the request to have Registrable Securities included therein and revoke the request for such Required Registration by providing a written notice to the Company, in which case such Required Registration that has been revoked will be deemed not to have been effected and will not count as a Required Registration for purposes of Section 2.1(i) if, and only if, the Holders of Registrable Securities which had requested inclusion of Registrable Securities in such Required Registration promptly reimburse the Company for all Registration Expenses incurred by the Company in connection with such Required Registration. Notwithstanding the foregoing sentence, the parties agree and acknowledge that the Holders may revoke any Required Registration (without any obligation to reimburse the Company for Registration Expenses incurred in connection therewith) if such revocation is based on (i) a material adverse change in circumstances with respect to the Company and its subsidiaries, taken as a whole, caused by an act or failure to act by the Company or any of its subsidiaries and not known to any Holder at the time the Required Registration was first made or (ii) the Company's failure to comply in any material respect with its obligations hereunder, and any such revocation based on an event described in (i) or (ii) above shall be exercisable at any time and shall not be counted as the one (1) revocation of a Required Registration permitted by the first sentence of this Section 2.4.

**2.5 Effective Required Registrations.** A Required Registration will not be deemed to be effected for purposes of Section 2.1(i) if the Registration Statement for such Required Registration has not been declared effective by the SEC or become effective in accordance with the Securities Act and the rules and regulations thereunder and kept effective for the Required Period. In addition, if after such Registration Statement has been declared or becomes effective, (i) the offering of Registrable Securities pursuant to such Registration Statement is interfered with by any stop order, injunction, or other order or requirement of the SEC or other governmental agency or court such that the continued offer and sale of Registrable Securities being offered pursuant to such Registration Statement would violate applicable Law and such stop order, injunction or other order or requirement of the SEC or other governmental agency or court does not result from any act or omission of any Holder whose Registrable Securities are registered pursuant to such Registration Statement (an "Interference") and (ii) any such Interference is not cured within sixty (60) days thereof, such Required Registration will be deemed not to have been effected and will not count as a Required Registration. In the event such Interference occurs and is cured, the Required Period relating to such Registration Statement will be extended by the number of days of such Interference, including the date such Interference is cured.

**2.6 Continuous Effectiveness of Registration Statement.** The Company will use all reasonable efforts to cause each Registration Statement filed pursuant to this Section 2 to be declared effective by the SEC or to become effective under the Securities Act as promptly as practicable and to keep each such Registration Statement that has been declared or becomes effective continuously effective for the Required Period.

**2.7 Obligations of the Company.** Whenever required under Section 2.1 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a Registration Statement with respect to such Registrable Securities sought to be included therein; provided that at least five (5) Business Days prior to filing any Registration Statement or Prospectus or any amendments or supplements thereto, the Company shall furnish to the Holders of the Registrable Securities covered by such Registration Statement, their counsel and the managing underwriter copies of all such documents proposed to be filed, and any such Holder shall have the opportunity to comment on any information pertaining solely to such Holder and its plan of distribution that is contained therein and the Company shall make the corrections reasonably requested by such Holder or the managing underwriter with respect to such information prior to filing any such Registration Statement or amendment;

(b) prepare and file with the SEC such amendments and post-effective amendments to any Registration Statement and any Prospectus used in connection therewith as may be necessary to keep such Registration Statement effective for the Required Period, and cause the Prospectus to be supplemented by any required prospectus supplement, and as so supplemented to be filed pursuant to Rule 424 under the Securities Act, to comply with the provisions of the Securities Act with respect to the disposition of all Registrable Securities covered by such registration statement for the Required Period; provided that at least five (5) Business Days prior to filing any such amendments and post effective amendments or supplements thereto, the Company shall furnish to the Holders of the Registrable Securities covered by such Registration Statement, their counsel and the managing underwriter copies of all such documents proposed to be filed, and any such Holder or managing underwriter shall have the opportunity to comment on any information pertaining solely to such Holder and its plan of distribution that is contained therein and the Company shall make the corrections reasonably requested by such Holder and the managing underwriter with respect to such information prior to filing any such Registration Statement or amendment;

(c) furnish to the Holders of Registrable Securities covered by such Registration Statement and the managing underwriter such numbers of copies of such Registration Statement, each amendment and supplement thereto, the Prospectus included in such Registration Statement (including each preliminary prospectus or free writing prospectus) in conformity with the requirements of the Securities Act, and such other documents as they may reasonably request in order to facilitate the disposition of Registrable Securities owned by them;

(d) notify the Holders of Registrable Securities covered by such Registration Statement, promptly after the Company shall receive notice thereof, of the time when such

Registration Statement becomes or is declared effective or when any amendment or supplement or any Prospectus forming a part of such Registration Statement has been filed;

(e) notify the Holders of Registrable Securities covered by such Registration Statement promptly of any request by the SEC for the amending or supplementing of such Registration Statement or Prospectus or for additional information and promptly deliver to such Holders copies of any comments received from the SEC;

(f) notify the Holders promptly of any stop order suspending the effectiveness of such Registration Statement or Prospectus or the initiation of any proceedings for that purpose, and use all reasonable efforts to obtain the withdrawal of any such order or the termination of such proceedings;

(g) use all reasonable efforts to register and qualify the Registrable Securities covered by such Registration Statement under such other securities or blue sky Laws of such jurisdictions as shall be reasonably requested by the Holders, use all reasonable efforts to keep each such registration or qualification effective, including through new filings, or amendments or renewals, during the Required Period, and notify the Holders of Registrable Securities covered by such Registration Statement of the receipt of any written notification with respect to any suspension of any such qualification; provided, however, that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions;

(h) enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriter of the Underwritten Offering pursuant to which such Registrable Securities are being offered;

(i) use all reasonable efforts to obtain: (A) at the time of effectiveness of the Registration Statement covering such Registrable Securities, a "cold comfort letter" from the Company's independent certified public accountants covering such matters of the type customarily covered by "cold comfort letters" as the underwriters may reasonably request; and (B) at the time of any underwritten sale pursuant to such Registration Statement, a "bring-down comfort letter," dated as of the date of such sale, from the Company's independent certified public accountants covering such matters of the type customarily covered by "bring-down comfort letters" as the underwriters may reasonably request.

(j) promptly notify each Holder of Registrable Securities covered by such Registration Statement at any time when a Prospectus relating thereto is required to be delivered under the Securities Act of the happening of any event as a result of which the Prospectus included in such Registration Statement or any offering memorandum or other offering document includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing, and promptly prepare a supplement or amendment to such Prospectus or file any other required document so that, as thereafter delivered to the purchasers of such Registrable Securities, such Prospectus will not contain an untrue statement of material fact or omit to state any fact necessary to make the statements therein not misleading;

(k) permit any Holder of Registrable Securities covered by such Registration Statement, which Holder in its reasonable judgment could reasonably be deemed to be an underwriter with respect to the Underwritten Offering pursuant to which such Registrable Securities are being offered, or to be a controlling Person of the Company, to reasonably participate in the preparation of such Registration Statement and to require the insertion therein of information to the extent concerning such Holder, furnished to the Company in writing, which in the reasonable judgment of such Holder and its counsel should be included;

(l) in connection with any Underwritten Offering, use all reasonable efforts to obtain an opinion or opinions addressed to the underwriter or underwriters in customary form and scope from counsel for the Company;

(m) upon reasonable notice and during normal business hours, subject to the Company receiving customary confidentiality undertakings or agreements from any Holder of Registrable Securities covered by such Registration Statement or other person obtaining access to Company records, documents, properties or other information pursuant to this subsection (m), make available for inspection by a representative of such Holder and any underwriter participating in any disposition of such Registrable Securities and any attorneys or accountants retained by any such Holder or underwriter, relevant financial and other records, pertinent corporate documents and properties of the Company, and use all reasonable efforts to cause the officers, directors and employees of the Company to supply all information reasonably requested by any such representative, underwriter, attorneys or accountants in connection with the Registration Statement;

(n) with respect to one (1) Required Registration which includes Registrable Securities the market value of which is at least one hundred million United States dollars (\$100,000,000), participate, to the extent requested by the managing underwriter, in efforts extending for no more than five (5) days scheduled by such managing underwriter and reasonably acceptable to the Company's senior management, to sell the Registrable Securities being offered pursuant to such Required Registration (including participating during such period in customary "roadshow" meetings with prospective investors);

(o) use all reasonable efforts to comply with all applicable rules and regulations of the SEC relating to such registration and make generally available to its security holders earning statements satisfying the provisions of Section 11(a) of the Securities Act, provided that the Company will be deemed to have complied with this Section 2.7(o) with respect to such earning statements if it has satisfied the provisions of Rule 158;

(p) if requested by the managing underwriter or any selling Holder, promptly incorporate in a prospectus supplement or post-effective amendment such information as the managing underwriter or any selling Holder reasonably requests to be included therein, with respect to the Registrable Securities being sold by such selling Holder, including, without limitation, the purchase price being paid therefor by the underwriters and with respect to any other terms of the Underwritten Offering of Registrable Securities to be sold in such offering, and promptly make all required filings of such prospectus supplement or post-effective amendment;

(q) cause the Registrable Securities covered by such Registration Statement to be listed on each securities exchange, if any, on which equity securities issued by the Company are then listed; and

(r) reasonably cooperate with each selling Holder and each underwriter participating in the disposition of such Registrable Securities and their respective counsel in connection with filings required to be made with the Financial Industry Regulatory Authority, Inc., if any.

**2.8 Furnish Information.** It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself and the Registrable Securities held by it as shall be reasonably necessary to effect the registration of such Holder's Registrable Securities.

**2.9 Expenses.** Except as specifically provided herein, all Registration Expenses shall be borne by the Company. All Selling Expenses incurred in connection with any registration hereunder shall be borne by the Holders of Registrable Securities covered by a Registration Statement, pro rata on the basis of the number of Registrable Securities registered on their behalf in such Registration Statement.

**2.10 Indemnification.** In the event any Registrable Securities are included in a Registration Statement under this Agreement:

(a) The Company shall indemnify and hold harmless each Holder including Registrable Securities in any such Registration Statement, any underwriter (as defined in the Securities Act) for such Holder and each Person, if any, who controls such Holder or underwriter within the meaning of Section 15 of the Securities Act or Section 20 of Exchange Act and the officers, directors, owners, agents and employees of such controlling Persons, against any and all losses, claims, damages or liabilities (joint or several) to which they may become subject under any securities Laws including, without limitation, the Securities Act, the Exchange Act, or any other statute or common law of the United States or any other country or political subdivision thereof, or otherwise, including the amount paid in settlement of any litigation commenced or threatened (including any amounts paid pursuant to or in settlement of claims made under the indemnification or contribution provisions of any underwriting or similar agreement entered into by such Holder in connection with any offering or sale of securities covered by this Agreement), and shall promptly reimburse them, as and when incurred, for any legal or other expenses incurred by them in connection with investigating any claims and defending any actions, insofar as any such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (each, a "Violation"): (i) any untrue statement or alleged untrue statement of a material fact contained in or incorporated by reference into such Registration Statement, including any preliminary prospectus or final prospectus contained therein or any free writing prospectus or any amendments or supplements thereto, or in any offering memorandum or other offering document relating to the offering and sale of such securities or (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; provided, however, the Company shall not be liable in any such case for any such loss, claim,

damage, liability or action to the extent that it (A) arises out of or is based upon a Violation which occurs solely in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder; or (B) is caused by such Holder's disposition of Registrable Shares during any period during which such Holder is obligated to discontinue any disposition of Registrable Shares as a result of any stop order suspending the effectiveness of any registration statement or prospectus with respect to Registrable Securities.

(b) Each Holder including Registrable Securities in a registration statement shall indemnify and hold harmless the Company, each of its directors, each of its officers who has signed the registration statement, each Person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act and the officers, directors, owners, agents and employees of such controlling Persons, any underwriter, any other Holder selling securities in such registration statement and any controlling Person of any such underwriter or other Holder, against any losses, claims, damages or liabilities (joint or several) to which any of the foregoing Persons may become subject, under liabilities (or actions in respect thereto) which arise out of or are based upon any Violation, in each case to the extent (and only to the extent) that such Violation: (i) arises out of or is based upon a Violation which occurs solely in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder; or (ii) is caused by such Holder's disposition of Registrable Shares during any period during which such Holder is obligated to discontinue any disposition of Registrable Shares as a result of any stop order suspending the effectiveness of any registration statement or prospectus with respect to Registrable Securities. Each such Holder shall pay, as incurred, any legal or other expenses reasonably incurred by any Person intended to be indemnified pursuant to this Section 2.10(b), in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the indemnity agreement contained in this Section 2.10(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without consent of the Holder, which consent shall not be unreasonably withheld.

(c) Promptly after receipt by an indemnified party under this Section 2.10 of notice of the commencement of any action (including any action by a Governmental Authority), such indemnified party shall, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.10, deliver to the indemnifying party a written notice of the commencement thereof and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly notified, to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party shall have the right to retain its own counsel, with the reasonable fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such indemnifying party of any liability to the indemnified party under this Section 2.10, but the omission so to deliver written notice to the indemnifying party shall not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.10.

(d) In order to provide for just and equitable contribution to joint liability in any case in which a claim for indemnification is made pursuant to this Section 2.10 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Section 2.10 provided for indemnification in such case, the Company and each Holder of Registrable Securities shall contribute to the aggregate losses, claims, damages or liabilities to which they may be subject (after contribution from others) in proportion to the relative fault of the Company, on the one hand, and such Holder, severally, on the other hand; provided, however, that in any such case, no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; provided further, however, that in no event shall any contribution under this Section 2.10(d) on the part of any Holder exceed the net proceeds received by such Holder from the sale of Registrable Securities giving rise to such contribution obligation.

(e) The obligations of the Company and the Holders under this Section 2.10 shall survive the completion of any offering of Registrable Securities in a registration statement under this Agreement and otherwise.

**2.11 SEC Reports.** With a view to making available to the Holders the benefits of Rule 144 under the Securities Act and any other rule or regulation of the SEC that may at any time permit a Holder to sell Registrable Securities of the Company to the public without registration, the Company agrees to at any time that it is a reporting company under Section 13 or 15(d) of the Exchange Act:

(a) file with the SEC in a timely manner all reports and other documents required of the Company under the Exchange Act; and

(b) furnish to any Holder, so long as such Holder owns any Registrable Securities, forthwith upon request (i) a written statement by the Company that it has complied with the reporting requirements of the Exchange Act, (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC (exclusive of Rule 144A) which permits the selling of any Registrable Securities without registration.

**2.12 Assignment of Registration Rights.** The rights to cause the Company to register any Registrable Securities pursuant to this Agreement may be assigned in whole or in part (but only with all restrictions and obligations set forth in this Agreement) by a Holder to a Permitted Transferee which acquires Registrable Securities from such Holder; provided, however, (a) such Holder shall, within five (5) days prior to such transfer, furnish to the Company written notice of the name and address of such Permitted Transferee, details of its status as a Permitted Transferee and details of the Registrable Securities with respect to which such registration rights are being assigned, (b) the Permitted Transferee, prior to or simultaneously with such transfer or assignment, shall agree in writing to be subject to and bound by all restrictions and obligations set forth in this Agreement, (c) the Purchaser Parties shall continue to be bound by all restrictions

and obligations set forth in this Agreement and (d) such transfer or assignment shall be effective only if immediately following such transfer or assignment the further disposition of such Registrable Securities by the Permitted Transferee is restricted under the Securities Act and other applicable securities Law.

### 3. Restrictions on Beneficial Ownership.

**3.1 Standstill.** During the period (such period, the “Standstill Term”) from and after the date of this Agreement until the later of (A) the fifth (5<sup>th</sup>) anniversary of the expiration or earlier termination of the “Term” (as such term is defined in the Aventis Collaboration Agreement) and (B) the fifth (5<sup>th</sup>) anniversary of the expiration or earlier termination of the “Term” (as such term is defined in the Sanofi License and Collaboration Agreement), neither the Purchaser Parties nor any of their respective Affiliates (collectively, the “Standstill Parties”) shall (and the Purchaser Parties shall cause their respective Affiliates not to), except as expressly approved or invited in writing by the Company:

(a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Common Stock and/or Common Stock Equivalents, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Common Stock and/or Common Stock Equivalents, if after giving effect to such acquisition, the Standstill Parties would beneficially own more than the Standstill Limit; provided, however, that notwithstanding the provisions of this Section 3.1(a), if the number of shares constituting Shares of Then Outstanding Common Stock is reduced or if the aggregate ownership of the Standstill Parties is increased as a result of a repurchase of Shares of Then Outstanding Common Stock, stock split, stock dividend or a recapitalization of the Company, the Standstill Parties shall not be required to dispose of any of their holdings of Shares of Then Outstanding Common Stock even though such action resulted in the Standstill Parties’ beneficial ownership totaling more than the Standstill Limit;

(b) directly or indirectly, seek to have called any meeting of the stockholders of the Company, propose or nominate for election to the Company’s Board of Directors any person whose nomination has not been approved by a majority of the Company’s Board of Directors or cause to be voted in favor of such person for election to the Company’s Board of Directors any Shares of Then Outstanding Common Stock;

(c) directly or indirectly, encourage or support a tender, exchange or other offer or proposal by any other Person or group (an “Offeror”) the consummation of which would result in a Change of Control of the Company (an “Acquisition Proposal”);

(d) directly or indirectly, solicit proxies or consents or become a participant in a solicitation (as such terms are defined in Regulation 14A under the Exchange Act) in opposition to the recommendation of a majority of the Company’s Board of Directors with respect to any matter, or seek to advise or influence any Person, with respect to voting of any Shares of Then Outstanding Common Stock of the Company;

(e) deposit any Shares of Then Outstanding Common Stock in a voting trust or subject any Shares of Then Outstanding Common Stock to any arrangement or agreement with respect to the voting of such Shares of Then Outstanding Common Stock;

(f) act in concert with any Third Party to take any action in clauses (a) through (e) above, or form, join or in any way participate in a “partnership, limited partnership, syndicate, or other group” within the meaning of Section 13(d)(3) of the Exchange Act.

(g) enter into discussions, negotiations, arrangements or agreements with any Person relating to the foregoing actions referred to in (a) through (e) above; or

(h) request or propose in writing to the Company’s Board of Directors, any member(s) thereof or any officer of the Company that the Company amend, waive, or consider the amendment or waiver of, any provisions set forth in this Section 3.1;

provided, however, that the mere voting in accordance with Section 5 hereof of any voting securities of the Company held by the Purchaser Parties or their Affiliates shall not constitute a violation of any of clauses (a) through (h) above.

**3.2 Amendment to Aventis Collaboration Agreement.** Sections 3.1 and 6.2 of this Agreement shall, effective as of the date of this Agreement, supersede and replace Sections 20.16 and 20.17 of the Aventis Collaboration Agreement. The foregoing sentence shall not impair the rights of the Company or constitute a waiver by the Company of any breach or default by Aventis, Sanofi US or any of their Affiliates under Sections 20.16 and 20.17 of the Aventis Collaboration Agreement. sanofi-aventis, the Investor, Sanofi US and the Company agree that Section 19.5 of the Aventis Collaboration Agreement is hereby amended and restated in its entirety to read:

“Notwithstanding anything to the contrary herein, Regeneron will have the unilateral right to terminate this Agreement in its entirety, upon written notice to Aventis, if any of the Standstill Parties (as defined in the Investor Agreement, dated as of [\_\_\_\_\_], 2007 (the “Investor Agreement”), by and among sanofi-aventis, sanofi-aventis US LLC, Aventis, sanofi-aventis Amérique du Nord and Regeneron) shall have breached Section 3.1 of the Investor Agreement. For the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of a de minimis breach of Section 3.1(a) of the Investor Agreement or an inadvertent breach of Section 3.1(g) of the Investor Agreement arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of Section 3.1 of the Investor Agreement.”

#### **4. Restrictions on Dispositions.**

**4.1 Lock-Up.** From and after the date of this Agreement and until the earlier of (i) the fifth (5<sup>th</sup>) anniversary of the date of this Agreement and (ii) the expiration, or earlier valid termination by Aventis in its entirety pursuant to Section 19.3 or 19.4 thereof, of the Sanofi License and Collaboration Agreement (the “Lock-Up Term”), without the prior approval of a majority of the Company’s Board of Directors, the Purchaser Parties shall not, and shall cause their respective Affiliates not to, Dispose of (x) any of the Purchased Shares or any shares of Common Stock beneficially owned by any Standstill Party as of the date of this Agreement, together with any shares of Common Stock issued in respect thereof as a result of any stock split,

stock dividend, share exchange, merger, consolidation or similar recapitalization, and (y) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the shares of Common Stock described in clause (x) of this sentence; provided, however, that the foregoing shall not prohibit the Investor or Aventis from (A) transferring Registrable Securities to a Permitted Transferee in accordance with and subject to the terms of Section 2.12, or (B) Disposing of any Shares of Then Outstanding Common Stock as they may hold from time to time in order to reduce the beneficial ownership of the Standstill Parties to 19.9% of the Shares of Then Outstanding Common Stock, provided that any such Disposition referred to in this clause (B), whether occurring before or after the expiration of the Lock-Up Term, shall be subject to the restrictions and requirements set forth in paragraphs (a), (b) and (c) of Section 4.2.

**4.2 Limitations Following Lock-Up Term.** The Purchaser Parties agree that, except for any transfer of Registrable Securities by the Investor or Aventis to a Permitted Transferee in accordance with and subject to the terms of Sections 2.12 and 4.1, they shall not, and shall cause their respective Affiliates not to, Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents at any time after the expiration of the Lock-Up Term except (i) pursuant to a registered underwritten public offering in accordance with Section 2, (ii) pursuant to Rule 144 under the Securities Act or (iii) pursuant to privately negotiated sales in transactions exempt from the registration requirements under the Securities Act; provided, however, that:

(a) In any Underwritten Offering in accordance with Section 2, the Holders whose Registrable Securities are included in such Underwritten Offering shall request that the underwriter for such Underwritten Offering, and shall require that the underwriter for such Underwritten Offering shall agree in writing to, use all reasonable efforts to make as broad a distribution as reasonably practical and to prevent any Person, or Affiliates of such Person, from purchasing in such offering Registrable Securities which would constitute, or result in such Person, together with such Person's Affiliates, having beneficial ownership of, five percent (5%) or more of the total shares of Common Stock then outstanding.

(b) The Purchaser Parties shall not (and shall cause their respective Affiliates not to), without the prior approval of a majority of the Company's Board of Directors, Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents if such Disposition, together with any Disposition(s) by any Standstill Parties during the immediately preceding three (3) months, would exceed one million (1,000,000) Shares of Then Outstanding Common Stock of the Company (assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents Disposed of by the Standstill Parties): provided, however, that, without limitation of Section 4.2(a), the foregoing limitations in this Section 4.2(b) shall not prohibit or limit any Disposition of Registrable Securities by a Holder as part of an Underwritten Offering with respect to such Registrable Securities in accordance with Section 2 hereof. This Section 4.2(b) shall, effective as of the date of this Agreement, supersede and replace Section 5.3(a) of the Aventis Stock Purchase Agreement. The foregoing sentence shall not impair the rights of the Company or constitute a waiver by the Company of any breach or default by Aventis or any of its Affiliates under such Section 5.3(a) with respect to events or circumstances occurring or existing prior to the date of this Agreement.

(c) The Purchasing Parties shall not (and shall cause their respective Affiliates not to), without the prior approval of a majority of the Company's Board of Directors, Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents to any Person if such Person is, or such Disposition would (in the case of a Disposition pursuant to Rule 144 under the Securities Act, to the knowledge of any Standstill Party) result in such Person becoming, after giving effect to such Disposition, the beneficial owner of five percent (5%) or more of the total shares of Common Stock then outstanding; provided, however, that, without limitation of Section 4.2(a), the foregoing limitation in this Section 4.2(c) shall not prohibit or limit any Disposition of Registrable Securities by a Holder as part of a registered offering with respect to such Registrable Securities in accordance with Section 2 hereof.

**4.3 Certain Tender Offers.** Notwithstanding any other provision of this Section 4, this Section 4 shall not prohibit or restrict any Disposition of Shares of Then Outstanding Common Stock and/or Common Stock Equivalents by the Standstill Parties into (a) a tender offer by a Third Party which is not opposed by the Company's Board of Directors (but only after the Company's filing of a Schedule 14D-9, or any amendment thereto, with the SEC disclosing the recommendation of the Company's Board of Directors with respect to such tender offer) or (b) an issuer tender offer by the Company.

**4.4 Offering Lock-Up.** The Holders shall, if requested by the Company and an underwriter of Common Stock of the Company, agree not to Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents for a specified period of time, such period of time not to exceed ninety (90) days. Such agreement shall be in writing in a form satisfactory to the Company and the underwriter(s) in such offering. The Company may impose stop transfer instructions with respect to the Shares of Then Outstanding Common Stock and/or Common Stock Equivalents subject to the foregoing restrictions until the end of the specified period of time. This Section 4.4 shall, effective as of the date of this Agreement, supersede and replace Section 5.3(c) of the Aventis Stock Purchase Agreement.

## **5. Voting Agreement.**

**5.1 Voting of Securities.** From and after the date of this Agreement, other than as permitted by Section 5.2 with respect to Extraordinary Matters, in any vote or action by written consent of the stockholders of the Company (including, without limitation, with respect to the election of directors), the Purchaser Parties shall, and shall cause their respective Affiliates to, vote or execute a written consent with respect to all voting securities of the Company as to which they are entitled to vote or execute a written consent, in the sole discretion of the Purchaser Parties, either (a) in accordance with the recommendation of the Company's Board of Directors or (b) if such Purchaser Party or Affiliate of a Purchaser Party has delivered written notice to the Company at any time prior to the vote on any given matter or the effective time of an action to be taken by written consent, setting forth its intent to vote pursuant to this Section 5.1(b), in the same proportion as the votes cast by all other holders of all classes of voting securities of the Company (as estimated by the inspector of election immediately prior to the closing of the polls with respect to the vote on any given matter, subject to adjustment for the inspector of election's final tabulation of votes cast). In the event that a Purchaser Party or Affiliate of a Purchaser Party does not deliver written notice to the Company as provided in Section 5.1(b), such Person shall be deemed to have elected to vote all voting securities of the Company as to which it is

entitled to vote as provided in Section 5.1(a). In furtherance of this Section 5.1, the Purchaser Parties shall, and shall cause their respective Affiliates to, if and when requested by the Company from time to time, promptly execute and deliver to the Company an irrevocable proxy, substantially in the form of Exhibit A attached hereto, and irrevocably appoint the Company or its designees, with full power of substitution, its attorney, agent and proxy to vote (or cause to be voted) or to give consent with respect to, all of the voting securities of the Company as to which such Purchaser Party or Affiliate of a Purchaser Party is entitled to vote, in the manner and with respect to the matters set forth in this Section 5.1. The Purchaser Parties acknowledge, and shall cause their Affiliates to acknowledge, that any such proxy executed and delivered shall be coupled with an interest, shall constitute, among other things, an inducement for the Company to enter into this Agreement, shall be irrevocable and binding on any successor in interest of such Purchaser Party or Affiliate of such Purchaser Party, as applicable, and shall not be terminated by operation of Law upon the occurrence of any event. Such proxy shall operate to revoke and render void any prior proxy as to any voting securities of the Company heretofore granted by such Purchaser Party or Affiliate of such Purchaser Party, as applicable, to the extent it is inconsistent herewith. Such proxy shall terminate upon the earlier of the expiration or termination of this Section 5.1.

**5.2 Certain Extraordinary Matters.** The Purchaser Parties and their Affiliates may vote, or execute a written consent with respect to, any or all of the voting securities of the Company as to which they are entitled to vote or execute a written consent, as they may determine in their sole discretion, with respect to the following matters (each such matter being an “Extraordinary Matter”):

(a) any transaction which would result in a Change of Control;

(b) any vote of the Company’s stockholders with respect to any stock option or stock purchase plan, or any material amendment thereto, or other equity compensation arrangement or material amendment thereto, which has been approved by the Company’s Compensation Committee and taken as a whole is not generally and materially consistent with the Company’s equity compensation historical practices;

(c) any other issuance of shares of Common Stock or Common Stock Equivalents voted upon by stockholders of the Company that equals or exceeds ten percent (10%) of, or ten percent (10%) of the voting power of, the Shares of Then Outstanding Common Stock, as of immediately prior to such issuance; and

(d) any liquidation or dissolution of the Company.

**5.3 Quorum.** In furtherance of Section 5.1, the Purchaser Parties shall be, and shall cause each of their Affiliates to be, present in person or represented by proxy at all meetings of stockholders to the extent necessary so that all voting securities of the Company as to which they are entitled to vote shall be counted as present for the purpose of determining the presence of a quorum at such meeting.

## 6. Termination of Certain Rights and Obligations.

**6.1 Termination of Registration Rights.** Except for Section 2.10, which shall survive until the expiration of any applicable statutes of limitation, Section 2 shall terminate automatically and have no further force or effect upon the earliest to occur of:

- (a) the expiration of the Registration Rights Term;
- (b) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act; and
- (c) a liquidation or dissolution of the Company.

**6.2 Termination of Standstill Agreement.** Provided that none of the Standstill Parties has violated Section 3.1(c), (d) or (f) with respect to the Offeror referred to in this Section 6.2, Section 3 (except for Section 3.2, but only to the extent such Section 3.2 amends Section 19.5 of the Aventis Collaboration Agreement) shall terminate and have no further force or effect, upon the earliest to occur of:

- (a) the public announcement by an Offeror of an Acquisition Proposal for the Company;
- (b) the public announcement by the Company or any Offeror of any definitive agreement providing for a Change of Control of the Company;
- (c) the expiration of the Standstill Term;
- (d) the date of any issuance by the Company to a Third Party of shares of Common Stock, which, when combined with all other Shares of Then Outstanding Common Stock beneficially owned by such Third Party immediately prior to such issuance, represents more than ten percent (10%) of the voting power represented by all Shares of Then Outstanding Common Stock outstanding immediately after giving effect to such issuance, if the Company does not enter into a standstill agreement with such Third Party having material terms substantially similar (i) with respect to restrictions on such Third Party, to the restrictions on the Standstill Parties set forth in Section 3.1 of this Agreement and (ii) with respect to the termination of such restrictions, to the provisions of this Section 6.2; provided, however, that any collaborative or other commercial arrangements between the Company and such Third Party entered into connection with such issuance of Common Stock to such Third Party shall be taken into consideration in determining whether the terms of the standstill agreement entered into with such Third Party are materially similar to the terms of Section 3.1 of this Agreement;
- (e) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act; and
- (f) a liquidation or dissolution of the Company;

provided, however, that if any of the transactions referred to in (a) or (b) above terminates and the Company has not made a public announcement of its intent to solicit or engage in a

transaction (or has announced its decision to discontinue pursuing such a transaction) the consummation of which would result in a Change of Control of the Company, then the restrictions contained in Section 3 shall again be applicable, unless a Standstill Party has announced a bona-fide Acquisition Proposal for the Company prior to such termination.

**6.3 Termination of Restrictions on Dispositions.** Section 4 shall terminate and have no further force or effect upon the earliest to occur of:

- (a) the consummation by an Offeror of a Change of Control of the Company;
- (b) a liquidation or dissolution of the Company; and
- (c) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act.

**6.4 Termination of Voting Agreement.** Section 5 shall terminate and have no further force or effect upon the earliest to occur of:

- (a) the consummation by an Offeror of a Change of Control of the Company;
- (b) a liquidation or dissolution of the Company;
- (c) the date on which the Standstill Parties beneficially own voting securities representing less than five percent (5%) of the voting power of the Shares of Then Outstanding Common Stock; and
- (d) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act.

**6.5 Effect of Termination.** No termination pursuant to any of Sections 6.1, 6.2 or 6.3 or 6.4 shall relieve any of the parties (or the Permitted Transferee, if any) for liability for breach of or default under any of their respective obligations or restrictions under any terminated provision of this Agreement, which breach or default arose out of events or circumstances occurring or existing prior to the date of such termination.

## **7. Miscellaneous.**

**7.1 Governing Law; Submission to Jurisdiction.** This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. The parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

**7.2 Waiver.** Waiver by a party of a breach hereunder by another party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder

shall preclude the later exercise of any such right, power or privilege by such party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

**7.3 Notices.** All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit B attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Any party may change its address by giving notice to the other parties in the manner provided above.

**7.4 Entire Agreement.** This Agreement and the Purchase Agreement contain the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.

**7.5 Amendments.** No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the parties hereto.

**7.6 Headings; Nouns and Pronouns; Section References.** Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

**7.7 Severability.** If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction (“Modified Clause”), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

**7.8 Assignment.** Neither this Agreement nor any rights or duties of a party hereto may be assigned by such party, in whole or in part, without (a) the prior written consent of the Company in the case of any assignment by the Purchaser Parties, except as provided by Section 2.12 with respect to the Investor's or Aventis' assignment to a Permitted Transferee; or (b) the prior written consent of the Purchaser Parties in the case of an assignment by the Company.

**7.9 Successors and Assigns.** This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

**7.10 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

**7.11 Third Party Beneficiaries.** None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.

**7.12 No Strict Construction.** This Agreement has been prepared jointly and will not be construed against any party.

**7.13 Remedies.** The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

**7.14 Specific Performance.** The Purchaser Parties hereby acknowledge and agree that the rights of the parties hereunder are special, unique and of extraordinary character, and that if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or the Purchaser Parties, as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged party at law or in equity, such damaged party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

**7.15 No Conflicting Agreements.** Each of the Purchaser Parties hereby represents and warrants to the Company that neither it nor any of its Affiliates is, as of the date of this Agreement, a party to, and agrees that neither it nor any of its Affiliates shall, on or after the date of this Agreement, enter into any agreement that conflicts with the rights granted to the Company in this Agreement. The Company hereby represents and warrants to each Holder that it is not, as of the date of this Agreement, a party to, and agrees that it shall not, on or after the date of this Agreement, enter into, any agreement or approve any amendment to its Organizational Documents (as defined in the Purchase Agreement) with respect to its securities that conflicts

with the rights granted to the Holders in this Agreement. The Company further represents and warrants that the rights granted to the Holders hereunder do not in any way conflict with the rights granted to any other holder of the Company's securities under any other agreements.

*(Signature Page Follows)*

26

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IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

**SANOFI-AVENTIS**

By: /s/ Jean-Michel Levy  
Name: Jean-Michel Levy  
Title: Senior Vice President, Business  
Development

By: /s/ Laurence Debroux  
Name: Laurence Debroux  
Title: Senior Vice President, Chief Financial  
Officer

**SANOFI-AVENTIS US LLC**

By: /s/ Karen Linehan  
Name: Karen Linehan  
Title: Authorized Representative

By: /s/ Robin White  
Name: Robin White  
Title: Authorized Representative

**AVENTIS PHARMACEUTICALS INC.**

By: /s/ Karen Linehan  
Name: Karen Linehan  
Title: Authorized Representative

By: /s/ Robin White  
Name: Robin White  
Title: Authorized Representative

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**SANOFLI-AVENTIS AMÉRIQUE DU NORD**

By: /s/ Karen Linehan  
Name: Karen Linehan  
Title: Authorized Representative

By: /s/ Jean-Luc Renard  
Name: Jean-Luc Renard  
Title: Authorized Representative

**REGENERON PHARMACEUTICALS, INC.**

By: /s/ Leonard Schleifer  
Name: Leonard Schleifer  
Title: President & CEO

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## EXHIBIT A — FORM OF IRREVOCABLE PROXY

In order to secure the performance of the duties of the undersigned pursuant to Section 5.1 of the Investor Agreement, dated as of [\_\_\_\_], 2007 (the "Agreement"), by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amérique du Nord and Regeneron Pharmaceuticals, Inc. (the "Company"), the undersigned hereby irrevocably appoints [\_\_\_\_] and [\_\_\_\_], and each of them, the attorneys, agents and proxies, with full power of substitution in each of them, for the undersigned, and in the name, place and stead of the undersigned, to vote (or cause to be voted) or, if applicable, to give consent, in such manners as each such attorney, agent and proxy or his substitute shall in his sole discretion deem proper to record such vote (or consent) in the manners, and with respect to such matters as set forth in Section 5.1 of the Agreement (but in any case, in accordance with any written instruction from the undersigned, properly delivered under Section 5.1 of the Agreement, to vote or give consent as contemplated by Section 5.1(b) of the Agreement) with respect to all voting securities (whether taking the form of shares of Common Stock, par value \$0.001 per share, or other voting securities of the Company), which the undersigned is or may be entitled to vote at any meeting of the Company held after the date hereof, whether annual or special and whether or not an adjourned meeting or, if applicable, to give written consent with respect thereto. This proxy is coupled with an interest, shall be irrevocable and binding on any successor in interest of the undersigned and shall not be terminated by operation of law upon the occurrence of any event. This proxy shall operate to revoke and render void any prior proxy as to voting securities heretofore granted by the undersigned which is inconsistent herewith. This proxy shall terminate upon the earlier of the expiration or termination of the voting agreement set forth in Section 5.1 of the Agreement.

[\_\_\_\_\_]

By: \_\_\_\_\_

Name:

Title:

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**EXHIBIT B**  
**NOTICES**

- (a) If to sanofi-aventis, the Investor, Aventis or Sanofi US:

sanofi-aventis  
174, avenue de France  
75013 Paris  
France  
Attention: Chief Financial Officer

with a copy to:

sanofi-aventis  
174, avenue de France  
75013 Paris  
France  
Attention: General Counsel

- (b) If to the Company:

Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591  
U.S.A.  
Attention: President  
Copy: General Counsel

with a copy to:

Skadden, Arps, Slate, Meagher & Flom LLP  
One Beacon Street, 31<sup>st</sup> Floor  
Boston, MA 02108  
Attention: Kent A. Coit

**Regeneron Pharmaceuticals, Inc.**  
**Computation of Ratio of Earnings to Combined Fixed Charges**  
*(Dollars in thousands)*

	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>
<b>Earnings:</b>					
Income (loss) from continuing operations before income (loss) from equity investee	\$(107,395)	\$41,565	\$(95,456)	\$(103,150)	\$(105,600)
Fixed charges	14,108	14,060	13,687	13,643	13,708
Amortization of capitalized interest	33	78	78	73	23
Interest capitalized	(276)	—	—	—	—
Adjusted earnings	<u>\$ (93,530)</u>	<u>\$55,703</u>	<u>\$(81,691)</u>	<u>\$ (89,434)</u>	<u>\$ (91,869)</u>
<b>Fixed charges:</b>					
Interest expense	\$ 11,932	\$12,175	\$ 12,046	\$ 12,043	\$ 12,043
Interest capitalized	276	—	—	—	—
Assumed interest component of rental charges	1,900	1,885	1,641	1,600	1,665
Total fixed charges	<u>\$ 14,108</u>	<u>\$14,060</u>	<u>\$ 13,687</u>	<u>\$ 13,643</u>	<u>\$ 13,708</u>
Ratio of earnings to fixed charges	(A)	3.96	(A)	(A)	(A)

(A) Due to the registrant's losses for the years ended December 31, 2003, 2005, 2006, and 2007 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.

	<u>2003</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>
Coverage deficiency	\$107,638	\$95,378	\$103,077	\$105,577

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 33-50480, 33-85330, 33-97176, 333-33891, 333-80663, 333-61132, 333-97375, and 333-119257) and on Form S-3 (Nos. 333-74464 and 333-121225) of Regeneron Pharmaceuticals, Inc., of our report dated February 27, 2008 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 27, 2008

**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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying 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 the registrant, particularly during the period in which this annual 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 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 annual 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 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 27, 2008

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

**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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying 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 the registrant, particularly during the period in which this annual 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 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 annual 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 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 27, 2008

By: /s/ MURRAY A. GOLDBERG

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

**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, 2007 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

Leonard S. Schleifer, M.D., Ph.D.

Chief Executive Officer

February 27, 2008

/s/ MURRAY A. GOLDBERG

Murray A. Goldberg

Chief Financial Officer

February 27, 2008