

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, 2009

OR

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

For the transition period from _____ to _____

Commission File Number 0-19034

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:

Title of each class

Common Stock - par value \$.001 per share

Name of each exchange on which registered

Nasdaq Global Select Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$1,355,426,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2009, 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 12, 2010:

<u>Class of Common Stock</u>	<u>Number of Shares</u>
Class A Stock, \$.001 par value	2,211,698
Common Stock, \$.001 par value	79,441,680

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2010 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 65 to 68 of this filing.

ITEM 1. BUSINESS

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

General

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have eight product candidates in clinical development, including three that are in late-stage (Phase 3) clinical development. Our late stage programs are rilonacept, which is being developed for the prevention and treatment of gout-related flares; VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs are REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain; REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis; REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology; REGN727, an antibody to PCSK9, which is being developed for low density lipoprotein (LDL) cholesterol reduction; and REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed for certain allergic and immune conditions. All five of our earlier stage clinical programs are fully human antibodies that are being developed in collaboration with sanofi-aventis.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies and combine that foundation with our clinical development and manufacturing capabilities. Our long-term objective is to build a successful, integrated biopharmaceutical company that provides patients and medical professionals with new and better options for preventing and treating human diseases. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*™ 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 (*VelociMab*™) may then be utilized to design and produce new product candidates directed against the disease target. Our five antibody product candidates currently in clinical trials were developed using *VelocImmune*. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Product:

ARCALYST® (rilonacept) – Cryopyrin-Associated Periodic Syndromes (CAPS)

In February 2008, we received marketing approval from the U.S. Food and Drug Administration (FDA) for ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We shipped \$20.0 million of ARCALYST® (rilonacept) to our distributors in 2009, compared to \$10.7 million in 2008. We own worldwide rights to ARCALYST.

In October 2009, rilonacept was approved under exceptional circumstances by the European Medicines Agency (EMA) for the treatment of CAPS with severe symptoms in adults and children aged 12 years and older. Such authorizations are permissible for products for which a company can demonstrate that comprehensive data cannot be provided, for example, because of the rarity of the condition. Each year, we will need to provide for review by the EMA any new or follow-up information that may become available. Rilonacept is not currently marketed in the European Union.

ARCALYST is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST is approved in the United States for patients with CAPS, a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. CAPS is caused by a range of mutations in the gene NLRP3 (formerly known as *CIAS1*) which encodes a protein named cryopyrin. In addition to FCAS and MWS, CAPS includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). ARCALYST has not been studied for the treatment of NOMID.

Clinical Programs:

1. Rilonacept – Inflammatory Diseases

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

Results from this study after the first 16 weeks of urate-lowering therapy were reported at the annual meeting of the European League Against Rheumatism (EULAR) in June 2009. Through 16 weeks, the mean number of flares per patient was 0.93 with placebo and 0.22 with rilonacept ($p=0.0036$). In the first 16 weeks of treatment, 47.6% of patients treated with placebo experienced a gout flare and, of those, 55.0% had more than one flare. Among patients treated with rilonacept, 22.0% experienced a gout flare ($p=0.0209$ versus placebo) and none had more than one flare. Adverse events after 16 weeks of treatment were similar to those reported after 12 weeks with the most frequently reported categories being infection and musculoskeletal complaints.

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

During the first quarter of 2009, we initiated a Phase 3 clinical development program with rilonacept for the treatment of gout. The program includes four clinical trials. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) are evaluating rilonacept versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) is evaluating treatment with rilonacept alone versus rilonacept in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The fourth Phase 3 trial is a placebo-controlled safety study (RE-SURGE) of rilonacept in patients receiving urate-lowering therapy. SURGE and PRE-SURGE 1 are fully enrolled. We expect to report initial data from SURGE and PRE-SURGE 1 during the first half of 2010 and from PRE-SURGE 2 and RE-SURGE during the first half of 2011.

Royalty Agreement with Novartis Pharma AG

In June 2009, we entered into a royalty agreement with Novartis Pharma AG that replaced a previous collaboration and license agreement. Under this agreement, we are entitled to receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1 β antibody. We waived our right to opt-in to the development and commercialization of canakinumab. Canakinumab is approved to treat Cryopyrin-Associated Periodic Syndrome (CAPS) and is in development for chronic gout, type 2 diabetes, and a number of other inflammatory diseases.

2. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of age-related macular degeneration (wet AMD). We and Bayer HealthCare are also conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. We and Bayer HealthCare also initiated a Phase 3 program in central retinal vein occlusion (CRVO) in July 2009. In connection with the dosing of the first patient in a Phase 3 study in CRVO, we received a \$20.0 million milestone payment from Bayer HealthCare.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), are comparing VEGF Trap-Eye and Lucentis[®] (ranibizumab injection), marketed by Genentech, Inc., an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly doses) compared with Lucentis (Genentech) dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents will be evaluated in the second year of the studies. VIEW 1 and VIEW 2 were fully enrolled in 2009, and initial data are expected in late 2010.

We and Bayer HealthCare have conducted a Phase 2 study in wet AMD which demonstrated that patients treated with VEGF Trap-Eye achieved durable improvements in visual acuity and retinal thickness for up to one year. These one-year study results were reported at the 2008 annual meeting of the Retina Society. In this double-masked Phase 2 trial, known as CLEAR-IT 2, 157 patients were initially treated for three months with VEGF Trap-Eye: two groups received monthly doses of 0.5 or 2.0 mg (at weeks 0, 4, 8, and 12) and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg (at baseline and week 12). Following the initial three-month fixed-dosing phase, patients continued to receive VEGF Trap-Eye at the same dose on a PRN dosing schedule through one year, based upon the physician assessment of the need for re-treatment in accordance with pre-specified criteria.

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

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

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

All patients who completed the one year CLEAR-IT 2 study were eligible to participate in an extension stage of the study. Twenty-four-month results of the extension stage were presented in October 2009 at the 2009 American Academy of Ophthalmology meeting. After receiving VEGF Trap-Eye for one year, the 117 patients who elected to enter the extension stage were dosed on a 2.0 mg PRN basis, irrespective of the dose at which they were treated earlier in the study. On a combined basis, for these 117 patients, the mean gain in visual acuity was 7.3 letters ($p < 0.0001$ versus baseline) at the three-month primary endpoint of the original Phase 2 study, 8.4 letters ($p < 0.0001$ versus baseline) at one year, and 6.1 letters ($p < 0.0001$ versus baseline) at month 12 of the extension stage. Thus, after 24 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 4.6 injections over the 21-month PRN dosing phase that extended from month three to month 24. The most common adverse events were those typically associated with intravitreal injections and included conjunctival hemorrhage at the injection site and transient increased intraocular pressure following an injection.

The DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye dosing regimens versus laser treatment. A total of 240 patients with clinically significant DME with central macular involvement were randomized to five groups. VEGF Trap-Eye achieved the primary endpoint of the study, a statistically significant improvement in visual acuity compared to focal laser therapy, the standard of care in DME. Visual acuity was measured by the mean number of letters gained over the initial 24 weeks of the study. Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving focal laser therapy (2.5 letters gained) at week 24 ($p < 0.01$ for each VEGF Trap-Eye group versus focal laser). VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported in the study. The adverse events reported were those typically associated with intravitreal injections or the underlying disease. Following the initial 24 weeks of treatment, patients continue to be treated for another 24 weeks on the same dosing regimens. Initial one-year results will be available later in 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of central retinal vein occlusion (CRVO), another cause of blindness. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Uility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. Enrollment in the COPERNICUS study began during the third quarter of 2009, and enrollment in the GALILEO study began in October 2009. Initial data are anticipated in early 2011.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and CRVO. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare. In 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing

of the first patient in a Phase 3 study of VEGF Trap-Eye in wet AMD. In July 2009, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in CRVO. We can earn up to \$70 million in additional development and regulatory milestones related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

3. 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), VEGF-B, and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are enrolling patients in three Phase 3 trials that combine aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial (called VELOUR) is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen independent prostate cancer in combination with docetaxel/prednisone. All three trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. VITAL and VENICE are fully enrolled, and the VELOUR study is approximately 95% enrolled. In addition, a Phase 2 study (called AFFIRM) of aflibercept in 1st line metastatic colorectal cancer in combination with FOLFOX (folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin) is approximately 75% enrolled.

Each of the Phase 3 studies is monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical experts. The IDMCs meet periodically to evaluate data from the studies and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a prespecified number of events have occurred in each trial. Based on current enrollment and event rates, (i) an interim analysis of VELOUR is expected to be conducted by an IDMC in the second half of 2010, (ii) final results are anticipated in the first half of 2011 from the VITAL study and in the second half of 2011 from the VELOUR study, and (iii) an interim analysis of VENICE is expected to be conducted by an IDMC in mid-2011, with final results anticipated in 2012.

A fourth Phase 3 trial (VANILLA) that was evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued in September 2009 following a planned interim efficacy analysis by that study's IDMC. The IDMC determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine in this study. The types and frequencies of adverse events reported in the combination arm with aflibercept were generally as anticipated.

During 2009, summary results were reported for a randomized, placebo-controlled Phase 2 single-agent study of aflibercept in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA), an abnormal build-up of fluid in the abdominal cavity. Patients receiving aflibercept experienced a statistically significant improvement (55 days with aflibercept as compared to 23 days for patients receiving placebo (p=0.0019)) in the primary study endpoint, mean time to first repeat paracentesis (removal of fluid from the abdominal cavity), versus placebo control. There was a statistically similar incidence of deaths in both treatment groups. Four fatal events were assessed by the investigators as aflibercept treatment related. The types and frequencies of adverse events reported with aflibercept in this study were generally consistent with those reported in clinical studies with other anti-VEGF therapies in AOC patients. Although the study demonstrated that aflibercept is a clinically active agent in this setting, given the small number of patients enrolled in this study and their fragile health status, we and sanofi-aventis concluded that it was difficult to definitively assess the overall clinical benefit that might be derived from treatment in the real-world clinical practice setting and, therefore, the data were not sufficient to submit for regulatory approval in the SMA indication.

Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) globally collaborate on the development and commercialization of aflibercept. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to the 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.

4. REGN475 (Anti-NGF Antibody) for pain

Nerve growth factor (NGF) is a member of the neurotrophin family of secreted proteins. NGF antagonists have been shown to prevent increased sensitivity to pain and abnormal pain response in animal models of neuropathic and chronic inflammatory pain. Mutations in the genes that code for the NGF receptors were identified in people suffering from a loss of deep pain perception. For these and other reasons, we believe blocking NGF could be a promising therapeutic approach to a variety of pain indications.

REGN475 is a fully human monoclonal antibody to NGF generated using our *VelocImmune*[®] technology. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4/5, or BDNF.

In the third quarter of 2009, we began a Phase 2 double-blind, placebo-controlled, dose-ranging, proof-of-concept study of REGN475 in persons with osteoarthritis of the knee. Preliminary data from that study are expected in the first half of 2010. Additionally, four Phase 2 proof-of-concept studies in other pain indications (sciatica, vertebral fracture, chronic pancreatitis, and thermal injury) were initiated in late 2009 and early 2010. REGN475 is being developed in collaboration with sanofi-aventis.

5. REGN88 (Anti-IL-6R Antibody) for inflammatory diseases

Interleukin-6 (IL-6) is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to the IL-6 receptor (IL-6R), tocilizumab, developed by Roche, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune* technology that is in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN421 (Anti-Dll4 Antibody) for advanced malignancies

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 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. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune* technology. REGN421 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

7. REGN727 (Anti-PCSK9 Antibody) for LDL cholesterol reduction

Elevated low density lipoprotein (LDL) levels is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 (proprotein convertase subtilisin/kexin type 9) is a protein that binds to LDLR, which prevents LDLR from binding to LDL and removes it from circulation. People who have a mutation that reduces the activity of PCSK9 have lower levels of LDL, as well as a reduced risk of adverse cardiovascular events. We used our *VelocImmune*[®] technology to derive a fully human monoclonal antibody called REGN727 that is designed to bind to PCSK9 and prevent it from inhibiting LDLR. REGN727 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

8. REGN668 (Anti-IL4R Antibody) for allergic and immune conditions

Interleukin-4 receptor (IL4Ra) is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis. REGN668 is a fully human *VelocImmune* antibody that is designed to bind to IL4R. REGN668 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

Research and Development Technologies:

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

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

***VelociSuite*TM**

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

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, 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 may be 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.

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

Antibody Collaboration and License Agreements

sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$175 million of research from the collaboration's inception through December 31, 2009. In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to \$160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In addition, sanofi-aventis will fund up to \$30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities. As under the original 2007 agreement, sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years.

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. To date, sanofi-aventis has opted into the development of five antibody candidates. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front, 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 will be shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

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

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

AstraZeneca UK Limited. 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 \$20.0 million annual, non-refundable payments to us in the first quarter of 2007, 2008, and 2009. AstraZeneca is required to make up to three additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the next annual payment in the first quarter of 2010. 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 Pharma Inc. 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 \$20.0 million annual, non-refundable payments to us in the second quarter of 2007, 2008, and 2009. Astellas is required to make up to three additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the next annual payment in the second quarter of 2010. 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 Grant

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

Under the NIH grant, as amended, we are entitled to receive a minimum of \$25.3 million over the five-year period beginning September 2006, including \$1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which are being supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

Research Programs

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, cardiovascular diseases, and infectious diseases.

Sales and Marketing

We have established a small commercial organization to support sales of ARCALYST[®] (riloncept) for the treatment of CAPS in the United States. We have no sales or distribution personnel and distribute the product through third party service providers. We currently have no sales, marketing, commercial, or distribution organization outside the United States. If we receive regulatory approval to market and sell additional products in the United States or in other countries, we may either expand our commercial organization or rely on third party product licensees or service providers.

Manufacturing

Our manufacturing facilities are located in Rensselaer, New York and consist of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space. We currently have approximately 27,500 liters of cell culture capacity at these facilities and have plans to increase our manufacturing capacity to approximately 54,000 liters in 2010. Up to \$30 million of agreed-upon costs related to this expansion will be funded by sanofi-aventis under the terms of our amended antibody collaboration. At December 31, 2009, we employed 278 people at our Rensselaer facilities. There were no impairment losses associated with long-lived assets at these facilities as of December 31, 2009.

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

Competition

We face substantial competition from pharmaceutical, biotechnology, and chemical companies (see "Risk Factors – Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs."). Our competitors include Genentech, Novartis, Pfizer Inc., Bayer HealthCare, Onyx Pharmaceuticals, Inc., Eli Lilly and Company, Abbott, sanofi-aventis, Merck & Co., Amgen Inc., Roche, and others. Many of our competitors have substantially greater research, preclinical, and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Competition from smaller competitors may also be or become more significant if those competitors acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even when we achieve product commercialization, one or more of our competitors may achieve product commercialization earlier than we do or obtain patent protection that dominates or adversely affects our activities. Our ability to compete will depend on how fast we can develop safe and effective product candidates, complete clinical testing and approval processes, and supply commercial quantities of the product to the market. Competition among product candidates approved for sale will also be based on efficacy, safety, reliability, availability, price, patent position, and other factors.

ARCALYST®(riloncept). In 2009, Novartis received regulatory approval in the U.S. and Europe for canakinumab (Ilaris®), a fully human anti-interleukin-IL1 β antibody, for the treatment of CAPS. Canakinumab is also in development for chronic gout and a number of other inflammatory diseases. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is significantly more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout. In addition, there are both small molecules and antibodies in development by other third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly 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 and/or commercialization of these competing molecules could delay or impair our ability to successfully develop and commercialize ARCALYST.

VEGF Trap-Eye. The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis) for the treatment of wet AMD, DME, and other eye indications. Lucentis (Genentech) was approved by the FDA in June 2006 for the treatment of wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF and VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin® (bevacizumab). The relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a significant competitive challenge in this indication. The National Eye Institute (NEI) initiated a Phase 3 trial to compare Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. Data from this NEI study are expected to be published in 2011. Avastin (Genentech) is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other areas.

Aflibercept (VEGF Trap). Many companies are developing therapeutic molecules designed to block the actions of VEGF specifically and angiogenesis in general. A variety of approaches have been employed, including antibodies to VEGF, antibodies to the VEGF receptor, small molecule antagonists to the VEGF receptor tyrosine kinase, 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, Amgen, Pfizer, Imclone/Eli Lilly, AstraZeneca, and GlaxoSmithKline. Many of these molecules are further along in development than aflibercept and may offer competitive advantages over our molecule. Pfizer and Onyx (together with its partner Bayer Healthcare) are selling and marketing oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors.

Monoclonal Antibodies. Our early-stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our *VelocImmune*[®] technology. Our antibody generation technologies and early-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

Numerous other companies are developing therapeutic antibody products. Companies such as Pfizer, Johnson & Johnson, MedImmune, LLC (a subsidiary of AstraZeneca), Amgen, Biogen Idec, Inc., Novartis, Roche, Genentech, Bristol-Myers Squibb, Abbott, and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market that are derived from recombinant DNA that comprise human antibody sequences. As noted above, AstraZeneca and Astellas have licensed our *VelocImmune* technology as part of their internal antibody development programs.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early-stage product candidates. For example, Pfizer, Johnson & Johnson, and Abbott are developing antibody product candidates against NGF. The Pfizer antibody against NGF is in Phase 3 clinical trials for the treatment of pain due to osteoarthritis. Roche is marketing an antibody against the interleukin-6 receptor (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Centocor Ortho Biotech, Inc. and Bristol Myers Squibb, have antibodies against IL-6 in clinical development for this disease. GlaxoSmithKline, in partnership with OncoMed Pharmaceuticals, Inc., has a Dll4 antibody in clinical development for the treatment of solid tumors. Aerovance has two formulations of a biologic directed against interleukin-4 in clinical development. Amgen previously had an antibody against the interleukin-4 receptor in clinical development for the treatment of asthma. We believe that several companies, including Amgen, have development programs for antibodies against PCSK9.

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. As of December 31, 2009, we held an ownership interest in a total of approximately 180 issued patents in the United States and over 750 issued patents in foreign countries with respect to our products and technologies. In addition, we held an ownership interest in hundreds of patent applications in the United States and foreign countries.

Our patent portfolio includes granted patents and pending patent applications covering our *VelociSuite*[™] technologies, including our *VelocImmune*[®] mouse platform which produces fully human monoclonal antibodies. Our issued patents covering these technologies generally expire between 2020 and 2030. However, we continue to file patent applications directed to improvements to these technology platforms.

Our patent portfolio also includes issued patents and pending applications relating to our marketed product, ARCALYST[®] (rilonacept), and our product candidates in clinical development. These patents cover the proteins and DNA encoding the proteins, manufacturing patents, method of use patents, pharmaceutical compositions, as well as various methods of using the products. For each of ARCALYST and our late-stage clinical candidates, aflibercept (VEGF Trap) and VEGF Trap-Eye, these patents generally expire between 2020 and 2026. However, the projected patent terms may be subject to extension based on potential patent term extensions in countries where such extensions are available.

We also are the nonexclusive licensee of a number of additional patents and patent applications. In July 2008 we entered into an Amended and Restated Non-Exclusive License Agreement with Cellectis S.A. pursuant to which we licensed certain patents and patent applications relating to a process for the specific replacement of a copy of a gene in the receiver genome by homologous recombination. Pursuant to this agreement, we agreed to pay Cellectis a low, single-digit royalty based on any future revenue received by us from any future licenses or sales of our *VelociGene*[®] or *VelocImmune* products or services. No royalties are payable on any revenue from commercial sales of antibodies from our *VelocImmune* technology, including antibodies developed under our collaboration with sanofi-aventis. We also have non-exclusive license agreements with Amgen and other organizations for patent rights related to ARCALYST. In exchange for these licenses, we pay a mid-single digit royalty on net sales of ARCALYST.

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. The degree of patent protection that will be afforded to our products in the United States and other important commercial markets is uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, and governments in these countries. There is no certainty that our existing patents or others, if obtained, will provide us protection from competition or provide commercial benefit.

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

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of ARCALYST and our product candidates (see “Risk Factors – *If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.*”). All of our product candidates will require regulatory approval before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval requirements by the FDA and foreign authorities. Many aspects of the structure and substance of the FDA and

foreign pharmaceutical regulatory practices have been reformed during recent years, and continued reform is under consideration in a number of jurisdictions. The ultimate outcome and impact of such reforms and potential reforms cannot be predicted.

The activities required before a product candidate may be marketed in the United States begin with preclinical tests. Preclinical tests include laboratory evaluations and animal studies to assess the potential safety and efficacy of the product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an Investigational New Drug Application, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase 1, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase 2, clinical trials are conducted with subjects afflicted with a specific disease or disorder to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. In Phase 3, large-scale clinical trials are conducted with patients afflicted with the specific disease or disorder in order to provide enough data to understand the efficacy and safety profile of the product candidate, as required by the FDA. The results of the preclinical and clinical testing of a biologic product candidate are then submitted to the FDA in the form of a Biologics License Application, or BLA, for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to a BLA, the FDA may grant marketing approval, request additional information, or deny the application.

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

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

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

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

Business Segments

We manage our business as one segment which includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions and the development and commercialization of these discoveries. This segment also includes revenues and expenses related to (i) research and development activities conducted under our collaboration agreements with third parties and our grant from the NIH, (ii) ARCALYST® (riloncept) product sales for the treatment of CAPS, (iii) licensing agreements to utilize our *VelocImmune*® technology, and (iv) the supply of specified, ordered research materials using our *VelociGene*® technology platform.

Employees

As of December 31, 2009, we had 1,029 full-time employees, of whom 192 held a Ph.D. and/or M.D., or PharmD degree. We believe that we have been successful in attracting skilled and experienced personnel in a highly competitive environment; however, competition for these personnel is intense. None of our personnel are covered by collective bargaining agreements and our management considers its relations with our employees to be good.

Available Information

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

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, 2009, we had a cumulative loss of \$941.1 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

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

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

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

As of December 31, 2009, cash, cash equivalents, restricted cash, and marketable securities totaled \$390.0 million and represented 53% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled \$181.3 million at December 31, 2009, are carried at fair value, and the unrealized gains and losses are included in other accumulated

comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized other-than-temporary impairment charges related to certain marketable securities of \$5.9 million, \$2.5 million and \$0.1 million in 2007, 2008, and 2009, respectively. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

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

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

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

We are testing aflibercept, VEGF Trap-Eye, and riloncept in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or modest effectiveness.

Aflibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd line metastatic colorectal cancer, 1st line androgen independent prostate cancer, and 2nd line metastatic non-small cell lung cancer. Aflibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that aflibercept will be safe or effective in any of these cancer settings.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of Central Retinal Vein Occlusion (CRVO). Although we reported positive Phase 2 trial results with VEGF Trap-Eye in wet AMD, based on a limited number of patients, the results from the larger Phase 3 trials may not demonstrate that VEGF Trap-Eye is safe and effective or compares favorably to Lucentis (Genentech). A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. VEGF Trap-Eye has not been previously studied in CRVO.

Riloncept is in Phase 3 clinical trials for two different gout indications – the prevention of gout flares in patients initiating urate-lowering drug therapy and acute gout. We do not have proof of concept data from Phase 2 clinical trials that riloncept will be safe or effective in the acute gout setting. Although we reported positive Phase 2 proof of concept data from a small number of patients initiating urate-lowering drug therapy, there is a risk that the results of the larger Phase 3 trials of riloncept in patients initiating urate-lowering drug therapy will differ from the previously reported Phase 2 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

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

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

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could harm the future development of our product candidate(s) and our business may be materially harmed.

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 Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

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

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

Aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria,

congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® (riloncept) in only a small number of patients. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (anakinra), marketed by Biogen, Enbrel® (etanercept), marketed by Amgen and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by 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 (Biogen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST in new disease settings. These side effects may also result in a reduction, or even the elimination, of sales of ARCALYST in approved indications.

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

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

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

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

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 pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third party challengers from time to time 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 VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop, and sell aflibercept or VEGF Trap-Eye or in a damage award.

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

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

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

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

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, including ARCALYST® (rilonacept) for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST and the EMEA approval of rilonacept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with Good Clinical Practice regulations (GCPs), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

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

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

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates, and a reduction in sales.

We and our third party providers are required to maintain compliance with current Good Manufacturing Practice, or cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

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

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

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

In addition to FDA and related regulatory requirements, we are subject to health care “fraud and abuse” laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

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

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

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

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

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

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

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

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

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

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial 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, 2009, 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.

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

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

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;

- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

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

Risks Related to Our Reliance on Third Parties

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

We rely heavily on the funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to \$1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, REGN475, REGN727, and REGN668 we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

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

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

that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

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

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

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

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical 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 in compliance with applicable Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), or Good Clinical Practice (GCP) Standards, we could experience additional costs, delays, and difficulties in the manufacture or development or in obtaining approval by regulatory authorities for our product candidates.

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

Risks Related to the Manufacture of Our Product Candidates

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

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis

and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

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

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

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

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

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

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

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

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

Risks Related to Commercialization of Products

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

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

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

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

Our only approved product is ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In October 2009 we received European marketing authorization for riloncept for CAPS. In 2009, Novartis received regulatory approval in the U.S. and Europe for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST in this indication.

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

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

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

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), DME, and other eye indications. Lucentis (Genentech) was approved by the FDA in June 2006 for the treatment of wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF and VEGF receptors,

and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin. The National Eye Institute is conducting a Phase 3 trial comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech) and the potential off-label use of Avastin (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a further competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to the VEGF Trap-Eye if it is ever approved for sale.

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

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma, and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing this IL-1 antibody in gout and other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. For example, Novartis' IL-1 antibody is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST. The successful development and/or commercialization of these competing molecules could impair our ability to successfully commercialize ARCALYST.

We have plans to develop rilonacept for the treatment of certain gout indications. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout. Novartis' IL-1 antibody is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over rilonacept in gout by some physicians, which would make it difficult for us to successfully commercialize rilonacept in that disease.

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

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

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we have announced plans to initiate a Phase 3 program studying the use of rilonacept for the treatment of certain gout indications. Patients suffering from these gout indications are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray

or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers 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 market and sell ARCALYST in the United States for the treatment of a group of rare genetic disorders called CAPS. We recently received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST. Physicians may not prescribe ARCALYST, and CAPS patients may not be able to afford ARCALYST, if third party payers do not agree to reimburse the cost of ARCALYST therapy and this would adversely affect our ability to commercialize ARCALYST profitably.

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

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

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

Risk Related to Employees

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

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

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;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST[®] (rilonacept) or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

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

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

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of December 31, 2009, our four largest shareholders plus Leonard Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 41.6% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2009. As of December 31, 2009, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18.8% of the shares of Common Stock then outstanding. Under our investor agreement, as amended, with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

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

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, 2009, holders of Class A Stock held 22.2% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, including any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate

transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in us taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of December 31, 2009:

- our current executive officers and directors beneficially owned 14.0% 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, 2009, and 28.5% 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, 2009; and
- our four largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 41.6% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2009. In addition, these five shareholders held 48.5% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, 2009.

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

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

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

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.*"

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We conduct our research, development, manufacturing, and administrative activities at our owned and leased facilities. Under our main lease in Tarrytown, New York, as amended, we lease 537,100 square feet of laboratory and office facilities, including approximately 406,200 square feet of space that we currently occupy and approximately 130,900 square feet of additional new space that is under construction and expected to be completed in mid-2011. The term of the lease will expire in June 2024. The lease contains three renewal options to extend the term of the lease by five years each and early termination options on approximately 290,400 square feet of space. The lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Monthly lease payments on the new space that is under construction will commence in January 2011 and additional charges for utilities, taxes and operating expenses commenced in January 2010.

In December 2009, we leased, on a short-term basis, approximately 16,700 square feet of laboratory and office space at our current Tarrytown location while construction is completed on our additional new facilities, as described above. We expect to lease this space through May 2011. We also entered into a separate agreement in December 2009 to lease approximately 6,600 additional square feet of laboratory and office space at our current Tarrytown location in facilities that are now under construction and expected to be completed in mid-2010. The term of this lease will expire in August 2011 after which time we have the option to include this space in our main Tarrytown lease, as described above. Monthly lease payments on this additional space that is under construction are expected to commence in June 2010.

In October 2008, we entered into an operating sublease for approximately 14,100 square feet of office space in Bridgewater, New Jersey. The term of the lease expires in July 2011.

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

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

Location	Square Footage	Expiration	Current Monthly Base Rental Charges ⁽¹⁾	Renewal Option Available
Tarrytown, New York ⁽²⁾	389,500	June, 2024	\$ 1,115,000	Three 5-year terms
Tarrytown, New York ⁽³⁾	130,900	June, 2024	—	Three 5-year terms
Tarrytown, New York ⁽²⁾	16,700	May, 2011	\$ 7,900	None
Tarrytown, New York ⁽⁴⁾	6,600	August, 2011	—	Incorporate into main Tarrytown lease
Bridgewater, New Jersey ⁽⁵⁾	14,100	July 2011	\$ 21,700	None

(1) Excludes additional charges for utilities, real estate taxes, and operating expenses, as defined, included in our rent.

(2) Represents space currently occupied in Tarrytown, New York as described above.

- (3) Represents space currently under construction. Rental payments will commence in January 2011.
- (4) Represents space currently under construction. Rental payments will commence in June 2010.
- (5) Relates to sublease in Bridgewater, New Jersey as described above.

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

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, 2009.

PART II

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

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

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

	High	Low
2008		
First Quarter	\$25.25	\$15.61
Second Quarter	21.68	13.75
Third Quarter	24.00	13.29
Fourth Quarter	22.82	12.62
2009		
First Quarter	\$20.08	\$11.81
Second Quarter	18.42	12.11
Third Quarter	23.49	16.05
Fourth Quarter	24.97	15.02

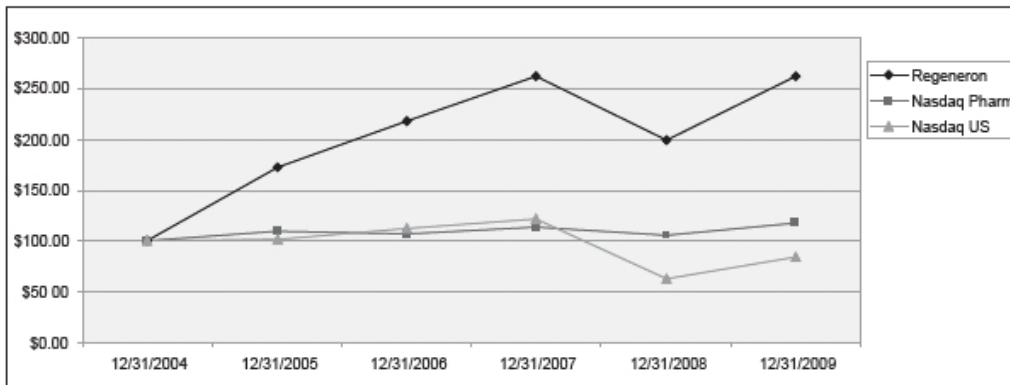
As of February 12, 2010, there were 462 shareholders of record of our Common Stock and 39 shareholders of record of our Class A Stock.

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 2010 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, 2004 through December 31, 2009. The comparison assumes that \$100 was invested on December 31, 2004 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.



	12/31/2004	12/31/2005	12/31/2006	12/31/2007	12/31/2008	12/31/2009
Regeneron	\$ 100.00	\$ 172.64	\$ 217.92	\$ 262.21	\$ 199.35	\$ 262.54
Nasdaq Pharm	100.00	110.12	107.79	113.36	105.48	118.52
Nasdaq US	100.00	102.13	112.19	121.68	62.73	84.28

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2009, 2008, and 2007 and at December 31, 2009 and 2008 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in this report. The selected financial data for the years ended December 31, 2006 and 2005 and at December 31, 2007, 2006, and 2005 are derived from our audited financial statements not included in this report.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
		<i>Revised*</i>	<i>Revised*</i>		
<i>(In thousands, except per share data)</i>					
Statement of Operations Data					
Revenues					
Collaboration revenue	\$ 314,457	\$ 185,138	\$ 87,648	\$ 47,763	\$ 49,372
Technology licensing	40,013	40,000	28,421		
Contract manufacturing				12,311	13,746
Net product sales	18,364	6,249			
Contract research and other	6,434	7,070	8,955	3,373	3,075
	<u>379,268</u>	<u>238,457</u>	<u>125,024</u>	<u>63,447</u>	<u>66,193</u>
Expenses					
Research and development	398,762	274,903	202,468	137,064	155,581
Contract manufacturing				8,146	9,557
Selling, general, and administrative	52,923	48,880	37,929	25,892	25,476
Cost of goods sold	1,686	923			
	<u>453,371</u>	<u>324,706</u>	<u>240,397</u>	<u>171,102</u>	<u>190,614</u>
Income (loss) from operations	<u>(74,103)</u>	<u>(86,249)</u>	<u>(115,373)</u>	<u>(107,655)</u>	<u>(124,421)</u>
Other income (expense)					
Other contract income					30,640
Investment income	4,488	18,161	20,897	16,548	10,381
Interest expense	(2,337)	(7,752)	(12,043)	(12,043)	(12,046)
Loss on early extinguishment of debt		(938)			
	<u>2,151</u>	<u>9,471</u>	<u>8,854</u>	<u>4,505</u>	<u>28,975</u>
Net loss before income tax expense and cumulative effect of a change in accounting principle	(71,952)	(76,778)	(106,519)	(103,150)	(95,446)
Income tax (benefit) expense	(4,122)	2,351			
Net loss before cumulative effect of a change in accounting principle	<u>(67,830)</u>	<u>(79,129)</u>	<u>(106,519)</u>	<u>(103,150)</u>	<u>(95,446)</u>
Cumulative effect of a change in accounting principle related to share-based payments				813	
Net loss	<u>\$ (67,830)</u>	<u>\$ (79,129)</u>	<u>\$ (106,519)</u>	<u>\$ (102,337)</u>	<u>\$ (95,446)</u>
Net loss per share, basic and diluted:					
Net loss before cumulative effect of a change in accounting principle	\$ (0.85)	\$ (1.00)	\$ (1.61)	\$ (1.78)	\$ (1.71)
Cumulative effect of a change in accounting principle related to share-based payments				0.01	
Net loss	<u>\$ (0.85)</u>	<u>\$ (1.00)</u>	<u>\$ (1.61)</u>	<u>\$ (1.77)</u>	<u>\$ (1.71)</u>

	At December 31,				
	2009	2008	2007	2006	2005
		Revised*	Revised*		
<i>(In thousands)</i>					
Balance Sheet Data					
Cash, cash equivalents, restricted cash, and marketable securities (current and non-current)	\$ 390,010	\$ 527,461	\$ 846,279	\$ 522,859	\$ 316,654
Total assets	741,202	724,220	957,881	585,090	423,501
Notes payable - current portion			200,000		
Notes payable - long-term portion				200,000	200,000
Facility lease obligations	109,022	54,182	21,623		
Stockholders' equity	396,762	421,514	459,348	216,624	114,002

* We have revised our financial statements at December 31, 2008 and 2007 and for the years ended December 31, 2008 and 2007 in connection with the application of authoritative guidance issued by the Financial Accounting Standards Board (FASB) to our December 2006 lease, as amended, of laboratory and office facilities in Tarrytown, New York. The revisions, and a description of the basis for the revisions, are more fully described in Note 11 to our audited financial statements included elsewhere in this report.

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

Overview

We are a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We also have eight product candidates in clinical development, including three product candidates that are in late-stage (Phase 3) clinical development. Our late stage programs are rilonacept, which is being developed for the prevention and treatment of gout-related flares; VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with sanofi-aventis. Our earlier stage clinical programs are REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain; REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis; REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology; REGN727, an antibody to PCSK9, which is being developed for LDL cholesterol reduction; and REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed for certain allergic and immune conditions. All five of our early stage clinical programs are fully human antibodies that are being developed 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, cardiovascular diseases, and infectious diseases.

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

From inception on January 8, 1988 through December 31, 2009, we had a cumulative loss of \$941.1 million. In the absence of significant revenues from the commercialization of ARCALYST® (rilonacept) or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and rilonacept in other indications; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

As a company that does not expect to be profitable over the next several years, management of cash flow is extremely important. The most significant use of our cash is for research and development activities, which include drug discovery, preclinical studies, clinical trials, and the manufacture of drug supplies for preclinical studies and clinical trials. We are reimbursed for some of these research and development activities by our collaborators. Our principal sources of cash to-date have been from (i) sales of common equity, both in public offerings and to our collaborators, including sanofi-aventis, (ii) funding from our collaborators and licensees in the form of up-front and milestone payments, research progress payments, and payments for our research and development activities, and (iii) a private placement of convertible debt, which was repaid in full during 2008.

In 2009, our research and development expenses totaled \$398.8 million. In 2010, we expect these expenses to increase substantially as we continue to expand our research and preclinical and clinical development activities, primarily in connection with our antibody collaboration with sanofi-aventis.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2009 was 980 compared with 810 in 2008 and 627 in 2007. In 2009 and 2008 our average headcount increased primarily to support our expanded research and development activities in connection with our antibody collaboration with sanofi-aventis. In 2007 our average headcount increased primarily to support our expanded development programs for VEGF Trap-Eye and rilonacept and our plans to move our first antibody candidate into clinical trials. In 2010, we expect our average headcount to increase to approximately 1,350-1,400, primarily to support the further expansion of our research, development, and marketing activities as described above, especially in connection with our antibody collaboration with sanofi-aventis.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2009 and 2010 to date were, and plans for the remainder of 2010 are, as follows:

Clinical Program	2009 and 2010 Events to Date	2010 Plans
Rilonacept (also known as IL-1 Trap)	<ul style="list-style-type: none"> • Initiated patient enrollment in two Phase 3 trials (PRE-SURGE 1 and PRE-SURGE 2) evaluating rilonacept in the prevention of gout flares associated with the initiation of urate-lowering drug therapy; completed patient enrollment in the PRE-SURGE 1 study • Initiated and completed patient enrollment in a Phase 3 study (SURGE) evaluating rilonacept in the treatment of acute gout flares 	<ul style="list-style-type: none"> • Report data from SURGE and PRE-SURGE 1 during the first half of 2010 • Complete patient enrollment of the remaining Phase 3 studies in gout
VEGF Trap-Eye (intravitreal injection)	<ul style="list-style-type: none"> • Completed patient enrollment in the Phase 3 wet AMD program (VIEW 1 and VIEW 2) • Initiated a Phase 3 CRVO program • Reported results from the Phase 2 DME trial 	<ul style="list-style-type: none"> • Report data from VIEW 1 and VIEW 2 trials in the fourth quarter of 2010 • Complete patient enrollment of the Phase 3 CRVO trials
Aflibercept (VEGF Trap – Oncology)	<ul style="list-style-type: none"> • Completed patient enrollment in the Phase 3 studies in non-small cell lung cancer and prostate cancer • Initiated a Phase 2 1st line study in metastatic colorectal cancer in combination with chemotherapy • Reported results of a Phase 2 single-agent study in symptomatic malignant ascites (SMA) • Discontinued a Phase 3 study in metastatic pancreatic cancer in combination with chemotherapy 	<ul style="list-style-type: none"> • Complete patient enrollment in the Phase 3 study in colorectal cancer • During the second half of 2010, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study in colorectal cancer
Monoclonal Antibodies	<ul style="list-style-type: none"> • REGN475: Initiated a Phase 1 trial in healthy volunteers, a dose-ranging, proof-of-concept study in osteoarthritis of the knee, and additional proof-of-concept studies in pain associated with sciatica, vertebral fracture, chronic pancreatitis, and thermal injury • REGN88: Initiated a Phase 2/3 dose-ranging study in rheumatoid arthritis and a Phase 2 dose-ranging study in ankylosing spondylitis • REGN421: Initiated a Phase 1 trial in oncology • REGN727: Initiated a Phase 1 program in healthy volunteers • REGN668: Initiated a Phase 1 program in healthy volunteers 	<ul style="list-style-type: none"> • REGN475: Report data from the study in osteoarthritis of the knee during the first half of 2010 and from the study in sciatica during the second half of 2010 • REGN727: Report proof-of-concept data from the Phase 1 program and initiate a Phase 2 program for LDL cholesterol reduction • REGN668: Initiate a Phase 2 program in the treatment of a chronic allergic condition • REGN88: Report data from a Phase 1 trial in rheumatoid arthritis • Advance additional antibody candidate(s) into clinical development

Critical Accounting Policies and Use of Estimates

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

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

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

Revenue Recognition

Collaboration Revenue

We earn collaboration revenue in connection with collaboration agreements to develop and commercialize product candidates and utilize our technology platforms. We currently have collaboration agreements with sanofi-aventis and Bayer HealthCare. The terms of collaboration 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 collaboration 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 connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, our estimated performance periods may change if development programs encounter delays or we and our collaborators decide to expand or contract our clinical plans for a drug candidate in various disease indications. For example, during the fourth quarter of 2008, we extended our estimated performance period in connection with the up-front and non-substantive milestone payments previously received from Bayer HealthCare pursuant to the companies' VEGF Trap-Eye collaboration and shortened our estimated performance period in connection with up-front payments from sanofi-aventis pursuant to the companies' aflibercept collaboration. The net effect of these changes in our estimates resulted in the recognition of \$0.4 million less in collaboration revenue in the fourth quarter of 2008, compared to amounts recognized in connection with these deferred payments in each of the prior three quarters of 2008. In addition, in connection with amendments to expand and extend our antibody collaboration with sanofi-aventis, during the fourth quarter of 2009, we extended our estimated performance period related to the up-front payment previously received from sanofi-aventis pursuant to the companies' antibody collaboration. The effect of this change in estimate resulted in the recognition of \$0.6 million less in collaboration revenue in the fourth quarter of 2009, compared to amounts recognized in each of the prior three quarters of 2009. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

Product Revenue

In March 2008, ARCALYST® (riloncept) became available for prescription in the United States for the treatment of CAPS. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and we have no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distributor fees, and other sales-related costs. Since we have limited historical return and rebate experience for ARCALYST, product sales revenues are deferred until (i) the right of return no longer exists or we can reasonably estimate returns and (ii) rebates have been processed or we can reasonably estimate rebates. We review our estimates of rebates payable each period and record any necessary adjustments in the current period's net product sales.

Clinical Trial Expenses

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

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

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue expense on an estimated cost-per-patient basis, 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, 2009, 2008, or 2007.

Stock-based Employee Compensation

We recognize stock-based compensation expense for grants of stock option awards and restricted stock to employees and non-employee members of our board of directors under our long-term incentive plans based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period.

We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our historical exercise experience with previously issued employee and board of directors option grants. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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

In addition, we have granted performance-based stock option awards which vest based upon the optionee satisfying certain performance and service conditions as defined in the agreements. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, we estimate that these options will vest, which is based on whether we consider the options' performance conditions to be probable of attainment. Our estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods. Changes in these estimates may materially affect the amount of stock-based compensation that we recognize in future periods related to performance-based options.

Marketable Securities

We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider our marketable securities to be "available-for-sale," as defined by authoritative guidance issued by the Financial Accounting Standards Board (FASB). These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a marketable security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that may be charged against income.

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

As a result of our quarterly reviews of our marketable securities portfolio, during 2009, 2008, and 2007 we recorded charges for other-than-temporary impairment of our marketable securities totaling \$0.1 million, \$2.5 million, and \$5.9 million, respectively. The current economic environment and the deterioration in the credit quality of issuers of securities that we hold increase the risk of potential declines in the current market value of marketable securities in our investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

Depreciation of Property, Plant, and Equipment

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

Results of Operations

Years Ended December 31, 2009 and 2008

Net Loss

Regeneron reported a net loss of \$67.8 million, or \$0.85 per share (basic and diluted), for the year ended December 31, 2009, compared to a net loss of \$79.1 million, or \$1.00 per share (basic and diluted) for 2008. The decrease in our net loss in 2009 was principally due to higher collaboration revenue in connection with our antibody collaboration with sanofi-aventis, receipt of a \$20.0 million substantive performance milestone payment in connection with our VEGF Trap-Eye collaboration with Bayer HealthCare, and higher ARCALYST® (rilonacept) sales, partially offset by higher research and development expenses, as detailed below.

Revenues

Revenues in 2009 and 2008 consist of the following:

<i>(In millions)</i>	2009	2008
Collaboration revenue		
Sanofi-aventis	\$247.2	\$154.0
Bayer HealthCare	67.3	31.2
Total collaboration revenue	314.5	185.2
Technology licensing revenue	40.0	40.0
Net product sales	18.4	6.3
Contract research and other revenue	6.4	7.0
Total revenue	<u>\$379.3</u>	<u>\$238.5</u>

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and 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.

Sanofi-aventis Collaboration Revenue	Years ended	
	December 31,	
	2009	2008
<i>(In millions)</i>		
Aflibercept:		
Regeneron expense reimbursement	\$ 26.6	\$ 35.6
Recognition of deferred revenue related to up-front payments	9.9	8.8
Total aflibercept	<u>36.5</u>	<u>44.4</u>
Antibody:		
Regeneron expense reimbursement	198.1	97.9
Recognition of deferred revenue related to up-front payment	9.9	10.5
Recognition of revenue related to <i>VelociGene</i> ® agreement	2.7	1.2
Total antibody	<u>210.7</u>	<u>109.6</u>
Total sanofi-aventis collaboration revenue	<u>\$ 247.2</u>	<u>\$ 154.0</u>

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in 2009 compared to 2008, primarily due to lower costs related to internal research activities and manufacturing aflibercept clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments increased in 2009 compared to 2008 due to shortening the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of December 31, 2009, \$42.5 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 2009, sanofi-aventis' reimbursement of our antibody expenses consisted of \$99.8 million under the discovery agreement and \$98.3 million of development costs under the license agreement, compared to \$72.2 million and \$25.7 million, respectively, in 2008. The higher reimbursement amounts in 2009 compared to 2008 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement. Recognition of deferred revenue related to sanofi-aventis' \$85.0 million up-front payment decreased in 2009 compared to 2008 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. As of December 31, 2009, \$63.7 million of the original \$85.0 million up-front payment was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene* agreement with sanofi-aventis. In 2009 and 2008, we recognized \$2.7 million and \$1.2 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses, substantive performance milestone payments, and recognition of revenue related to a non-refundable \$75.0 million up-front payment and a \$20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	Years ended	
	December 31,	
	2009	2008
<i>(In millions)</i>		
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	\$ 37.4	\$ 18.8
Substantive performance milestone payment	20.0	
Recognition of deferred revenue related to up-front and other milestone payments	9.9	12.4
Total Bayer HealthCare collaboration revenue	<u>\$ 67.3</u>	<u>\$ 31.2</u>

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in 2009 compared to 2008. Under the terms of the collaboration, in 2009, all agreed-upon VEGF Trap-Eye development expenses incurred by Regeneron and Bayer HealthCare under a global development plan were shared equally. In 2008, the first \$70.0 million of agreed-upon VEGF Trap-Eye development expenses were shared equally, and we were solely responsible for up to the next \$30.0 million. During the fourth quarter of 2008, we were solely responsible for most of the collaboration's VEGF Trap-Eye development expenses, which reduced the amount of cost-sharing revenue we earned from Bayer HealthCare in 2008. In addition, cost-sharing revenue increased in 2009, compared to 2008, due

to higher clinical development costs in connection with our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and Phase 3 trial in CRVO. In July 2009, we received a \$20.0 million substantive performance milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO, which was recognized as collaboration revenue. Recognition of deferred revenue related to the up-front and August 2007 milestone payments from Bayer HealthCare decreased in 2009 from 2008 due to an extension of the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of December 31, 2009, \$56.8 million of these up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune*[®] license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In both 2009 and 2008, we recognized \$40.0 million of technology licensing revenue related to these agreements.

Net Product Sales

In 2009 and 2008, we recognized as revenue \$18.4 million and \$6.3 million, respectively, of ARCALYST[®] (rilonacept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated. At December 31, 2009, deferred revenue related to ARCALYST net product sales totaled \$4.8 million.

Contract Research and Other Revenue

Contract research and other revenue in 2009 and 2008 included \$5.5 million and \$4.9 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.

Expenses

Total operating expenses increased to \$453.4 million in 2009 from \$324.7 million in 2008. Our average headcount in 2009 increased to 980 from 810 in 2008 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2009 and 2008 include a total of \$31.3 million and \$32.5 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

Expenses	For the year ended December 31, 2009		
	Expenses before		
	inclusion of Non-cash	Non-cash	Expenses as
	Compensation	Compensation	
Expense	Expense	Reported	
<i>(In millions)</i>			
Research and development	\$380.0	\$18.8	\$398.8
Selling, general, and administrative	40.4	12.5	52.9
Cost of goods sold	1.7		1.7
Total operating expenses	<u>\$422.1</u>	<u>\$31.3</u>	<u>\$453.4</u>

Expenses	For the year ended December 31, 2008		
	Expenses before		
	inclusion of Non-cash	Non-cash	Expenses as
	Compensation	Compensation	
Expense	Expense	Reported	
<i>(In millions)</i>			
Research and development	\$255.9	\$19.0	\$274.9
Selling, general, and administrative	35.4	13.5	48.9
Cost of goods sold	0.9		0.9
Total operating expenses	<u>\$292.2</u>	<u>\$32.5</u>	<u>\$324.7</u>

The decrease in total Non-cash Compensation Expense in 2009 was primarily attributable to the lower fair market value of our Common Stock on the date of our annual employee option grants made in December 2008 as compared to the fair market value of annual employee option grants made in recent years prior to 2008.

Research and Development Expenses

Research and development expenses increased to \$398.4 million in 2009 from \$274.9 million in 2008. The following table summarizes the major categories of our research and development expenses in 2009 and 2008:

Research and Development Expenses	Year Ended		Increase
	December 31,		
	2009	2008	
<i>(In millions)</i>			
Payroll and benefits ⁽¹⁾	\$ 99.9	\$ 81.7	\$ 18.2
Clinical trial expenses	111.6	49.3	62.3
Clinical manufacturing costs ⁽²⁾	66.7	53.8	12.9
Research and preclinical development costs	42.3	29.6	12.7
Occupancy and other operating costs	40.6	30.5	10.1
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses ⁽³⁾	37.7	30.0	7.7
Total research and development	\$ 398.8	\$ 274.9	\$ 123.9

(1) Includes \$16.2 million and \$16.7 million of Non-cash Compensation Expense in 2009 and 2008, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$2.6 million and \$2.3 million of Non-cash Compensation Expense in 2009 and 2008, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD, DA VINCI trial in DME, and COPERNICUS trial in CRVO, (ii) riloncept, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibody candidates, which are in earlier stage clinical development. Clinical manufacturing costs increased due to higher costs related to manufacturing clinical supplies of riloncept and monoclonal antibodies, partially offset by lower costs related to manufacturing aflibercept clinical supplies. Research and preclinical development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

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

Project Costs	Year ended		Increase (Decrease)
	December 31,		
(In millions)	2009	2008	
Rilonacept	\$ 67.7	\$ 39.2	\$ 28.5
VEGF Trap-Eye	109.8	82.7	27.1
Aflibercept	23.3	32.1	(8.8)
REGN88	36.9	21.4	15.5
Other antibody candidates in clinical development	74.4	27.4	47.0
Other research programs & unallocated costs	86.7	72.1	14.6
Total research and development expenses	\$ 398.8	\$ 274.9	\$ 123.9

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: Phases 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 rilonacept, aflibercept, and VEGF Trap-Eye in different disease indications.

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

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We shipped \$20.0 million and \$10.7 million of ARCALYST to our U.S. distributors in 2009 and 2008, respectively.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$52.9 million in 2009 from \$48.9 million in 2008. In 2009, we incurred (i) higher compensation expense, (ii) higher patent-related costs, (iii) higher facility-related costs due primarily to increases in administrative headcount, and (iv) higher patient assistance costs related to ARCALYST® (rilonacept). These increases were partially offset by (i) lower marketing costs related to ARCALYST, (ii) a decrease in administrative recruitment costs, and (iii) lower professional fees related to various corporate matters.

Cost of Goods Sold

During 2008, we began recognizing revenue and cost of goods sold from net product sales of ARCALYST. We began capitalizing inventory costs associated with commercial supplies of ARCALYST subsequent to receipt of marketing approval from the FDA in February 2008. Costs for manufacturing supplies of ARCALYST prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not included in cost of goods sold when revenue is recognized from the sale of those supplies of ARCALYST. Cost of goods sold in 2009 and 2008 was \$1.7 million and \$0.9 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST commercial supplies.

Other Income and Expense

Investment income decreased to \$4.5 million in 2009 from \$18.2 million in 2008, due primarily to lower yields on, and lower balances of, cash and marketable securities. In addition, in 2009 and 2008, deterioration in the credit quality of specific marketable securities in our investment portfolio subjected us to the risk of not being able to recover these securities' carrying values. As a result, in 2009 and 2008, we recognized charges of \$0.1 million and \$2.5 million, respectively, related to these securities, which we considered to be other than temporarily impaired. In 2009 and 2008, these charges were either wholly or partially offset by realized gains of \$0.2 million and \$1.2 million, respectively, on sales of marketable securities during the year.

Interest expense decreased to \$2.3 million in 2009 from \$7.8 million in 2008. Interest expense in 2009 was attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. Interest expense in 2008 related to \$200.0 million of 5.5% Convertible Senior Subordinated Notes until they were retired. During the second and third quarters of 2008, we repurchased a total of \$82.5 million in principal amount of these convertible notes for \$83.3 million. In connection with these repurchases, we recognized a \$0.9 million loss on early extinguishment of debt, representing the premium paid on the notes plus related unamortized debt issuance costs. The remaining \$117.5 million of convertible notes were repaid in full upon their maturity in October 2008.

Income Tax (Benefit) Expense

In 2009, we recognized a \$4.1 million income tax benefit, consisting primarily of (i) \$2.7 million resulting from a provision in the Worker, Homeownership, and Business Assistance Act of 2009 that allows us to claim a refund of U.S. federal alternative minimum tax that we paid in 2008, as described below, and (ii) \$0.7 million resulting from a provision in the American Recovery and Reinvestment Act of 2009 that allows us to claim a refund for a portion of our unused pre-2006 research tax credits.

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

Net Loss

Regeneron reported a net loss of \$79.1 million, or \$1.00 per share (basic and diluted), for the year ended December 31, 2008, compared to a net loss of \$106.5 million, or \$1.61 per share (basic and diluted) for 2007. The decrease in net loss was principally due to revenues earned in 2008 in connection with our November 2007 antibody collaboration with sanofi-aventis, partly offset by higher research and development expenses.

Revenues

Revenues in 2008 and 2007 consist of the following:

<i>(In millions)</i>	2008	2007
Collaboration revenue		
Sanofi-aventis	\$ 154.0	\$ 51.7
Bayer HealthCare	31.2	35.9
Total collaboration revenue	185.2	87.6
Technology licensing revenue	40.0	28.4
Net product sales	6.3	
Contract research and other revenue	7.0	9.0
Total revenue	<u>\$238.5</u>	<u>\$125.0</u>

Sanofi-Aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and 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.

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

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

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

In August 2008, we entered into a separate *VelociGene*[®] agreement with sanofi-aventis. In 2008, we recognized \$1.2 million in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable \$75.0 million up-front payment and a \$20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

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

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue. In the fourth quarter of 2007, we and Bayer HealthCare approved a global development plan for VEGF Trap-Eye in wet AMD. The plan included estimated development steps, timelines, and costs, as well as the projected responsibilities of each of the companies. In addition, in the fourth quarter of 2007, we and Bayer HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. The \$75.0 million up-front licensing and \$20.0 million milestone payments from Bayer HealthCare are being recognized as collaboration revenue over the related estimated performance period. In periods when we recognize VEGF Trap-Eye development expenses that we incur under the collaboration, we also recognize, as collaboration revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, we commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up.

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare decreased in 2008 compared to 2007. Under the terms of the collaboration, in 2008, the first \$70.0 million of agreed-upon VEGF Trap-Eye development expenses incurred by Regeneron and Bayer HealthCare under a global development plan were shared equally, and we were solely responsible for up to the next \$30.0 million. Since both we and Bayer HealthCare incurred higher VEGF Trap-Eye development expenses in 2008 compared to 2007, during the fourth quarter of 2008, we were solely responsible for most of the collaboration's VEGF Trap-Eye development expenses, which partly contributed to the revenue decrease in 2008 compared to 2007. In addition, the decrease was due in part to the cumulative catchup recognized in 2007 from the inception of the collaboration in October 2006, as described above. Recognition of deferred revenue related to Bayer HealthCare's \$75.0 million up-front and \$20.0 million milestone payments also decreased in 2008 from 2007 as a result of the cumulative catch-up. As of December 31, 2008, \$66.7 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

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

Net Product Sales

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

Contract Research and Other Revenue

Contract research and other revenue in 2008 and 2007 included \$4.9 million and \$5.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to \$324.7 million in 2008 from \$240.4 million in 2007. Our average headcount in 2008 increased to 810 from 627 in 2007 principally as a result of our expanding research and development activities which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2008 and 2007 include a total of \$32.5 million and \$28.1 million, respectively, of Non-cash Compensation Expense, as detailed below:

Expenses	For the year ended December 31, 2008		
	Expenses before		Expenses as Reported
	inclusion of Non-cash	Non-cash	
	Compensation	Compensation	
Expense	Expense		
(In millions)			
Research and development	\$255.9	\$19.0	\$274.9
Selling, general, and administrative	35.4	13.5	48.9
Cost of goods sold	0.9		0.9
Total operating expenses	<u>\$292.2</u>	<u>\$32.5</u>	<u>\$324.7</u>
Expenses	For the year ended December 31, 2007		
	Expenses before		Expenses as Reported
	inclusion of Non-cash	Non-cash	
	Compensation	Compensation	
Expense	Expense		
(In millions)			
Research and development	\$186.3	\$16.2	\$202.5
Selling, general, and administrative	26.0	11.9	37.9
Total operating expenses	<u>\$212.3</u>	<u>\$28.1</u>	<u>\$240.4</u>

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

Research and Development Expenses

Research and development expenses increased to \$274.9 million in 2008 from \$202.5 million in 2007. The following table summarizes the major categories of our research and development expenses in 2008 and 2007:

Research and Development Expenses	Year ended		Increase
	December 31,		
	2008	2007	
<i>(In millions)</i>			
Payroll and benefits ⁽¹⁾	\$ 81.7	\$ 60.6	\$21.1
Clinical trial expenses	49.3	37.6	11.7
Clinical manufacturing costs ⁽²⁾	53.8	47.0	6.8
Research and preclinical development costs	29.6	23.2	6.4
Occupancy and other operating costs	30.5	23.5	7.0
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses ⁽³⁾	30.0	10.6	19.4
Total research and development	\$ 274.9	\$ 202.5	\$72.4

(1) Includes \$16.7 million and \$13.2 million of Non-cash Compensation Expense in 2008 and 2007, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$2.3 million and \$3.0 million of Non-cash Compensation Expense in 2008 and 2007, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, we commenced recognizing cost-sharing of our and Bayer HealthCare's VEGF Trap-Eye development expenses. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

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

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

Project Costs	Year ended		Increase (Decrease)
	December 31,		
(In millions)	2008	2007	
Rilonacept	\$ 39.2	\$ 38.1	\$ 1.1
Aflibercept	32.1	33.7	(1.6)
VEGF Trap-Eye	82.7	53.7	29.0
REGN88	21.4	13.6	7.8
Other research programs & unallocated costs	99.5	63.4	36.1
Total research and development expenses	<u>\$274.9</u>	<u>\$202.5</u>	<u>\$72.4</u>

For the reasons described above in Results of Operations for the years ended December 31, 2009 and 2008, under the caption "Research and Development Expenses", and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In the first quarter of 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. We shipped \$10.7 million of ARCALYST to our U.S. distributors in 2008.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$48.9 million in 2008 from \$37.9 million in 2007. In 2008, we incurred \$5.2 million of selling expenses related to ARCALYST for the treatment of CAPS. General and administrative expenses increased in 2008 due to (i) higher compensation expense primarily resulting from increases in administrative headcount to support our expanded research and development activities, (ii) higher recruitment and related costs associated with expanding our headcount, (iii) higher fees for professional services related to various general corporate matters, and (iv) higher administrative facility-related costs.

Cost of Goods Sold

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

Other Income and Expense

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

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

Income Tax Expense

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

Revision of Previously Issued Financial Statements

The application of FASB authoritative guidance, under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, we became aware that certain of these conditions were applicable to our December 2006 lease, as amended, of new laboratory and office facilities in Tarrytown, New York. As a result, we are deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on our books as a non-cash transaction, offset by a corresponding lease obligation on our balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

We revised our previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which we are leasing and to adjust our previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability) at each balance sheet date. We also revised our statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of our lease, with a corresponding adjustment to other long-term liabilities.

As previously disclosed in our Quarterly Reports on Form 10-Q for the quarters ended June 30 and September 30, 2009, the above described revisions consisted entirely of non-cash adjustments. They had no impact on our business operations, existing capital resources, or our ability to fund our operating needs, including the preclinical and clinical development of our product candidates. The revisions also had no impact on our previously reported net increases or decreases in cash and cash equivalents in any period and, except for the quarter ended March 31, 2009, had no impact on our previously reported net cash flows from operating activities, investing activities, and financing activities. In addition, these revisions had no impact on our previously reported current assets, current liabilities, and operating revenues. We have not amended previously issued financial statements because, after considering both qualitative and quantitative factors, we determined that the judgment of a reasonable person relying on our previously issued financial statements would not have been changed or influenced by these revisions.

For comparative purposes, the impact of the above described revisions to our balance sheet as of December 31, 2008 is as follows:

Balance Sheet Impact at December 31, 2008
(In millions)

	December 31, 2008
<u>As originally reported</u>	
Property, plant, and equipment, net	\$ 87.9
Total assets	670.0
Other long-term liabilities	5.1
Total liabilities	251.2
Accumulated deficit	(875.9)
Total stockholders' equity	418.8
Total liabilities and stockholders' equity	670.0
<u>As revised</u>	
Property, plant, and equipment, net	\$ 142.0
Total assets	724.2
Facility lease obligation	54.2
Other long-term liabilities	2.4
Total liabilities	302.7
Accumulated deficit	(873.3)
Total stockholders' equity	421.5
Total liabilities and stockholders' equity	724.2

For comparative purposes, the impact of the above described revisions to our statements of operations for the period(s) set forth below is as follows:

Statements of Operations Impact for the years ended December 31, 2008 and 2007
(In millions, except per share data)

	December 31,	
	2008	2007
<u>As originally reported</u>		
Research and development expenses	\$278.0	\$ 201.6
Selling, general, and administrative expenses	49.3	37.9
Total expenses	328.3	239.5
Net loss	(82.7)	(105.6)
Net loss per share, basic and diluted	\$ (1.05)	\$ (1.59)
<u>As revised</u>		
Research and development expenses	\$274.9	\$ 202.5
Selling, general, and administrative expenses	48.9	37.9
Total expenses	324.7	240.4
Net loss	(79.1)	(106.5)
Net loss per share, basic and diluted	\$ (1.00)	\$ (1.61)

These revised amounts are reflected in this Annual Report on Form 10-K for the year ended December 31, 2009.

Liquidity and Capital Resources

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

Sources and Uses of Cash for the Years Ended December 31, 2009, 2008, and 2007

At December 31, 2009, we had \$390.0 million in cash, cash equivalents, restricted cash, and marketable securities compared with \$527.5 million at December 31, 2008 and \$846.3 million at December 31, 2007. Under the terms of our non-exclusive license agreements with AstraZeneca and Astellas, each company made \$20.0 million annual, non-refundable payments to us in each of 2009, 2008, and 2007. In July 2009 and August 2007, we received \$20.0 million milestone payments from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO and wet AMD, respectively. In December 2007, we received an \$85.0 million upfront payment in connection with our original antibody collaboration agreement with sanofi-aventis. Sanofi-aventis also purchased 12 million newly issued, unregistered shares of our Common Stock in December 2007 for gross proceeds to us of \$312.0 million.

Cash (Used in) Provided by Operations

Net cash used in operations was \$72.2 million in 2009 and \$89.1 million in 2008, and net cash provided by operations was \$27.4 million in 2007. Our net losses of \$67.8 million in 2009, \$79.1 million in 2008, and \$106.5 million in 2007 included \$31.3 million, \$32.5 million, and \$28.1 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of \$14.2 million, \$11.3 million, and \$11.5 million in 2009, 2008, and 2007, respectively.

At December 31, 2009, accounts receivable increased by \$30.4 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Our deferred revenue balances at December 31, 2009 decreased by \$27.5 million, compared to end-of-year 2008, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. Accounts payable, accrued expenses, and other liabilities increased \$13.0 million at December 31, 2009, compared to end-of-year 2008, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for clinical-related expenses, which were partially offset by an \$8.6 million decrease in the cost-sharing payment due to Bayer HealthCare in connection with our VEGF Trap-Eye collaboration.

At December 31, 2008, accounts receivable increased by \$16.9 million, compared to end-of-year 2007, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Our deferred revenue balances at December 31, 2008 decreased by \$26.8 million, compared to end-of-year 2007, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partially offset by the deferral of \$4.0 million of ARCALYST® (rilonacept) net product sales at December 31, 2008.

At December 31, 2007, accounts receivable increased by \$10.8 million, compared to end-of-year 2006, due to higher receivable balances related to our collaborations with sanofi-aventis and Bayer HealthCare. Also, prepaid expenses and other assets increased \$9.6 million at December 31, 2007, compared to end-of-year 2006, due primarily to higher prepaid clinical trial costs. Our deferred revenue balances at December 31, 2007 increased by \$89.8 million, compared to end-of-year 2006, due primarily to (i) the \$85.0 million up-front payment received from sanofi-aventis, (ii) the \$20.0 million milestone payment from Bayer HealthCare which was not considered to be substantive for revenue recognition purposes and, therefore, fully deferred, and (iii) the two \$20.0 million licensing payments received from each of AstraZeneca and Astellas, all as described above, partly offset by 2007 revenue recognition, principally from amortization of these deferred payments and prior year deferred payments from sanofi-aventis and Bayer HealthCare. Accounts payable, accrued expenses, and other liabilities increased \$19.1 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.

The majority of our cash expenditures in 2009, 2008, and 2007 were to fund research and development, primarily related to our clinical programs and our preclinical human monoclonal antibody programs. In 2008 and 2007, we made interest payments totaling \$9.3 million and \$11.0 million, respectively, on our convertible senior subordinated notes. The convertible notes were repaid in full in 2008.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$146 thousand in 2009 and \$30.8 million in 2008, and net cash used in investing activities was \$85.7 million in 2007. In 2009 and 2008, sales or maturities of marketable securities exceeded purchases by \$97.4 million and \$65.7 million, respectively, whereas in 2007, purchases of marketable securities exceeded sales or maturities by \$67.3 million. Capital expenditures in 2009 and 2008 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our December 2006 Tarrytown, New York lease, as described below. Capital expenditures in 2007 included the purchase of land and a building in Rensselaer for \$9.0 million.

Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was \$31.4 million in 2009 and \$319.4 million in 2007, respectively, and net cash used in financing activities was \$192.9 million in 2008. In 2009, we received a \$23.6 million reimbursement of tenant improvements from our landlord in connection with our new Tarrytown facilities, which we are deemed to own in accordance with FASB authoritative guidance. In the second and third quarters of 2008, we repurchased \$82.5 million in principal amount of our convertible senior subordinated notes for \$83.3 million. The remaining \$117.5 million of convertible notes were repaid in full upon their maturity in October 2008. In 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of our Common Stock for gross proceeds to us of \$312.0 million. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were \$8.6 million in 2009, \$7.9 million in 2008, and \$7.6 million in 2007.

Fair Value of Marketable Securities

At December 31, 2009 and 2008, we held marketable securities whose aggregate fair value totaled \$181.3 million and \$278.0 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

Investment type	2009		2008	
	Fair Value	Percent	Fair Value	Percent
U.S. Treasury securities	\$ 80.4	44%	\$ 113.9	41%
U.S. government agency securities	29.6	16%	58.3	21%
U.S. government-guaranteed corporate bonds	48.7	27%	29.8	11%
U.S. government guaranteed collateralized mortgage obligations	3.7	2%	17.4	6%
Corporate bonds	10.3	6%	37.1	13%
Mortgage-backed securities	3.2	2%	10.0	4%
Other asset-backed securities			7.8	3%
Other	5.4	3%	3.7	1%
Total marketable securities	\$181.3	100%	\$278.0	100%

In addition, at December 31, 2009 and 2008, we had \$208.7 million and \$249.5 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2009, as marketable securities in our portfolio matured or paid down, we purchased primarily U.S. Treasury securities, U.S. government agency obligations, and U.S. government-guaranteed debt. This shift toward higher quality securities, which we initiated in 2008, reduced the risk profile, as well as the overall yield, of our portfolio during 2009.

In particular, we reduced the proportion of mortgage-backed securities in, and eliminated other asset-backed securities from, the portfolio since they had deteriorated in credit quality and declined in value due to higher delinquency rates on the underlying collateral supporting these securities. The mortgage-backed securities that we

held at December 31, 2009 are backed by prime and sub-prime residential mortgages and home equity loans. The estimated fair value of our mortgage-backed securities generally ranged from 77% to 99% of par value at December 31, 2009. Our mortgage-backed securities are all senior tranches that are paid-down before other subordinated tranches as the loans in the underlying collateral are repaid. Through December 31, 2009, we continued to receive monthly payments of principal and interest on our mortgage-backed securities holdings. If the monthly principal and interest payments continue at approximately the current rate, we anticipate that all of the mortgage-backed securities in our portfolio will be repaid within the next two years, and most would be repaid in 2010. However, higher delinquency rates in the underlying collateral supporting mortgage-backed securities in our investment portfolio could result in future impairment charges related to these securities, which could be material.

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

Changes in Level 3 marketable securities during the year ended December 31, 2009 and 2008 were as follows:

<i>(In millions)</i>	Level 3 Marketable Securities	
	2009	2008
Balance January 1	\$ 0.1	\$ 7.9
Settlements		(8.2)
Realized gain		1.1
Impairments	(0.1)	(0.7)
Balance December 31	<u>0.0</u>	<u>\$ 0.1</u>

During the years ended December 31, 2009 and 2008, there were no transfers of marketable securities between Level 2 and Level 3 classifications.

Our methods for valuing our marketable securities are described in Note 2 to our financial statements included in this Annual Report on Form 10-K. With respect to valuations for pricing our Level 2 marketable securities, we consider quantitative and qualitative factors such as financial conditions and near term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. For valuations that we determine for our Level 3 marketable securities, we regularly monitor these securities and adjust their valuations as deemed appropriate based on the facts and circumstances.

Collaborations with the sanofi-aventis Group

Aflibercept

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

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

In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a \$25.0 million non-refundable up-front payment to us, which was received in January 2006. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to

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

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

Under the collaboration agreement, as amended, agreed upon worldwide aflibercept development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the \$25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of an aflibercept product for intraocular delivery to the eye predates the first commercial sale of an aflibercept product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to \$7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs. Since inception of the collaboration agreement through December 31, 2009, we and sanofi-aventis have incurred \$598.4 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.

Sanofi-aventis funded \$26.6 million, \$35.6 million, and \$38.3 million, respectively, of our aflibercept development costs in 2009, 2008, and 2007, of which \$3.6 million, \$6.3 million, and \$10.5 million, respectively, were included in accounts receivable as of December 31, 2009, 2008, and 2007. In addition, the up-front payments from sanofi-aventis of \$80.0 million in September 2003 and \$25.0 million in January 2006 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 2009, 2008, and 2007, we recognized \$9.9 million, \$8.8 million, and \$8.8 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

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$175 million of research from the collaboration's inception through December 31, 2009. In November 2009, we and sanofi-aventis amended these collaboration agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to \$160 million per year of our antibody discovery activities in 2010 through 2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. The discovery agreement will expire on December 31, 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Under the license agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate (called Shared Phase 3 Trial Costs) will be shared 80% by sanofi-aventis and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of \$140.2 million as of December 31, 2009)

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. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs. 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 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the collaboration until commercial supplies of that drug candidate are being manufactured. In connection with the November 2009 amendment of the collaboration's discovery agreement, sanofi-aventis will fund up to \$30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which \$0.5 million were included in accounts receivable at December 31, 2009.

In 2009, 2008, and 2007, sanofi-aventis funded \$99.8 million, \$72.2 million, and \$3.0 million, respectively, of our expenses under the collaboration's discovery agreement and \$98.3 million, \$25.7 million, and \$0.7 million, respectively, of our development costs under the license agreement. Of these amounts, \$57.9 million and \$25.5 million were included in accounts receivable as of December 31, 2009 and 2008, respectively. The \$85.0 million up-front payment received from sanofi-aventis in December 2007 was recorded to deferred revenue and is being recognized as collaboration revenue over the period during which we expect to perform services. In 2009, 2008, and 2007, we recognized \$9.9 million, \$10.5 million, and \$0.9 million of revenue, respectively, related to this up-front payment. In addition, reimbursements by sanofi-aventis of our costs to expand our manufacturing capacity will be recorded to deferred revenue and recognized prospectively as collaboration revenue over the same period applicable to recognition of the \$85.0 million up-front payment, as described above.

In connection with the antibody collaboration, in August 2008, we entered into a separate agreement with sanofi-aventis to use our proprietary *VelociGene*[®] technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. The agreement provides for minimum annual order quantities for the term of the agreement, which extends through December 2012, for which we expect to receive payments totaling a minimum of \$21.5 million, of which \$5.1 million had been received as of December 31, 2009.

With respect to each antibody product which enters development under the license agreement, sanofi-aventis or we may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. We may also opt-out of the further development of an antibody product if we give notice to sanofi-aventis within thirty days of the date that sanofi-aventis elects to jointly develop such antibody product under the license agreement. Each of the discovery agreement and the license agreement contains other termination provisions, including for material breach by the other party. Prior to December 31, 2017, 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, 2017. 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. This agreement, which was amended in November 2009, contains certain demand rights, "stand-still provisions", and other restrictions, which are more fully described in Note 12 to our Financial Statements.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, VEGF Trap-Eye. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to us of \$75.0 million. In August 2007, we received a \$20.0 million milestone payment (which, for the purpose of revenue recognition, was not considered substantive) from Bayer HealthCare following dosing of the first patient in the Phase 3 study of VEGF Trap-Eye in wet AMD. In July 2009, we received a \$20.0 million substantive performance milestone payment from Bayer HealthCare following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in CRVO. We are eligible to receive up to \$70 million in additional development and regulatory milestones related to the VEGF Trap-Eye program. We are also eligible to receive up to an additional \$135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

We will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer HealthCare out of our share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of \$138.4 million at December 31, 2009) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and our share of the collaboration profits, or at a faster rate at our option. Within the United States, we are responsible for any future commercialization of VEGF Trap-Eye and retain exclusive rights to any future profits from such commercialization in the United States. To date, we and Bayer HealthCare have initiated Phase 3 programs of VEGF Trap-Eye in wet AMD and CRVO and a Phase 2 clinical study in DME. We are also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

The \$75.0 million up-front payment and the \$20.0 million milestone payment received in August 2007 from Bayer HealthCare were recorded to deferred revenue. In 2009, 2008, and 2007, we recognized \$9.9 million, \$12.4 million, and \$15.9 million, respectively, of revenue related to these deferred payments. The \$20.0 million substantive performance milestone payment received from Bayer HealthCare in July 2009 was recognized as revenue in 2009.

Under the terms of the agreement, in 2009 and thereafter, all agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared equally. In 2009, this resulted in a net payment by us of \$0.3 million to Bayer HealthCare. In 2008, the first \$70.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next \$30.0 million, which resulted in a net payment by us of \$11.3 million to Bayer HealthCare. In 2007, the first \$50.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next \$40.0 million, which resulted in a net reimbursement of \$9.4 million from Bayer HealthCare to us. At December 31, 2009 and 2008, accrued expenses included \$1.2 million and \$9.8 million, respectively, due to Bayer HealthCare.

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

License Agreements with AstraZeneca and Astellas

Under these non-exclusive license agreements, AstraZeneca and Astellas each made \$20.0 million annual, non-refundable payments to us in each of 2009, 2008, and 2007. AstraZeneca and Astellas are each required to make up to three additional annual payments of \$20.0 million, subject to each licensee's ability to terminate its license agreement with us after making the next annual payment in 2010.

National Institutes of Health Grant

Under our five-year grant from the NIH, as amended, we are entitled to receive a minimum of \$25.3 million over the five-year period beginning in September 2006, subject to compliance with the grant's terms and annual funding approvals, including \$1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium. In 2009, 2008, and 2007, we recognized \$5.5 million, \$4.9 million, and \$5.5 million, respectively, of

revenue related to the NIH Grant, of which \$1.2 million and \$1.3 million, respectively, was receivable at the end of 2009 and 2008. In 2010, we expect to receive funding of approximately \$5.5 million for reimbursement of Regeneron expenses related to the NIH Grant.

License Agreement with Collectis

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

We are amortizing our \$12.5 million payment to Collectis in proportion to past and anticipated future revenues under our license agreements with AstraZeneca and Astellas and our antibody discovery agreement with sanofi-aventis (as amended in November 2009). In 2009 and 2008, we recognized \$2.3 million and \$2.7 million, respectively, of expense related to the Collectis agreement.

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

Lease – Tarrytown, New York Facilities:

We lease approximately 537,100 square feet of laboratory and office space at facilities in Tarrytown, New York, under a December 2006 lease agreement, as amended. These facilities include approximately 230,000 square feet of newly constructed space in two new buildings (Buildings A and B) that were completed during the third quarter of 2009 and, under a December 2009 amendment to the lease, approximately 130,900 square feet of additional new space that is under construction in a third new building (Building C), which is expected to be completed in mid-2011. The lease will expire in June 2024 and contains three renewal options to extend the term of the lease by five years each, as well as early termination options on approximately 290,400 square feet of space. The lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Certain premises under the lease are accounted for as operating leases. However, for the newly constructed space that we are leasing, we are deemed, in substance, to be the owner of the landlord's buildings in accordance with the application of FASB authoritative guidance (as described above under "Revision of Previously Issued Financial Statements"), and the landlord's costs of constructing these new facilities are required to be capitalized on our books as a non-cash transaction, offset by a corresponding lease obligation on our balance sheet.

In connection with the lease, 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.

In connection with Buildings A and B, we capitalized our landlord's costs of constructing these new facilities, which totaled \$58.2 million as of December 31, 2009, and recognized a corresponding facility lease obligation of \$58.2 million. We also recognized, as an additional facility lease obligation, reimbursements totaling \$23.6 million from our landlord during 2009 for tenant improvement costs that we incurred since, under FASB authoritative guidance, these reimbursements from our landlord are deemed to be a financing obligation. Monthly lease payments on these facilities are allocated between the land element of the lease (which is accounted for as an operating lease) and the facility lease obligation, based on the estimated relative fair values of the land and buildings. The imputed interest rate applicable to the facility lease obligation is approximately 11%. At December 31, 2009 and 2008, the facility lease obligation balance in connection with these new facilities was \$81.0 million and \$54.2 million, respectively.

In addition, as described above, we amended our lease in December 2009 to include additional new laboratory and office space in Building C that is under construction. As of December 31, 2009, we capitalized \$27.8 million of our landlord's costs of constructing these new facilities, and recognized a corresponding facility lease obligation of \$27.8 million. Monthly lease payments on these facilities will commence in January 2011 and additional charges for utilities, taxes, and operating expenses commenced in January 2010. Rent expense in connection with the land element of these additional facilities, which is accounted for as an operating lease, commenced in December 2009 and is recorded as a deferred liability until lease payments commence in January 2011. In addition, interest expense is imputed at a rate of approximately 9%, and is capitalized and deferred in connection with this facility lease obligation. At December 31, 2009, the facility lease obligation balance in connection with these additional new facilities was \$28.0 million.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled \$97.3 million in 2009, \$34.9 million in 2008, and \$18.4 million in 2007. As described above, \$23.6 million of tenant improvement costs we incurred in Tarrytown were reimbursed by our landlord in 2009. We expect to incur capital expenditures of approximately \$80 to \$110 million in 2010 and approximately \$40 to \$60 million in 2011, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our newly leased Tarrytown facilities in Building C. In February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. We also expect to be reimbursed for a portion of the capital expenditures for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements

Our total expenses for research and development from inception through December 31, 2009 have been approximately \$2.0 billion. 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 *Velocigen*[®] technology platform. We 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, of \$333.7 million, \$230.6 million, and \$108.2 million in 2009, 2008, and 2007, 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 our collaborators, and exclusive of anticipated funding for capital expenditures as described above, we currently anticipate that approximately 65-75% of our expenditures for 2010 will be directed toward the preclinical and clinical development of product candidates, including rilonacept, aflibercept, VEGF Trap-Eye, and clinical stage monoclonal antibodies; approximately 15-25% of our expenditures for 2010 will be applied to our basic research and early preclinical activities; and the remainder of our expenditures for 2010 will be used for the continued development of our novel technology platforms and general corporate purposes. While we expect that funding requirements for our research and development activities will continue to increase in 2010, we also expect that a greater proportion of our research and development expenditures will be reimbursed by our collaborators, especially in connection with our amended and expanded antibody collaboration with sanofi-aventis.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2009. These obligations and commitments assume non-termination of agreements and represent expected payments based on current operating forecasts, which are subject to change:

	Payments Due by Period				
	Total	Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
	<i>(In millions)</i>				
Operating leases ⁽¹⁾	\$ 96.2	\$ 6.3	\$11.6	\$12.4	\$ 65.9
Purchase obligations ⁽²⁾	150.6	112.5	38.1		
Other long-term liabilities ⁽³⁾	205.4	8.2	22.4	26.6	148.2
Total contractual obligations	<u>\$452.2</u>	<u>\$127.0</u>	<u>\$72.1</u>	<u>\$39.0</u>	<u>\$214.1</u>

-
- (1) Excludes future contingent costs for utilities, real estate taxes, and operating expenses included in our rent. In 2009, these costs were \$8.4 million. See Note 11(a) to our Financial Statements.
 - (2) Purchase obligations primarily relate to (i) research and development commitments, including those related to clinical trials, (ii) capital expenditures for equipment acquisitions, and (iii) license payments. Our obligation to pay certain of these amounts may increase or be reduced based on certain future events. Open purchase orders for the acquisition of goods and services in the ordinary course of business are excluded from the table above.
 - (3) Represents payments with respect to facility lease obligations in connection with our lease of facilities in Tarrytown, New York, as described above. See Note 11(a) to our Financial Statements.

As described above, in February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. As a result, total contractual obligations, as detailed in the table above, will increase (i) from 127.0 million to \$130.9 million for the year ending December 31, 2010, (ii) from \$72.1 million to \$80.0 million for the two-year period beginning January 1, 2011, (iii) from \$39.0 million to \$47.0 million for the two-year period beginning January 1, 2013, and (iv) from \$214.1 million to \$251.6 million for the fiscal years beginning January 1, 2015 and thereafter.

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

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

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

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. For example, if we choose to commercialize products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that

could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we would expect to prioritize available capital to fund selected preclinical and clinical development programs or license selected products.

Other than our operating leases and a \$1.6 million letter of credit issued to our landlord in connection with our 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, 2009, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In October 2009, the FASB amended its authoritative guidance on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate arrangement consideration in a multiple-element revenue arrangement by requiring the use of estimated selling prices to allocate arrangement consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. This guidance may be applied retrospectively or prospectively for new or materially modified arrangements. We are required to adopt this amended guidance effective for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. We are currently evaluating the impact that this guidance will have on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates principally in connection with our investment of excess cash in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a \$0.6 million and \$1.9 million decrease in the fair value of our investment portfolio at December 31, 2009 and 2008, respectively.

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. We have recognized other-than-temporary impairment charges related to certain marketable securities of \$0.1 million, \$2.5 million, and \$5.9 million in 2009, 2008, and 2007, respectively.

The current economic environment and the deterioration in the credit quality of issuers of securities that we hold increase the risk of potential declines in the current market value of marketable securities in our investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item are included on pages F-1 through F-35 of this report. The supplementary financial information required by this Item is included at page F-35 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, 2009. The effectiveness of our internal control over financial reporting as of December 31, 2009 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, 2009 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, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2010 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

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

ITEM 11. EXECUTIVE COMPENSATION

The information called for by this item will be included in our definitive proxy statement with respect to our 2010 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

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

The information called for by this item will be included in our definitive proxy statement with respect to our 2010 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

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

The information required by this item will be included in our definitive proxy statement with respect to our 2010 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item will be included in our definitive proxy statement with respect to our 2010 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)1. Financial Statements

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

2. Financial Statement Schedules

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

3. Exhibits

Exhibit Number	Description
3.1	(o) - Restated Certificate of Incorporation.
3.2	(a) - By-Laws, as amended.
10.1 +	(b) - 1990 Amended and Restated Long-Term Incentive Plan.
10.2 +	(p) - Amended and Restated 2000 Long-Term Incentive Plan.
10.2.1 +	(c) - Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers.
10.2.2 +	(c) - Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10.2.3 +	(d) - Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers.
10.2.4 +	(d) - Form of option agreement and related notice of grant for use in connection with the grant of stock options to certain of the Registrant's executive officers in connection with a January 2005 Option Exchange Program.
10.2.5 +	(t) - Form of option agreement and related notice of grant for use in connection with the grant of time based vesting stock options to the Registrant's non-employee directors and executive officers.
10.2.6 +	(t) - Form of option agreement and related notice of grant for use in connection with the grant of performance based vesting stock options to the Registrant's executive officers.
10.3 +	(s) - Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D.
10.4* +	(e) - Employment Agreement, dated as of December 31, 1998, between the Registrant and P. Roy Vagelos, M.D.
10.5 +	(s) - Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008.
10.6*	(f) - IL-1 License Agreement, dated June 26, 2002, by and among the Registrant, Immunex Corporation, and Amgen Inc.
10.7*	(u) - IL-1 Antibody Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009.
10.8*	(u) - Trap-2 Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009.
10.9*	(g) - Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and the Registrant.
10.9.1*	(e) - Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December 31, 2004.
10.9.2	(h) - Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of January 7, 2005.
10.9.3*	(i) - Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December 21, 2005.
10.9.4*	(i) - Amendment No. 4 to Collaboration Agreement, by and between sanofi-aventis U.S., LLC (successor in interest to Aventis Pharmaceuticals, Inc.) and the Registrant, effective as of January 31, 2006.
10.10*	(j) - License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and the Registrant.
10.11*	(k) - Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007, by and between AstraZeneca UK Limited and the Registrant.
10.12	(l) - Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and the Registrant.
10.12.1*	(n) - First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of October 24, 2007.

10.12.2	(r)	- Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of September 30, 2008.
10.12.3	(t)	- Third Amendment to lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of April 29, 2009.
10.12.4	(v)	- Fourth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of December 3, 2009.
10.12.5	(w)	- Fifth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of February 11, 2010.
10.13*	(m)	- Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and the Registrant.
10.14*		- Amended and Restated Discovery and Preclinical Development Agreement, dated as of November 10, 2009, by and between Aventis Pharmaceuticals Inc. and the Registrant.
10.15*		- Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique Du Nord, and the Registrant.
10.16	(o)	- Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amerique Du Nord, sanofi-aventis US LLC, and the Registrant.
10.17	(o)	- 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 the Registrant.
10.17.1		- First Amendment to the December 20, 2007 Investor Agreement, dated as of November 10, 2009, by and among sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and the Registrant.
10.18*	(q)	- Amended and Restated Non-Exclusive License Agreement, dated as of July 1, 2008 by and between Collectis, S.A. and the Registrant.
23.1		- Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1		- Power of Attorney (included on the signature page of this Annual Report on Form 10-K)
31.1		- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2		- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32		- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Description:

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

- (j) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2006, filed November 6, 2006.
- (k) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2006, filed March 12, 2007.
- (l) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.
- (m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2007, filed May 4, 2007.
- (n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2007, filed November 7, 2007.
- (o) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2007, filed February 27, 2008.
- (p) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed June 17, 2008.
- (q) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2008, filed August 1, 2008.
- (r) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2008, filed November 5, 2008.
- (s) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2008, filed February 26, 2009.
- (t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2009, filed April 30, 2009.
- (u) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2009, filed August 4, 2009.
- (v) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 8, 2009.
- (w) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed February 16, 2010.

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

+ Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

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

REGENERON PHARMACEUTICALS, INC.

BY: /s/ LEONARD S. SCHLEIFER

Leonard S. Schleifer, M.D., Ph.D.

President and Chief Executive Officer

Dated: Tarrytown, New York
February 18, 2010

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 annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

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

REGENERON PHARMACEUTICALS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

In our opinion, the accompanying balance sheets and the related statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Regeneron Pharmaceuticals, Inc. at December 31, 2009 and December 31, 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 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, 2009, 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.

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 18, 2010

REGENERON PHARMACEUTICALS, INC.
BALANCE SHEETS

December 31, 2009 and 2008

(In thousands, except share data)

	2009	2008
		<i>(Revised - see Note 11)</i>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 207,075	\$ 247,796
Marketable securities	134,255	226,954
Accounts receivable from the sanofi-aventis Group	62,703	33,302
Accounts receivable - other	2,865	1,910
Prepaid expenses and other current assets	18,610	11,480
Total current assets	425,508	521,442
Restricted cash	1,600	1,650
Marketable securities	47,080	51,061
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	259,676	142,035
Other assets	7,338	8,032
Total assets	\$ 741,202	\$ 724,220
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 49,031	\$ 36,168
Deferred revenue from sanofi-aventis, current portion	17,523	21,390
Deferred revenue - other, current portion	27,021	26,114
Total current liabilities	93,575	83,672
Deferred revenue from sanofi-aventis	90,933	105,586
Deferred revenue - other	46,951	56,835
Facility lease obligations	109,022	54,182
Other long term liabilities	3,959	2,431
Total liabilities	344,440	302,706
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 - 2,244,698 in 2009 and 2,248,698 in 2008	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 78,860,862 in 2009 and 77,642,203 in 2008	79	78
Additional paid-in capital	1,336,732	1,294,813
Accumulated deficit	(941,095)	(873,265)
Accumulated other comprehensive income (loss)	1,044	(114)
Total stockholders' equity	396,762	421,514
Total liabilities and stockholders' equity	\$ 741,202	\$ 724,220

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

REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2009, 2008, and 2007

(In thousands except share data)

	<u>2009</u>	<u>2008</u> <i>(Revised - see Note 11)</i>	<u>2007</u> <i>(Revised - see Note 11)</i>
Revenues			
Sanofi-aventis collaboration revenue	\$247,140	\$153,972	\$ 51,687
Other collaboration revenue	67,317	31,166	35,961
Technology licensing	40,013	40,000	28,421
Net product sales	18,364	6,249	
Contract research and other	6,434	7,070	8,955
	<u>379,268</u>	<u>238,457</u>	<u>125,024</u>
Expenses			
Research and development	398,762	274,903	202,468
Selling, general, and administrative	52,923	48,880	37,929
Cost of goods sold	1,686	923	
	<u>453,371</u>	<u>324,706</u>	<u>240,397</u>
Loss from operations	<u>(74,103)</u>	<u>(86,249)</u>	<u>(115,373)</u>
Other income (expense)			
Investment income	4,488	18,161	20,897
Interest expense	(2,337)	(7,752)	(12,043)
Loss on early extinguishment of debt		(938)	
	<u>2,151</u>	<u>9,471</u>	<u>8,854</u>
Net loss before income tax expense	<u>(71,952)</u>	<u>(76,778)</u>	<u>(106,519)</u>
Income tax (benefit) expense	<u>(4,122)</u>	<u>2,351</u>	
Net loss	<u>\$ (67,830)</u>	<u>\$ (79,129)</u>	<u>\$ (106,519)</u>
Net loss per share, basic and diluted	<u>\$ (0.85)</u>	<u>\$ (1.00)</u>	<u>\$ (1.61)</u>
Weighted average shares outstanding, basic and diluted	79,782	78,827	66,334

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

REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY

For the Years Ended December 31, 2009, 2008, and 2007
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	Total Comprehensive Loss
	Shares	Amount	Shares	Amount					
Balance, December 31, 2006	2,270	\$2	63,131	\$ 63	\$ 904,407	\$(687,617)	\$ (231)	\$ 216,624	
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						(106,519)		(106,519)	\$(106,519)
Change in net unrealized gain (loss) on marketable securities							401	401	401
Balance, December 31, 2007 (Revised- see Note 11)	2,260	2	76,592	77	1,253,235	(794,136)	170	459,348	<u>\$ (106,118)</u>
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			980	1	7,948			7,949	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			59		1,107			1,107	
Conversion of Class A Stock to Common Stock	(11)		11						
Stock-based compensation expense					32,523			32,523	
Net loss, 2008						(79,129)		(79,129)	\$(79,129)
Change in net unrealized gain (loss) on marketable securities							(284)	(284)	(284)
Balance, December 31, 2008 (Revised - see Note 11)	2,249	2	77,642	78	1,294,813	(873,265)	(114)	421,514	<u>\$ (79,413)</u>
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			1,134	1	9,269			9,270	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			81		1,391			1,391	
Conversion of Class A Stock to Common Stock	(4)		4						
Stock-based compensation expense					31,259			31,259	
Net loss, 2009						(67,830)		(67,830)	\$(67,830)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of \$0.7 million							1,158	1,158	1,158
Balance, December 31, 2009	2,245	\$2	78,861	\$ 79	\$1,336,732	\$(941,095)	\$1,044	\$ 396,762	<u>\$ (66,672)</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, 2009, 2008, and 2007

	2009	2008	2007
	<i>(In thousands)</i>		
Cash flows from operating activities			
Net loss	\$ (67,830)	\$ (79,129)	\$ (106,519)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities			
Depreciation and amortization	14,247	11,287	11,487
Non-cash compensation expense	31,259	32,523	28,075
Other non-cash expenses	(382)		
Loss on early extinguishment of debt		938	
Net realized (gain) loss on marketable securities	(56)	1,310	5,943
Changes in assets and liabilities			
Increase in accounts receivable	(30,356)	(16,892)	(10,827)
Increase in prepaid expenses and other assets	(4,574)	(6,560)	(9,649)
(Decrease) increase in deferred revenue	(27,497)	(26,834)	89,764
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	12,959	(5,729)	19,098
Total adjustments	(4,400)	(9,957)	133,891
Net cash (used in) provided by operating activities	(72,230)	(89,086)	27,372
Cash flows from investing activities			
Purchases of marketable securities	(199,997)	(581,139)	(594,446)
Sales or maturities of marketable securities	297,411	646,861	527,169
Capital expenditures	(97,318)	(34,857)	(18,446)
Decrease (increase) in restricted cash	50	(50)	
Net cash provided by (used in) investing activities	146	30,815	(85,723)
Cash flows from financing activities			
Repurchases or repayment of notes payable		(200,807)	
Proceeds in connection with facility lease obligation	23,640		
Payments in connection with facility lease obligation	(875)		
Net proceeds from the issuance of Common Stock	8,598	7,949	319,400
Net cash provided by (used in) financing activities	31,363	(192,858)	319,400
Net (decrease) increase in cash and cash equivalents	(40,721)	(251,129)	261,049
Cash and cash equivalents at beginning of period	247,796	498,925	237,876
Cash and cash equivalents at end of period	\$ 207,075	\$ 247,796	\$ 498,925
Supplemental disclosure of cash flow information			
Cash paid for interest	\$ 2,525	\$ 9,348	\$ 11,000
Cash paid for income taxes		\$ 3,079	

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

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
For the years ended December 31, 2009, 2008, and 2007
(Unless otherwise noted, dollars in thousands, except per share data)

1. Organization and Business

Regeneron Pharmaceuticals, Inc. (the "Company" or "Regeneron") was incorporated in January 1988 in the State of New York. The Company is engaged in the research, development, and commercialization of therapeutics to treat human disorders and conditions. In 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for the Company's first commercial drug product, ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company's facilities are primarily located in New York. The Company's business is subject to certain risks including, but not limited to, uncertainties relating to conducting pharmaceutical research, obtaining regulatory approvals, commercializing products, and obtaining and enforcing patents.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

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

Marketable Securities

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The Company has invested its excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities, and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. The Company considers its marketable securities to be "available-for-sale," as defined by authoritative guidance issued by the Financial Accounting Standards Board ("FASB"). These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a marketable security in the Company's investment portfolio is deemed to be other-than-temporary, the Company writes down the security to its current fair value and recognizes a loss that may be charged against income. As described under "Use of Estimates" below, on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary.

Capitalization of Inventory Costs

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

Property, Plant, and Equipment

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

Building and improvements	7-35 years
Laboratory and other equipment	3-10 years
Furniture and fixtures	5 years

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)
For the years ended December 31, 2009, 2008, and 2007
(Unless otherwise noted, dollars in thousands, except per share data)

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

Accounting for the Impairment of Long-Lived Assets

The Company periodically assesses the recoverability of long-lived assets, such as property, plant, and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Asset impairment is determined to exist if estimated future undiscounted cash flows are less than the carrying amount. 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 for product candidates under development are expensed as incurred. Patent costs related to commercial products are capitalized and amortized over the remaining patent term. To date, the Company has no capitalized patent costs.

Operating Leases

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

Revenue Recognition

Certain reclassifications have been made to our prior year revenue amounts to conform to the 2009 presentation.

a. Collaboration Revenue

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

The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, such as in the Company's VEGF Trap-Eye collaboration with Bayer

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)
For the years ended December 31, 2009, 2008, and 2007
(Unless otherwise noted, dollars in thousands, except per share data)

HealthCare LLC, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities, such as in the Company's aflibercept and antibody collaborations with the sanofi-aventis Group. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as collaboration 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 connection with non-refundable licensing payments, the Company's performance period estimates are principally based on projections of the scope, progress, and results of its research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, estimated performance periods may change if development programs encounter delays, or the Company and its collaborators decide to expand or contract the clinical plans for a drug candidate in various disease indications. For example, during the fourth quarter of 2008, the Company extended its estimated performance period in connection with the up-front and non-substantive milestone payments previously received from Bayer HealthCare pursuant to the companies' VEGF Trap-Eye collaboration and shortened its estimated performance period in connection with up-front payments from sanofi-aventis pursuant to the companies' aflibercept collaboration. The net effect of these changes in the Company's estimates resulted in the recognition of \$0.4 million less in collaboration revenue in the fourth quarter of 2008, compared to amounts recognized in connection with these deferred payments in each of the prior three quarters of 2008. In addition, in connection with amendments to expand and extend the Company's antibody collaboration with sanofi-aventis, during the fourth quarter of 2009, the Company extended its estimated performance period related to the up-front payment previously received from sanofi-aventis pursuant to the companies' antibody collaboration. The effect of this change in estimate resulted in the recognition of \$0.6 million less in collaboration revenue in the fourth quarter of 2009, compared to amounts recognized in each of the prior three quarters of 2009. 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. *VelocImmune*[®] Technology Licensing

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

c. Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST[®] (rilonacept) for the treatment of CAPS. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and the Company has no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distribution fees, and other sales-related costs. Since the Company currently has limited historical return and rebate experience for ARCALYST, product sales revenues are deferred until (i) the right of return no longer exists or the Company can reasonably

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)
For the years ended December 31, 2009, 2008, and 2007
(Unless otherwise noted, dollars in thousands, except per share data)

estimate returns and (ii) rebates have been processed or the Company can reasonably estimate rebates. The Company reviews its estimates of rebates payable each period and records any necessary adjustments in the current period's net product sales.

Investment Income

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

Research and Development Expenses

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

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

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by contract research organizations ("CROs"). CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these startup costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of the Company's contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, the Company accrues expense on an estimated cost-per-patient basis, 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.

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)
For the years ended December 31, 2009, 2008, and 2007
(Unless otherwise noted, dollars in thousands, except per share data)

Stock-based Compensation

The Company recognizes stock-based compensation expense for grants of stock option awards and restricted stock under the Company's Long-Term Incentive Plans, to employees and non-employee members of the Company's board of directors, based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period. In addition, the Company has granted performance-based stock option awards which vest based upon the optionee satisfying certain performance and service conditions as defined in the agreements. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, the Company estimates that these options will vest, which is based on whether the Company consider the options' performance conditions to be probable of attainment. The Company's estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods.

The Company uses the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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.

Uncertain tax positions are accounted for in accordance with FASB authoritative guidance, which the Company adopted on January 1, 2007. Such guidance prescribes a comprehensive model for the manner in which a company should recognize, measure, present, and disclose in its financial statements all material uncertain tax positions that the company has taken or expects to take on a tax return. Those positions, for which management's assessment is that there is more than a 50% probability of sustaining the position upon challenge by a taxing authority based upon its technical merits, are subjected to certain measurement criteria. For the years ended December 31, 2009, 2008, and 2007, the Company has not recognized any income tax positions that were deemed uncertain under the recognition thresholds and measurement attributes prescribed by FASB authoritative guidance.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense.

Comprehensive Income (Loss)

Comprehensive income (loss) of the Company includes net income (loss) adjusted for the change in net unrealized gain or loss on marketable securities, net of any tax effect. Comprehensive income (loss) for the years ended December 31, 2009, 2008, and 2007 have been included in the Statements of Stockholders' Equity.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities (see Note 6), and receivables from sanofi-aventis.

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)
For the years ended December 31, 2009, 2008, and 2007
(Unless otherwise noted, dollars in thousands, except per share data)

Per Share Data

Net income (loss) per share, basic and diluted, is computed on the basis of the net income (loss) for the period divided by the weighted average number of shares of Common Stock and Class A Stock outstanding during the period. Basic net income (loss) per share excludes restricted stock awards until vested. Diluted net income per share is based upon the weighted average number of shares of Common Stock and Class A Stock outstanding, and of common stock equivalents outstanding when dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock awards under the Company's Long-Term Incentive Plans, which are included under the "treasury stock method" when dilutive, and (ii) Common Stock to be issued under the assumed conversion of the Company's formerly outstanding convertible senior subordinated notes, which are included under the "if-converted method" when dilutive. The computation of diluted net loss per share for the years ended December 31, 2009, 2008, and 2007 does not include common stock equivalents, since such inclusion would be antidilutive.

Risks and Uncertainties

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

The Company has generally incurred net losses and negative cash flows from operations since its inception. Revenues to date have principally been limited to (i) up-front, license, milestone, and reimbursement payments from the Company's collaborators and other entities related to the Company's development activities and technology platforms, (ii) payments for past contract manufacturing activities, (iii) ARCALYST product sales, and (iv) investment income. Collaboration revenue in 2009 was earned from sanofi-aventis and Bayer HealthCare under collaboration agreements (see Note 3 for the terms of these agreements). These collaboration agreements contain early termination provisions that are exercisable by sanofi-aventis or Bayer HealthCare, as applicable.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Estimates which could have a significant impact on the Company's financial statements include:

- Periods over which payments, including non-refundable up-front, license, and milestone payments, are recognized as revenue in connection with collaboration and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms.
- Product rebates and returns in connection with the recognition of revenue from product sales.
- Periods over which certain clinical trial costs, including costs for clinical activities performed by contract research organizations, are recognized as research and development expenses.

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- In connection with stock option awards, (i) the fair value of stock options on their date of grant using the Black-Scholes option-pricing model, based on assumptions with respect to (a) expected volatility of the Company's Common Stock price, (b) the periods of time for which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (c) expected dividend yield on the Company's Common Stock, and (d) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives; (ii) the number of stock option awards that are expected to be forfeited; and (iii) with respect to performance-based stock option awards, if and when we consider the options' performance conditions to be probable of attainment.
- The Company's determination of whether marketable securities are other than temporarily impaired. The Company conducts a quarterly review of its portfolio of marketable securities, using both quantitative and qualitative factors, to determine, for securities whose current fair value is less than their cost, whether the decline in fair value below cost is other-than-temporary. In making this determination, the Company considers factors such as the length of time and the extent to which fair value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. This review process also includes an evaluation of the Company's ability and intent to hold individual securities until they mature or their full value can be recovered. This review is subjective and requires a high degree of judgment.
- Useful lives of property, plant, and equipment.
- The extent to which deferred tax assets and liabilities are offset by a valuation allowance.

In addition, the Company's share of VEGF Trap-Eye development expenses incurred by Bayer HealthCare, including the Company's share of Bayer HealthCare's estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter, are included in research and development expenses. The Bayer HealthCare estimate for the most recent fiscal quarter is adjusted in the subsequent quarter to reflect actual expenses for the quarter.

Future Impact of Recently Issued Accounting Standards

In October 2009, the FASB amended its authoritative guidance on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate arrangement consideration in a multiple-element revenue arrangement by requiring the use of estimated selling prices to allocate arrangement consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. This guidance may be applied retrospectively or prospectively for new or materially modified arrangements. The Company will be required to adopt this amended guidance effective for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management is currently evaluating the impact that this guidance will have on the Company's financial statements.

3. Collaboration and Contract Research 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 totaled \$320.9 million, \$192.2 million, and \$96.6 million in 2009, 2008, and 2007, 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 \$333.7 million, \$230.6 million, and \$108.2 million in 2009, 2008, and 2007, respectively. Significant agreements of this kind are described below.

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a. The sanofi-aventis Group

Aflibercept

In September 2003, the Company entered into a collaboration agreement (the "Aflibercept 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 Aflibercept 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 December 2005, the Company and sanofi-aventis amended the Aflibercept 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 Aflibercept Agreement, as amended, the Company and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan, for disease indications included in the companies' collaboration. The Company is entitled to a royalty of approximately 35% on annual sales of aflibercept in Japan, subject to certain potential adjustments. The Company may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to the receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

Under the Aflibercept 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 \$598.4 million as of December 31, 2009, 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 Aflibercept 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.

In accordance with the Company's revenue recognition policy described in 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 collaboration revenue over the related performance period. The Company recognized \$36.5 million, \$44.4 million, and \$47.1 million of collaboration development revenue in 2009, 2008, and 2007, respectively, in connection with the Aflibercept Agreement, as amended. At December 31, 2009 and 2008, amounts receivable from sanofi-aventis totaled \$3.6 million and \$6.3 million, respectively, and deferred revenue was \$42.5 million and \$52.4 million, respectively, in connection with the Aflibercept Agreement.

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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 12).

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, under the Discovery Agreement, sanofi-aventis funded \$174.5 million of the Company’s research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against those targets from the collaboration’s inception through December 31, 2009. In November 2009, the Company and sanofi-aventis amended these collaboration agreements to expand and extend the Antibody Collaboration. Pursuant to the Discovery Agreement, as amended, sanofi-aventis will fund up to \$160 million per year of the Company’s research activities in 2010 through 2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. The amended Discovery Agreement will expire on December 31, 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the Discovery Agreement, sanofi-aventis has the option to license rights to the candidate under the License Agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with the Company through product approval. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the License Agreement, the Company will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. The Company and sanofi-aventis are currently co-developing five therapeutic antibodies 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 \$140.2 million as of December 31, 2009) 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. However, the Company is not required to apply more than 10% of its share of the profits from the antibody collaboration in any calendar quarter to reimburse sanofi-aventis for these development costs.

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

Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the Antibody Collaboration until commercial supplies of that drug candidate are being manufactured. In connection with the November 2009 amendment of the collaboration’s Discovery Agreement, sanofi-aventis will fund up to \$30 million of agreed-upon costs incurred by the Company to expand its manufacturing capacity at the Company’s Rensselaer, New York facilities.

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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. Prior to December 31, 2017, 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, 2017. 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.

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

In accordance with the Company's revenue recognition policy described in Note 2, the (i) \$85.0 million up-front payment received in December 2007, (ii) reimbursement of Regeneron-incurred expenses under the Discovery and License Agreements, (iii) \$21.5 million of aggregate minimum payments under the *VelociGene* Agreement, and (iv) reimbursement of agreed-upon costs to expand the Company's manufacturing capacity are being recognized as collaboration revenue over the related performance period. In connection with the Antibody Collaboration, the Company recognized \$210.7 million, \$109.6 million, and \$4.6 million of collaboration revenue in 2009, 2008, and 2007, respectively. In addition, at December 31, 2009 and 2008, amounts receivable from sanofi-aventis totaled \$59.1 million and \$27.0 million and deferred revenue was \$66.0 million and \$74.6 million, respectively.

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 August 2007, the Company received a \$20.0 million milestone payment from Bayer HealthCare (which, for the purpose of revenue recognition, was not considered substantive) following dosing of the first patient in a Phase 3 study of *VEGF Trap-Eye* in the neovascular form of age-related macular degeneration ("*wet AMD*"). In July 2009, the Company received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in a Phase 3 study of *VEGF Trap-Eye* in Central Retinal Vein Occlusion ("*CRVO*"). In addition, the Company is eligible to receive up to \$70 million in additional development and regulatory milestones related to the *VEGF Trap-Eye* program. The Company is also eligible to receive up to \$135 million in sales milestones when and if total annual sales of *VEGF Trap-Eye* outside the United States achieve certain specified levels starting at \$200 million.

The Company will share equally with Bayer HealthCare in any future profits arising from the commercialization of *VEGF Trap-Eye* outside the United States. If *VEGF Trap-Eye* is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer HealthCare out of its share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of \$138.4 million as of December 31, 2009) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. Within the United States, the Company is responsible for any future commercialization of *VEGF Trap-Eye* and retains exclusive rights to any future profits from such commercialization in the United States.

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

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

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

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

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

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue for financial statement purposes. In the fourth quarter of 2007, Regeneron and Bayer HealthCare approved a global development plan for VEGF Trap-Eye in wet AMD. The plan included estimated development steps, timelines, and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. In addition, in the fourth quarter of 2007, Regeneron and Bayer HealthCare reaffirmed the companies' commitment to a diabetic macular edema ("DME") development program and had initial estimates of development costs for VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's VEGF Trap-Eye development expenses. The \$75.0 million up-front licensing payment and the \$20.0 million milestone payment received in August 2007 from Bayer HealthCare are being recognized as collaboration revenue over the related estimated performance period in accordance with the Company's revenue recognition policy as described in 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 collaboration 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, the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up.

The Company recognized \$67.3 million, \$31.2 million, and \$35.9 million of collaboration revenue from Bayer HealthCare in 2009, 2008, and 2007, respectively. In 2009, collaboration revenue from Bayer HealthCare included the \$20.0 million milestone payment received in July 2009 which, for the purpose of revenue recognition, was considered substantive. In addition, in 2009, 2008, and 2007, the Company recognized as additional research and development expense \$37.7 million, \$30.0 million, and \$10.6 million, respectively, of VEGF Trap-Eye development expenses that the Company was obligated to reimburse to Bayer HealthCare.

In connection with cost-sharing of VEGF Trap-Eye expenses under the collaboration, \$1.2 million and \$9.8 million was payable to Bayer HealthCare at December 31, 2009 and 2008, respectively. In addition, at December 31, 2009 and 2008, deferred revenue from the Company's collaboration with Bayer HealthCare was \$56.8 million and \$66.7 million, respectively.

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c. National Institute of Health

In September 2006, the Company was awarded a grant from the National Institutes of Health (“NIH”) as part of the NIH’s Knockout Mouse Project. As amended, the NIH grant provides a minimum of \$25.3 million in funding over a five-year period, including \$1.5 million in funding to optimize certain existing technology, subject to compliance with its terms and annual funding approvals, for the Company’s use of its *VelociGene*[®] technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells which can be used to produce knockout mice. The Company records revenue in connection with the NIH 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 2009, 2008, and 2007, the Company recognized contract research revenue of \$5.5 million, \$4.9 million, and \$5.5 million, respectively, from the NIH Grant.

4. 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 annual, non-refundable payment to the Company in each of 2009, 2008, and 2007. Each annual payment is deferred and recognized as revenue ratably over approximately the ensuing twelve-month period. AstraZeneca is required to make up to three additional annual payments of \$20.0 million, subject to their ability to terminate the agreement after making the next annual payment in 2010. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company’s *VelocImmune* technology. In connection with the AstraZeneca license agreement, for the years ended December 31, 2009, 2008, and 2007, the Company recognized \$20.0 million, \$20.0 million, and \$17.1 million of technology licensing revenue. In addition, deferred revenue at December 31, 2009, 2008, and 2007 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 annual, non-refundable payment to the Company in each of 2009, 2008, and 2007. Each annual payment is deferred and recognized as revenue ratably over approximately the ensuing twelve-month period. Astellas is required to make up to three additional annual payments of \$20.0 million, subject to their ability to terminate the agreement after making the next annual payment in 2010. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company’s *VelocImmune* technology. In connection with the Astellas license agreement, for the years ended December 31, 2009, 2008, and 2007, the Company recognized \$20.0 million, \$20.0 million, and \$11.3 million of technology licensing revenue. In addition, deferred revenue at December 31, 2009, 2008, and 2007 was \$8.7 million.

5. ARCALYST[®] (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST for the treatment of CAPS. For the years-ended December 31, 2009 and 2008, the Company recognized as revenue \$18.4 million and \$6.3 million, respectively, of ARCALYST net product sales for which the right of return no longer existed and rebates could be reasonably estimated. At December 31, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled \$4.8 million and \$4.0 million, respectively.

Cost of goods sold related to ARCALYST sales totaled \$1.7 million and \$0.9 million for the years ended December 31, 2009 and 2008, respectively, and consisted primarily of royalties (see Note 11b). To date, ARCALYST shipments to the Company’s customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST; therefore, the costs of these supplies were not included in costs of goods sold. At December 31, 2009, the Company had \$0.4 million of inventoried work-in-process costs related to ARCALYST, which is included in prepaid expenses and other current assets. There were no capitalized inventory costs at December 31, 2008.

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6. Marketable Securities

Marketable securities at December 31, 2009 and 2008 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was \$5.5 million and \$3.7 million at December 31, 2009 and 2008, respectively, and the aggregate cost basis of which was \$4.0 million and \$4.1 million at December 31, 2009 and 2008, respectively. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at December 31, 2009 and 2008. The Company classifies its debt securities, other than mortgage-backed and other asset-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed and other asset-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

At December 31, 2009	Amortized	Fair	Unrealized Holding		
	Cost Basis	Value	Gains	(Losses)	Net
Maturities within one year					
U.S. government obligations	\$ 100,491	\$ 100,573	\$ 82		\$ 82
U.S. government guaranteed corporate bonds	17,176	17,340	164		164
Corporate bonds	10,142	10,342	200		200
Mortgage-backed securities	2,471	2,338		\$ (133)	(133)
U.S. government guaranteed collateralized mortgage obligations	3,612	3,662	50		50
	<u>133,892</u>	<u>134,255</u>	<u>496</u>	<u>(133)</u>	<u>363</u>
Maturities between one and two years					
U.S. government obligations	9,413	9,367		(46)	(46)
U.S. government guaranteed corporate bonds	31,064	31,344	280		280
Mortgage-backed securities	1,168	900		(268)	(268)
	<u>41,645</u>	<u>41,611</u>	<u>280</u>	<u>(314)</u>	<u>(34)</u>
	<u>\$ 175,537</u>	<u>\$ 175,866</u>	<u>\$ 776</u>	<u>\$ (447)</u>	<u>\$ 329</u>
At December 31, 2008					
Maturities within one year					
U.S. government obligations	\$ 170,993	\$ 172,253	\$ 1,260		\$ 1,260
Corporate bonds	26,894	26,662	25	\$ (257)	(232)
Mortgage-backed securities	9,098	8,420		(678)	(678)
Other asset-backed securities	7,842	7,829		(13)	(13)
U.S. government guaranteed collateralized mortgage obligations	11,742	11,792	50		50
	<u>226,569</u>	<u>226,956</u>	<u>1,335</u>	<u>(948)</u>	<u>387</u>
Maturities between one and three years					
U.S. government guaranteed corporate bonds	29,853	29,811	82	(124)	(42)
Corporate bonds	10,446	10,414	77	(109)	(32)
Mortgage-backed securities	1,821	1,556		(265)	(265)
U.S. government guaranteed collateralized mortgage obligations	5,297	5,570	273		273
	<u>47,417</u>	<u>47,351</u>	<u>432</u>	<u>(498)</u>	<u>(66)</u>
	<u>\$ 273,986</u>	<u>\$ 274,307</u>	<u>\$ 1,767</u>	<u>\$ (1,446)</u>	<u>\$ 321</u>

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At December 31, 2009 and 2008, marketable securities included an additional unrealized gain of \$1.4 million and an additional unrealized loss of \$0.4 million, respectively, related to one equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at December 31, 2009 and 2008. The debt securities listed at December 31, 2009 mature at various dates through December 2011.

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
At December 31, 2009						
U.S. government obligations	\$ 9,367	\$ (46)			\$ 9,367	\$ (46)
Mortgage-backed securities			3,238	(401)	3,238	(401)
	<u>\$ 9,367</u>	<u>\$ (46)</u>	<u>\$ 3,238</u>	<u>\$ (401)</u>	<u>\$12,605</u>	<u>\$ (447)</u>
At December 31, 2008						
Corporate bonds	\$15,559	\$(287)	\$ 2,933	\$(79)	\$18,492	\$(366)
Government guaranteed corporate bonds	11,300	(124)			11,300	(124)
Mortgage-backed securities	871	(74)	9,104	(869)	9,975	(943)
Other asset-backed securities	7,829	(13)			7,829	(13)
Equity securities	3,608	(436)			3,608	(436)
	<u>\$39,167</u>	<u>\$(934)</u>	<u>\$12,037</u>	<u>\$(948)</u>	<u>\$51,204</u>	<u>\$(1,882)</u>

Realized gains and losses are included as a component of investment income. For the years ended December 31, 2009 and 2008, realized gains on sales of marketable securities totaled \$0.2 million and \$1.2 million, respectively, and realized losses on sales of marketable securities were not significant. For the year ended December 31, 2007, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at December 31, 2009 and 2008, were as follows:

Description	Fair Value at December 31, 2009	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale marketable securities				
U.S. government obligations	\$109,940		\$109,940	
U.S. government guaranteed corporate bonds	48,684		48,684	
Corporate bonds	10,342		10,342	
Mortgage-backed securities	3,238		3,238	
U.S. government guaranteed collateralized mortgage obligations	3,662		3,662	
Equity securities	5,469	5,469		
Total	<u>\$181,335</u>	<u>\$5,469</u>	<u>\$175,866</u>	

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Description	Fair Value Measurements at Reporting Date Using			
	Fair Value at December 31, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale marketable securities				
U.S. government obligations	\$172,253		\$172,253	
U.S. government guaranteed corporate bonds	29,811		29,811	
Corporate bonds	37,076		37,076	
Mortgage-backed securities	9,976		9,976	
Other asset backed securities	7,829		7,829	
U.S. government guaranteed collateralized mortgage obligations	17,362		17,362	
Equity securities	3,708	\$3,608		\$100
Total	\$278,015	\$3,608	\$274,307	\$100

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During the years ended December 31, 2009 and 2007, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities. During the year ended December 31, 2008, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the security's \$2.0 million carrying value. As a result, the Company recognized a \$1.8 million charge related to this Level 2 marketable security, which the Company considered to be other than temporarily impaired.

Marketable securities included in Level 3 were valued using information provided by the Company's investment advisors, including quoted bid prices which take into consideration the securities' current lack of liquidity. During the year ended December 31, 2007, deterioration in the credit quality of marketable securities from two issuers subjected the Company to the risk of not being able to recover the full principal value of these securities. As a result, the Company recognized a \$5.9 million charge related to these marketable securities, which the Company considered to be other than temporarily impaired. During the years ended December 31, 2009 and 2008, the Company recognized an additional \$0.1 million and \$0.7 million, respectively, in other-than-temporary impairment charges related to one of these marketable securities.

There were no unrealized gains or losses related to the Company's Level 3 marketable securities for the years ended December 31, 2009 and 2008. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities, and no transfers of marketable securities between the Level 2 and Level 3 classifications, during the years ended December 31, 2009 and 2008.

Changes in marketable securities included in Level 3 during the years ended December 31, 2009 and 2008 were as follows:

	Level 3 Marketable Securities	
	2009	2008
Balance, January 1	\$ 100	\$ 7,950
Settlements		(8,194)
Realized gain		1,044
Impairments	(100)	(700)
Balance, December 31	<u>\$</u>	<u>\$ 100</u>

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As described in Note 2 above under "Use of Estimates", on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

The current economic environment and the deterioration in the credit quality of issuers of securities that the Company holds increase the risk of potential declines in the current market value of marketable securities in the Company's investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

7. Property, Plant, and Equipment

Property, plant, and equipment as of December 31, 2009 and 2008 consist of the following:

	2009	2008
Land	\$ 2,117	\$ 2,117
Building and improvements	177,710	74,343
Leasehold improvements	4,023	2,720
Construction-in-progress	58,541	78,702
Laboratory and other equipment	114,099	75,935
Furniture, computer and office equipment, and other	15,964	7,501
	<u>372,454</u>	<u>241,318</u>
Less, accumulated depreciation and amortization	(112,778)	(99,283)
	<u>\$ 259,676</u>	<u>\$ 142,035</u>

Building and improvements at December 31, 2009 includes \$58.2 million of costs incurred by the Company's landlord to construct new laboratory and office facilities in Tarrytown, New York in connection with the Company's December 2006 lease, as amended, of these new facilities. In addition, construction-in-progress at December 31, 2009 and 2008 includes \$27.8 million and \$54.2 million, respectively, of costs incurred by the Company's landlord in connection with these new facilities. See Note 11a.

The Company capitalized interest costs of \$0.5 million in 2009. The Company did not capitalize any interest costs in 2008 or 2007.

Depreciation and amortization expense on property, plant, and equipment amounted to \$14.2 million, \$10.6 million, and \$10.4 million for the years ended December 31, 2009, 2008, and 2007, respectively.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2009 and 2008 consist of the following:

	2009	2008
Accounts payable	\$ 18,638	\$ 6,268
Payable to Bayer HealthCare	1,186	9,799
Accrued payroll and related costs	9,444	5,948
Accrued clinical trial expense	11,673	4,273
Accrued property, plant, and equipment expenses	1,883	5,994
Accrued expenses, other	6,207	3,886
	<u>\$ 49,031</u>	<u>\$ 36,168</u>

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9. Deferred Revenue

Deferred revenue as of December 31, 2009 and 2008 consists of the following:

	2009	2008
Current portion:		
Received from sanofi-aventis (see Note 3a)	\$ 17,523	\$ 21,390
Received from Bayer HealthCare (see Note 3b)	9,884	9,884
Received for technology license agreements (see Note 4)	11,579	11,579
Other	5,558	4,651
	<u>\$ 44,544</u>	<u>\$ 47,504</u>
Long-term portion:		
Received from sanofi-aventis (see Note 3a)	\$ 90,933	\$ 105,586
Received from Bayer HealthCare (see Note 3b)	46,951	56,835
	<u>\$ 137,884</u>	<u>\$ 162,421</u>

10. Convertible Debt

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

11. Commitments and Contingencies

a. Leases

Descriptions of Lease Agreements

The Company leases laboratory and office facilities in Tarrytown, New York, under a December 2006 lease agreement, as amended (the “Tarrytown Lease”). The facilities leased by the Company under the Tarrytown Lease include (i) space in previously existing buildings, (ii) newly constructed space in two new buildings (“Buildings A and B”) that was completed during the third quarter of 2009 and, (iii) under a December 2009 amendment to the Tarrytown Lease, additional new space that is under construction in a third new building (“Building C”), which is expected to be completed in mid-2011. The Tarrytown Lease will expire in June 2024 and contains three renewal options to extend the term of the lease by five years each, as well as early termination options for various portions of the space exclusive of the newly constructed space in Buildings A and B. The Tarrytown Lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Certain premises under the Tarrytown Lease are accounted for as operating leases. However, for the newly constructed space that the Company is leasing, the Company is deemed, in substance, to be the owner of the landlord’s buildings in accordance with the application of FASB authoritative guidance, and the landlord’s costs of constructing these new facilities are required to be capitalized on the Company’s books as a non-cash transaction, offset by a corresponding lease obligation on the Company’s balance sheet.

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In connection with the Tarrytown Lease, at lease inception, 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, 2009 and 2008.

In October 2008, the Company entered into a sublease with sanofi-aventis U.S. Inc. for office space in Bridgewater, New Jersey. The lease commenced in January 2009 and expires in July 2011. The Company also formerly leased additional office space in Tarrytown, New York under operating subleases that ended at various times through September 2009.

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

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

Revisions of Previously Issued Financial Statements

The application of FASB authoritative guidance, under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, the Company became aware that certain of these conditions were applicable to its Tarrytown Lease of new laboratory and office facilities in Buildings A and B. As a result, the Company is deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on the Company's books as a non-cash transaction, offset by a corresponding lease obligation on the Company's balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

The Company revised its previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which the Company is leasing and to adjust the Company's previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability) at each balance sheet date. The Company also revised its statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of its lease, with a corresponding adjustment to other long-term liabilities.

As previously disclosed in the Company's Quarterly Reports on Form 10-Q for the quarters ended June 30 and September 30, 2009, the above described revisions consisted entirely of non-cash adjustments. They had no impact on the Company's business operations, existing capital resources, or the Company's ability to fund its operating needs, including the preclinical and clinical development of its product candidates. The revisions also had no impact on the Company's previously reported net increases or decreases in cash and cash equivalents in any period and, except for the quarter ended March 31, 2009, had no impact on the Company's previously reported net cash flows from operating activities, investing activities, and financing activities. In addition, these revisions had no impact on the Company's previously reported current assets, current liabilities, and operating revenues. We have not amended previously issued financial statements because, after considering both qualitative and quantitative factors, the Company determined that the judgment of a reasonable person relying on the Company's previously issued financial statements would not have been changed or influenced by these revisions.

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For comparative purposes, the impact of the above described revisions to the Company's balance sheet as of December 31, 2008 is as follows:

Balance Sheet Impact at December 31, 2008
(in millions)

	December 31, 2008
As originally reported	
Property, plant, and equipment, net	\$ 87.9
Total assets	670.0
Other long-term liabilities	5.1
Total liabilities	251.2
Accumulated deficit	(875.9)
Total stockholders' equity	418.8
Total liabilities and stockholders' equity	670.0
As revised	
Property, plant, and equipment, net	\$ 142.0
Total assets	724.2
Facility lease obligation	54.2
Other long-term liabilities	2.4
Total liabilities	302.7
Accumulated deficit	(873.3)
Total stockholders' equity	421.5
Total liabilities and stockholders' equity	724.2

For comparative purposes, the impact of the above described revisions to the Company's statements of operations for the period(s) set forth below is as follows:

Statements of Operations Impact for the years ended December 31, 2008 and 2007
(in millions, except per share data)

	December 31,	
	2008	2007
As originally reported		
Research and development expenses	\$278.0	\$ 201.6
Selling, general, and administrative expenses	49.3	37.9
Total expenses	328.3	239.5
Net loss	(82.7)	(105.6)
Net loss per share, basic and diluted	\$ (1.05)	\$ (1.59)
As revised		
Research and development expenses	\$274.9	\$ 202.5
Selling, general, and administrative expenses	48.9	37.9
Total expenses	324.7	240.4
Net loss	(79.1)	(106.5)
Net loss per share, basic and diluted	\$ (1.00)	\$ (1.61)

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These revised amounts are reflected in the Company's financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2009.

Commitments under Operating Leases

The estimated future minimum noncancelable lease commitments under operating leases were as follows:

December 31,	Facilities	Equipment	Total
2010	\$ 5,919	\$387	\$ 6,306
2011	6,336	160	6,496
2012	5,020	48	5,068
2013	6,159	2	6,161
2014	6,262		6,262
Thereafter	65,883		65,883
	<u>\$95,579</u>	<u>\$597</u>	<u>\$96,176</u>

Rent expense under operating leases was:

Year Ending December 31,	Facilities	Equipment	Total
2009	\$7,722	\$395	\$8,117
2008	6,530	416	6,946
2007	5,551	363	5,914

In addition to its rent expense for various facilities, the Company paid additional rental charges for utilities, real estate taxes, and operating expenses of \$8.4 million, \$8.4 million, and \$8.8 million for the years ended December 31, 2009, 2008, and 2007, respectively.

Facility Lease Obligations

As described above, in connection with the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Buildings A and B, the Company capitalized the landlord's costs of constructing the new facilities, which totaled \$58.2 million as of December 31, 2009, and recognized a corresponding facility lease obligation of \$58.2 million. The Company also recognized, as additional facility lease obligation, reimbursements totaling \$23.6 million from the Company's landlord during 2009 for tenant improvement costs that the Company incurred since, under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation. Monthly lease payments on these facilities are allocated between the land element of the lease (which is accounted for as an operating lease) and the facility lease obligation, based on the estimated relative fair values of the land and buildings. The imputed interest rate applicable to the facility lease obligation is approximately 11%. The new facilities were placed in service by the Company in September 2009. For the year ended December 31, 2009, the Company recognized in its statement of operations \$2.3 million of interest expense in connection with the facility lease obligation. At December 31, 2009 and 2008, the facility lease obligation balance in connection with these new facilities was \$81.0 million and \$54.2 million, respectively.

In addition, as described above, in December 2009, the Company amended its December 2006 agreement to lease additional new laboratory and office facilities in Building C that is under construction. In connection with the application of FASB authoritative guidance to the Company's lease of these additional new facilities, the Company is deemed, in substance, to be the owner of the landlord's building, and the landlord's costs of constructing these new facilities is required to be capitalized on the Company's books as a non-cash transaction, offset by a corresponding lease obligation on the Company's balance sheet. As of December 31, 2009, the Company capitalized \$27.8 million of the landlord's costs of constructing the new facilities, and recognized a corresponding facility lease obligation of \$27.8 million. Monthly lease payments on these facilities will commence in January 2011. Rent expense in connection with the land element of these additional facilities, which is accounted for as an operating lease, commenced in December 2009 and is recorded as a deferred liability until lease payments commence in January 2011. In addition,

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interest expense is imputed at a rate of approximately 9%, and is capitalized and deferred in connection with this facility lease obligation. At December 31, 2009, the facility lease obligation balance in connection with these additional new facilities was \$28.0 million.

The estimated future minimum noncancelable commitments under these facility lease obligations, as of December 31, 2009, were as follows:

December 31,	Buildings A and B	Building C	Total
2010	\$ 8,152		\$ 8,152
2011	8,381	\$ 2,675	11,056
2012	8,616	2,753	11,369
2013	8,856	4,270	13,126
2014	9,103	4,389	13,492
Thereafter	99,981	48,172	148,153
	<u>\$143,089</u>	<u>\$62,259</u>	<u>\$ 205,348</u>

In February 2010, the Company received \$47.5 million from the Company's landlord in connection with tenant improvement costs for Buildings A, B, and C. As a result, future minimum noncancellable commitments under facility lease obligations, as detailed in the table above, will increase by \$3.9 million in each of the five years from 2010 to 2014 and \$37.5 million for the years thereafter.

b. Research Collaboration and Licensing Agreements

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

Certain agreements under which the Company is required to pay fees permit the Company, upon 30 to 90-day written notice, to terminate such agreements. With respect to payments associated with these agreements, the Company incurred expenses of \$2.8 million, \$3.5 million, and \$1.0 million for the years ended December 31, 2009, 2008, and 2007, respectively.

In connection with the Company's receipt of marketing approval from the FDA for ARCALYST[®] (rilonacept) for the treatment of CAPS, in 2008, the Company commenced paying royalties under various licensing agreements based on ARCALYST net product sales. For the years ended December 31, 2009 and 2008, ARCALYST royalties totaled \$1.5 million and \$0.6 million, respectively, and are included in cost of goods sold.

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

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The Company began amortizing the Collectis Payment in the second quarter of 2008 in proportion to past and future anticipated revenues under the Company's license agreements with AstraZeneca and Astellas and the Discovery and Preclinical Development Agreement under the Company's antibody collaboration with sanofi-aventis (as amended in November 2009). In 2009 and 2008, the Company recognized \$2.3 million and \$2.7 million, respectively, of expense in connection with the Collectis Payment. At December 31, 2009 and 2008, the unamortized balance of the Collectis Payment, which was included in other assets, was \$7.6 million and \$9.8 million, respectively. The Company estimates that it will recognize expense of \$1.1 million in 2010, \$1.0 million in 2011, and \$0.9 million in each of 2012, 2013, and 2014, in connection with the Collectis Payment.

12. Stockholders Equity

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

In September 2003, sanofi-aventis purchased 2,799,552 newly issued, unregistered shares of the Company's Common Stock for \$45.0 million. See Note 3.

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, which was amended in November 2009. Under the amended 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 3) and the Company's collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept (see Note 3), 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. Under the amended investor agreement, sanofi-aventis has also agreed not to dispose of any shares of the Company's Common Stock that were beneficially owned by sanofi-aventis immediately after the closing of the transaction until December 20, 2017, subject to certain limited exceptions. Following December 20, 2017, sanofi-aventis will be permitted to sell shares of the Company's Common Stock (i) in a registered underwritten public offering undertaken pursuant to the demand registration rights granted to sanofi-aventis and described above, subject to the underwriter's broad distribution of securities sold, (ii) pursuant to Rule 144 under the Securities Act and transactions exempt from registration under the Securities Act, subject to a volume limitation of one million shares of the Company's Common Stock every three months and a prohibition on selling to beneficial owners, or persons that would become beneficial owners as a result of such sale, of 5% or 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.

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13. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan which, as amended and restated (the "2000 Incentive Plan"), provides for the issuance of up to 28,816,184 shares of Common Stock in respect of awards. In addition, shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, (collectively, "Participants") may receive awards as determined by a committee of independent directors ("Committee"). The awards that may be made under the 2000 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

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

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

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

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

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

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

As of December 31, 2009, there were 3,949,767 shares available for future grants under the 2000 Incentive Plan.

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)
For the years ended December 31, 2009, 2008, and 2007
(Unless otherwise noted, dollars in thousands, except per share data)

a. Stock Options

Transactions involving stock option awards during 2009 under the 1990 and 2000 Incentive Plans are summarized in the table below.

Stock Options:	Number of Shares	Weighted-Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Intrinsic Value (in thousands)
Outstanding at December 31, 2008	20,133,910	\$17.53		
2009: Granted	3,490,560	\$20.69		
Forfeited	(390,328)	\$19.17		
Expired	(74,589)	\$21.46		
Exercised	(1,370,798)	\$10.19		
Outstanding at December 31, 2009	21,788,755	\$18.45	6.45	\$150,472
Vested and expected to vest at December 31, 2009	21,263,460	\$18.44	6.39	\$147,516
Exercisable at December 31, 2009	12,504,511	\$18.18	4.98	\$ 96,967

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 2009, 2008, and 2007 was \$13.2 million, \$11.9 million, and \$12.6 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 average market price of the Company's Common Stock on the date of grant ("Market Price"). 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, 2007, 2008, and 2009. The fair value of each option granted under the 2000 Incentive Plan during 2009, 2008, and 2007 was estimated on the date of grant using the Black-Scholes option-pricing model.

	Number of Options Granted	Weighted- Average Exercise Price	Weighted- Average Fair Value
2007:			
Exercise price equal to Market Price	3,415,743	\$21.78	\$11.13
2008:			
Exercise price equal to Market Price	4,126,600	\$17.38	\$ 8.45
2009:			
Exercise price equal to Market Price	3,490,560	\$20.69	\$10.89

For the years ended December 31, 2009, 2008, and 2007, \$27.4 million, \$30.3 million, and \$28.0 million, respectively, of non-cash stock-based compensation expense related to non-performance based stock option awards was recognized in operating expenses. As of December 31, 2009, there was \$44.8 million of stock-based compensation cost related to outstanding non-performance based 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 1.9 years.

In addition, there were 1,939,760 performance-based options which were unvested as of December 31, 2009 of which, subject to the optionee satisfying certain service conditions, 664,760 options that were issued in 2007 would vest upon achieving certain defined sales targets for the Company's products and 1,275,000 options that were issued in 2008 and 2009 would vest upon achieving certain development milestones for the Company's product candidates. In light of the status of the Company's development programs at December 31, 2009, the Company estimates that approximately 850,000 of the performance-based options tied to achieving development milestones will vest since

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)
For the years ended December 31, 2009, 2008, and 2007
(Unless otherwise noted, dollars in thousands, except per share data)

the Company considers these options' performance conditions to be probable of attainment. As a result, in 2009, the Company recognized \$1.7 million of non-cash stock-based compensation expense related to these performance options. As of December 31, 2009, there was \$8.7 million of stock-based compensation cost which had not yet been recognized in operating expenses related to the performance-based options that the Company currently estimates will vest. The Company expects to recognize this compensation cost over a weighted-average period of 2.5 years. In addition, potential compensation cost of \$7.7 million related to those performance options whose performance conditions (based on current facts and circumstances) are not currently considered by the Company to be probable of attainment will begin to be recognized only if, and when, the Company estimates that it is probable that these options will vest. The Company's estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods. Changes in these estimates may materially affect the amount of stock-based compensation recognized in future periods related to performance-based options.

Fair value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2009, 2008, and 2007.

	2009	2008	2007
Expected volatility	54%	53%	53%
Expected lives from grant date	5.9 years	5.5 years	5.6 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	2.87%	1.73%	3.60%

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 historical exercise experience with previously issued employee and board of directors option grants. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives.

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the year ended December 31, 2009 is summarized below:

Restricted Stock:	Number of Shares	Weighted- Average Grant Date Fair Value
Outstanding at December 31, 2008	500,000	\$21.92
Outstanding at December 31, 2009	500,000	\$21.92

In December 2007, the Company awarded a grant of Restricted Stock to the Company's executive vice president. In accordance with generally accepted accounting principles, the Company records unearned compensation in Stockholders' Equity related to grants of Restricted Stock awards. This amount is based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restriction on these shares lapses, which is five years for the grant made in 2007. In addition, unearned compensation in Stockholders' Equity is reduced due to forfeitures of Restricted Stock resulting from employee terminations.

In connection with the 2007 grant of Restricted Stock, the Company recorded unearned compensation in Stockholders' Equity of \$11.0 million, which was combined with additional paid-in capital. The Company recognized non-cash stock-based employee compensation expense from Restricted Stock awards of \$2.2 million, \$2.2 million, and \$0.1 million in 2009, 2008, and 2007, respectively. As of December 31, 2009, there were 500,000 unvested shares

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)
For the years ended December 31, 2009, 2008, and 2007
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of Restricted Stock outstanding and \$6.5 million of stock-based compensation cost related to these unvested shares which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 3 years.

14. Executive Stock Purchase Plan

In 1989, the Company adopted an Executive Stock Purchase Plan (the "Plan") under which 1,027,500 shares of Class A Stock were reserved for restricted stock awards. The Plan provides for the compensation committee of the board of directors to award employees, directors, consultants, and other individuals ("Plan participants") who render service to the Company the right to purchase Class A Stock at a price set by the compensation committee. The Plan provides for the vesting of shares as determined by the compensation committee and, should the Company's relationship with a Plan participant terminate before all shares are vested, unvested shares will be repurchased by the Company at a price per share equal to the original amount paid by the Plan participant. During 1989 and 1990, a total of 983,254 shares were issued, all of which vested as of December 31, 1999. As of December 31, 2009, there were 44,246 shares available for future grants under the Plan.

15. Employee Savings Plan

In 1993, the Company adopted the provisions of the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan (the "Savings Plan"). The terms of the Savings Plan provide for employees who have met defined service requirements to participate in the Savings Plan by electing to contribute to the Savings Plan a percentage of their compensation to be set aside to pay their future retirement benefits, as defined. The Savings Plan, as amended and restated, provides for the Company to make discretionary contributions ("Contribution"), as defined. The Company recorded Contribution expense of \$2.6 million in 2009, \$1.5 million in 2008, and \$1.4 million in 2007, and such amounts were accrued as liabilities at December 31, 2009, 2008, and 2007, respectively. During the first quarter of 2010, 2009, and 2008, the Company contributed 111,419, 81,086, and 58,575 shares, respectively, of Common Stock to the Savings Plan in satisfaction of these obligations.

16. Income Taxes

For the year ended December 31, 2009, the Company incurred a net loss for tax purposes and recognized a full tax valuation against deferred taxes. In 2009, the Company recognized a \$4.1 million income tax benefit, consisting of (i) \$2.7 million resulting from a provision in the Worker, Homeownership, and Business Assistance Act of 2009 that allows the Company to claim a refund of U.S. federal alternative minimum tax ("AMT") that the Company paid in connection with its 2007 U.S. federal income tax return, as described below, (ii) \$0.7 million income tax benefit resulting from a provision in the American Recovery and Reinvestment Act of 2009 that allows the Company to claim a refund for a portion of its unused pre-2006 research tax credits on its 2009 U.S. federal income tax return, and (iii) \$0.7 million income tax benefit in connection with the net tax effect of the Company's unrealized gain on "available-for-sale" marketable securities, which is included in other comprehensive income in 2009.

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

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)
For the years ended December 31, 2009, 2008, and 2007
(Unless otherwise noted, dollars in thousands, except per share data)

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

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2009 and 2008 is as follows:

	2009	2008
Deferred tax assets:		
Net operating loss carry-forward	\$ 200,266	\$ 161,790
Fixed assets	13,833	18,612
Deferred revenue	73,865	85,251
Deferred compensation	29,736	22,942
Research and experimental tax credit carry-forward	22,377	22,295
Capitalized research and development costs	49,107	59,661
Other	10,142	9,825
Valuation allowance	(399,326)	(380,376)
	<u>—</u>	<u>—</u>

The Company's valuation allowance increased by \$19.0 million in 2009, due primarily to the increase in the net operating loss carry-forward. In 2008, the Company's valuation allowance increased by \$37.4 million, due primarily to the increase in the temporary difference related to capitalized research and development costs, resulting from the implementation of the tax planning strategy described above.

The Company is primarily subject to U.S. federal and New York State income tax. The difference between the Company's effective income tax rate and the U.S. federal statutory rate of 35% is primarily attributable to an increase in the deferred tax valuation allowance. Due to the Company's history of losses, all tax years remain open to examination by U.S. federal and state tax authorities. As described in Note 2 under "Income Taxes", the implementation of FASB authoritative guidance on January 1, 2007, and for the years ended December 31, 2009, 2008, and 2007, had no impact on the Company's financial statements as the Company has not recognized any income tax positions that were deemed uncertain under the prescribed recognition thresholds and measurement attributes.

As of December 31, 2009 and 2008, the Company had no accruals for interest or penalties related to income tax matters.

As of December 31, 2009, the Company had available for tax purposes unused net operating loss carry-forwards of \$516.3 million which will expire in various years from 2018 to 2029 and included \$21.7 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 2010 to 2029. 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.

17. Legal Matters

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

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)
For the years ended December 31, 2009, 2008, and 2007
(Unless otherwise noted, dollars in thousands, except per share data)

18. 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 2009, 2008, and 2007, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	December 31,		
	2009	2008	2007
Net loss (Numerator)	\$(67,830)	\$(79,129)	\$(106,519)
Weighted-average shares, in thousands (Denominator)	79,782	78,827	66,334
Basic and diluted net loss per share	\$ (0.85)	\$ (1.00)	\$ (1.61)

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,		
	2009	2008	2007
Options:			
Weighted average number, in thousands	20,040	17,598	15,385
Weighted average exercise price	\$ 17.66	\$ 17.31	\$ 15.97
Restricted Stock:			
Weighted average number, in thousands	500	500	21
Convertible Debt:			
Weighted average number, in thousands			6,611
Conversion price			\$ 30.25

19. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at December 31, 2009, 2008, and 2007 were \$9.8 million, \$7.0 million, and \$1.7 million of accrued capital expenditures, respectively.

Pursuant to the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Tarrytown, New York (see Note 11a), the Company recognized a facility lease obligation of \$31.7 million and \$32.6 million during 2009 and 2008, respectively, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in accounts payable and accrued expenses at December 31, 2008, 2007, and 2006 were \$1.5 million, \$1.1 million, and \$1.4 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2009, 2008, and 2007, the Company contributed 81,086, 58,575, and 64,532, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in other assets at December 31, 2009 was \$0.7 million due to the Company in connection with employee exercises of stock options in December 2009.

Included in marketable securities at December 31, 2009, 2008, and 2007 were \$0.6 million, \$1.7 million, and \$2.2 million of accrued interest income, respectively.

REGENERON PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)
For the years ended December 31, 2009, 2008, and 2007
(Unless otherwise noted, dollars in thousands, except per share data)

20. Subsequent Events

The Company has evaluated subsequent events through February 18, 2010, the date on which the financial statements were issued, and has determined that there are no subsequent events that require adjustments to the financial statements for the year ended December 31, 2009. As described in Note 11a under "Facility Lease Obligations," in February 2010, the Company received \$47.5 million from the Company's landlord in Tarrytown, New York, in connection with tenant improvement costs.

21. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2009 and 2008 are set forth in the following tables.

	First Quarter Ended March 31, 2009	Second Quarter Ended June 30, 2009	Third Quarter Ended September 30, 2009	Fourth Quarter Ended December 31, 2009
	<i>(Unaudited)</i>			
Revenues	\$ 74,981	\$ 90,032	\$ 117,455	\$ 96,800
Net loss	(15,388)	(14,938)	(1,015)	(36,489)
Net loss per share, basic and diluted:	\$ (0.19)	\$ (0.19)	\$ (0.01)	\$ (0.46)

	First Quarter Ended March 31, 2008	Second Quarter Ended June 30, 2008	Third Quarter Ended September 30, 2008	Fourth Quarter Ended December 31, 2008
	<i>(Unaudited)</i>			
Revenues	\$ 56,383	\$ 60,653	\$ 65,584	\$ 55,837
Net loss	(11,847)	(18,689)	(19,084)	(29,509)
Net loss per share, basic and diluted:	\$ (0.15)	\$ (0.24)	\$ (0.24)	\$ (0.37)

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

AMENDED AND RESTATED DISCOVERY AND PRECLINICAL DEVELOPMENT
AGREEMENT

By and Between

AVENTIS PHARMACEUTICALS INC.

and

REGENERON PHARMACEUTICALS, INC.

Dated as of November 10, 2009

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Portions of this Exhibit Have Been Omitted and Separately
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AMENDED AND RESTATED DISCOVERY AND PRECLINICAL DEVELOPMENT
AGREEMENT

THIS AMENDED AND RESTATED DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT (“Agreement”), dated as of November 10, 2009 (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 Drive, 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, Sanofi and Regeneron are parties to a Discovery and Preclinical Development Agreement dated as of November 28, 2007 (the “Original Agreement”); and

WHEREAS, the Parties have undertaken a broad therapeutic antibody discovery and development program under the Original Agreement 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 Regeneron’s proprietary VelocImmune® and related suite of technologies;

WHEREAS, the Parties plan to expand these antibody discovery and development efforts under the terms set forth in this Agreement; and

WHEREAS, Sanofi is interested in continuing to collaborate with Regeneron to discover and validate potential drug discovery targets for the purpose of discovering fully human monoclonal antibody product candidates and to receive 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);

WHEREAS, the Parties now desire to amend the Original Agreement in accordance with Section 14.5 of the Original Agreement and restate the amended Original Agreement as set forth in 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:

“Acquired Antibody” shall mean a specific Antibody against a Program Target in preclinical or clinical development acquired by a Party or its Affiliate from a Third Party (other than Sanofi Pasteur or Merial Limited in the case of Sanofi), whether such acquisition is by direct acquisition, by license or through the acquisition of a Third Party that owns or controls the applicable Antibody.

“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 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.

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

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

“Annual Draft Meeting” shall have the meaning set forth in Section 2.4(a).

“Antibody” shall mean*****.

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

“Arm” shall mean *****.

“Available Slots” shall mean the difference between***** and the total number of Program Targets that were on the Rolling Target List the day immediately preceding the Special JRC Meeting or Annual Draft Meeting, as the case may be, as described in Section 2.4(a).

“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.

“*****” *****.

“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.

“Collaboration Objectives” shall have the meaning set forth in Section 2.1(b).

“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;

*****.

“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 at the time the applicable Product Candidate becomes a Refused Candidate and for the duration of time for which such Licensed Product is licensed to Sanofi under the License and Collaboration Agreement).

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

“Contract Year” shall mean the period beginning on the Original Agreement 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).

“Conventional Antibody” shall mean*****.

“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).

“CPI Adjustment” shall mean 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*****.

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

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

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

“Discovery Expiration Date” shall mean December 31, 2017.

“Discovery Program” shall mean *****.

“Discovery Program Costs” shall mean all Out-of-Pocket Costs, FTE Costs and Manufacturing Costs incurred by Regeneron after the Original Agreement 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).

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

“Excluded Candidates” shall mean Antibodies (including MTCs) against Excluded Targets.

“Excluded Targets” shall mean (i) Targets set forth in Schedule 2, (ii) Targets removed from the Rolling Target List pursuant to Section 2.4(b), (iii) Targets excluded or removed from the Rolling Target List by Sanofi pursuant to Section 2.4(c), (iv) Targets of Sanofi Divested Antibodies, (v) Targets of Sanofi Regulatory Divested Antibodies, and (vi) Program Targets that are not included on the Target List during the Tail Period pursuant to Section 2.9.

“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.

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

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

“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 ***** per year.

“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.

“FTE Rate” shall mean ***** in the Contract Year ending December 31, 2009 and ***** in the Contract Year ending December 31, 2010, such amount to be adjusted as of January 1, 2011 and annually thereafter by the CPI Adjustment.

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

“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.

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

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

“Immunize” or “Immunization” shall mean the introduction of an antigen to a Mouse for the purpose of generating Antibodies against a Target.

“Immunized Target List” shall mean and shall reflect those Targets identified in Schedule 3, together with Targets for which Immunization has begun under the Discovery Program after the Effective Date.

“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), but excluding *****.

“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.

“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.

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

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

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

“Investor Agreement” shall mean the Investor Agreement, dated as of December 20, 2007, by and between (a) Sanofi, Sanofi Parent, sanofi-aventis US LLC, and Sanofi-Aventis Amerique du Nord and (b) Regeneron, as amended as of the Effective Date, and as the same may be further amended from time to time.

“Joint Research Committee” or “JRC” shall mean the Joint Research Committee described in Section 3.1(a).

“Joint Inventions” shall have the meaning set forth in Section 6.1(b).

“Joint Patent Rights” shall mean Patent Rights that cover a Joint Invention.

“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.

“Law” or “Laws” shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions, and/or ordinances of any Governmental Authority in the Territory.

“Lead Candidate” shall mean, for any Program Target, each Antibody, including MTCs, that satisfies the applicable criteria set forth in Schedule 4 and is selected by Regeneron to begin IND Preparation under this Agreement.

“License and Collaboration Agreement” shall mean the Amended and Restated 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, as the same may be amended from time to time.

“Licensed Product” shall mean any Product Candidate for which Sanofi has exercised its Opt-In Rights pursuant to Section 5.4 below.

“Licensed Refused Sanofi Candidate” shall have the meaning set forth in Section 2.12.

“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 5.

“Maximum Annual Discovery Program Costs” shall have the meaning set forth in Section 4.2.

“Mice” or “Mouse” shall mean *****.

“Mice-Derived Therapeutic (or Diagnostic) Candidate” or “MTC” shall mean *****.

“Modified Clause” shall have the meaning set forth in Section 14.7.

“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 4.7 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.

"Original Agreement Effective Date" shall mean November 28, 2007.

"Opt-In Notice" shall have the meaning set forth in Section 5.4.

"Opt-In Period" shall have the meaning set forth in Section 5.4.

"Opt-In Report" shall have the meaning set forth in Section 5.2.

"Opt-In Rights" shall have the meaning set forth in Section 5.1.

"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.

"Party" or "Parties" shall have the meaning set forth in the introductory paragraph.

"Patent Application" shall mean any application for a Patent.

"Patent Rights" shall mean unexpired Patents and Patent Applications.

"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.

"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.

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

“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.

“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.

“Program Targets” shall mean all Targets on the Target List.

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

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

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

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

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

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

“Regeneron Know-How” shall mean any and all Know-How as of the Original Agreement Effective Date or thereafter 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.

“Regeneron Patent Rights” shall mean those Patent Rights as of the Original Agreement Effective Date or thereafter 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.

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

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

“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.

“Rolling Target List” shall mean the rolling list of Targets designated for Immunization under the Discovery Program over a two-Contract Year period, as initially prepared and thereafter revised in accordance with Section 2.4.

“Royalty Product” shall mean *****.

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

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

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

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

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

“Sanofi Know-How” shall mean any and all Know-How as of the Original Agreement Effective Date or thereafter 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.

“Sanofi Patent Rights” shall mean those Patent Rights as of the Original Agreement Effective Date or thereafter 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.

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

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

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

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

“Sanofi Target IP” shall mean *****.

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

“Special JRC Meeting” shall have the meaning set forth in Section 2.4(a).

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

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

“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,
*****.

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

“Target List” shall mean the list of Targets on the Rolling Target List and the Immunized Target List, but excluding Excluded Targets.

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

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

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

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

“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, reexamination, disclaimer or otherwise.

ARTICLE 2

DISCOVERY PROGRAM

2.1 Discovery Program. (a) From the Effective Date, the objective of the Parties during the Discovery Program is for Regeneron to discover, identify and/or validate Targets from which Regeneron shall select Targets for the Rolling Target List, generate MTCs (and, if agreed to by the JRC, other Antibodies) against Program Targets (including Program Targets that are Sanofi Targets) from which to select Lead Candidates, and develop such Lead Candidates 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 ten (10) Contract Years, Regeneron will use Commercially Reasonable Efforts to discover, identify and validate Targets as part of the Discovery Program. The Parties will select Targets for the Rolling Target List pursuant to Section 2.4. *****. Regeneron will use Commercially Reasonable Efforts to generate MTCs (and if agreed by the JRC, other Antibodies) against Program Targets and manufacture preclinical and clinical supplies of the Lead Candidates and Product Candidates for the Discovery Program and Phase 1 Clinical Trials. The JRC will evaluate and prioritize Program Targets. Subject to the JRC’s prioritization of Program Targets, Sanofi’s Target selection and exclusion rights under Section 2.4, 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. The JRC will also 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 4. Sanofi shall be responsible for completing relevant portions of Schedule 4 for all Sanofi Targets at the time that such Target is selected for the Rolling Target List to the extent such information is not available at Regeneron. Sanofi, through the JRC, will provide consultation and advice to support Regeneron’s efforts. Neither Regeneron nor Regeneron’s representative on the JRC shall have the right to discriminate against Sanofi Targets without the agreement of Sanofi’s representatives on the JRC.

(b) In addition to the broad objectives of the Parties set forth in Section 2.1(a), above, commencing from Contract Year 3 (January 1, 2010) and except as set forth in Section 4.9, the annual objectives of the Discovery Program for each Contract Year through the Discovery Expiration Date (the "Collaboration Objectives") are *****. Regeneron shall use Commercially Reasonable Efforts to achieve the Collaboration Objectives. For the avoidance of doubt, (i) nothing in the preceding sentence shall require Regeneron to use efforts beyond the FTEs and Out-of-Pocket Costs reimbursed by Sanofi under this Agreement, and (ii) if Regeneron exercises Commercially Reasonable Efforts to achieve the Collaboration Objectives, then the failure to achieve the Collaboration Objectives shall not be considered a breach of this Agreement.

(c) As part of the Discovery Program, Regeneron may *****.

2.2 Term of the Discovery Program. The Discovery Program commenced on the Original Agreement Effective Date and shall end on December 31, 2017 unless (a) this Agreement is earlier terminated in accordance with Article 12, in which event the Discovery Program shall end on the effective date of such termination or (b) extended by Sanofi for the Tail Period pursuant to the terms of Section 2.9 in which event the Discovery Program shall end upon the earlier of the expiration of the Tail Period or the earlier termination of this Agreement.

2.3 Discovery Plans. Regeneron will annually prepare a "Target Discovery Plan" and an "Antibody Discovery Plan" for the Discovery Program.

(a) The Target Discovery Plan shall set forth the overall strategy, plan and goals over the next Contract Year for identifying and validating Targets from which Regeneron shall choose its Targets for the Rolling Target List; it being understood that the Target Discovery Plan will not include information on the identity of Targets that are the subject of Regeneron's discovery research activities under the Discovery Program that have not yet been selected as Program Targets. The Target Discovery Plan will also include an estimated budget for the portion of the Discovery Program covered by the Target Discovery Plan for the ensuing Contract Year. Regeneron will submit each Target Discovery Plan, including the estimated budget, to the JRC for review and comment.

(b) The Antibody Discovery Plan shall set forth the overall strategy and plans over the next Contract Year for generating Antibodies against Program Targets, conducting research on Program Targets and Antibodies generated against Program Targets, and preclinically developing Antibodies under the Discovery Program through IND Preparation. The Antibody Discovery Plan will also include an estimated budget for the portion of the Discovery Program covered by the Antibody Discovery Plan for the ensuing Contract Year. Regeneron will submit each Antibody Discovery Plan, including the estimated budget, to the JRC for review and comment. For each Lead Candidate, the Antibody Discovery Plan will include activities and a planned timeline for IND Preparation. Regeneron shall consider in good faith comments on the Antibody Discovery Plan from Sanofi's representatives on the JRC.

(c) Except for the initial Target Discovery Plan and Antibody Discovery Plan (which will be provided to the JRC within ninety (90) days of the Effective Date), Regeneron will present an updated Target Discovery Plan and Antibody Discovery Plan to the JRC at least two (2) months prior to the end of each Contract Year.

2.4 Target List.

(a) Subject to the other terms of this Section 2.4, (i) the Rolling Target List will include up to ***** designated for Immunization in each two-consecutive Contract Year period, and ***** (all such Targets selected by Sanofi for the Rolling Target List pursuant to this Section 2.4 being referred to as "Sanofi Targets"). The Parties shall conduct a meeting of the JRC within ten (10) Business Days of the Effective Date (the "Special JRC Meeting") to ***** The Rolling Target List will be updated on an annual basis at a meeting of the JRC to be held in January of each Contract Year, commencing in 2010 and ending in 2017 (the "Annual Draft Meeting"). At least thirty (30) days prior to the Annual Draft Meeting to be held in 2017, Regeneron shall provide to Sanofi information on the identity and status of Targets validated by Regeneron under the Discovery Program that were not previously selected as Targets on to the Rolling Target List. Targets on the Rolling Target List are progressed from the Rolling Target List to the Immunized Target List at commencement of Immunization. Any Targets on the Rolling Target List which have not progressed to the Immunized Target List during a Contract Year shall remain on the Rolling Target List, subject to Sections 2.4(b), 2.4(c), and 2.8 below. At each Annual Draft Meeting, the Parties shall select Targets for the Available Slots to bring the total number of Targets on the Rolling Target List back to ***** At the Special JRC Meeting and each Annual Draft Meeting, the Parties shall alternate selecting Targets for the Available Slots on the Rolling Target List, with Sanofi designating first, Regeneron second and the process repeating until Sanofi has selected as many Targets as it desires up to ***** Regeneron shall designate all Targets for the Available Slots remaining after Sanofi's selections pursuant to this Section 2.4(a). For clarity, an Excluded Target cannot be selected onto the Rolling Target List without the mutual consent of the Parties. All Targets selected by the Parties for the Rolling Target List pursuant to this Section 2.4 shall be identified by their HUGO name, if applicable.

(b) Targets may be removed from the Rolling Target List or replaced by new Targets at any time prior to Immunization by the mutual written consent of the Parties. Targets removed (either by removal or replacement) from the Rolling Target List pursuant to this Section 2.4(b) shall become Excluded Targets. Each Party shall have the right to select up to ***** to be added to the Rolling Target List outside the applicable Annual Draft Meeting at any time during each Contract Year (such Party being a “Pre-Selecting Party”). The applicable Pre-Selecting Party shall be considered to have included the applicable Target(s) onto the Rolling Target List upon its written notice to the other Party. Unless the Target selected by the Pre-Selecting Party is excluded or removed from the Rolling Target List pursuant to Section 2.4(c) or Section 2.8, it shall be considered one of the Targets selected by the Pre-Selecting Party for the Rolling Target List at the next scheduled Annual Draft Meeting and the number of Targets the Pre-Selecting Party may select for the Available Slots at such Annual Draft Meeting shall be reduced accordingly. In addition, Regeneron shall have the right to replace a Target removed from the Rolling Target List by Sanofi pursuant to Section 2.8 at any time during each Contract Year upon written notice to Sanofi.

(c) Sanofi shall have the right to exclude from the Rolling Target List a Target selected by Regeneron for the Rolling Target List as provided in Section 2.4(c)(i), and shall have the right to remove a Program Target from the Target List, as provided in Sections 2.4(c)(ii) and (iii).

(i) Sanofi shall have the right to exclude from the Rolling Target List a Target selected by Regeneron for the Rolling Target List (a “Regeneron Selected Target”) if *****.

(ii) *****.

(iii) *****.

(d) Within sixty (60) days after the end of Contract Year 5 (ending December 31, 2012), the Executive Officers of both Parties may agree that the maximum percentage of Targets that Sanofi may select for the Rolling Target List should change ***** . In deciding whether to make such a change, the Executive Officers shall take into consideration, among other criteria agreed to by the Executive Officers, ***** . If the Executive Officers both agree to change the maximum percentage of Targets Sanofi may select for the Rolling Target List, then the Parties will promptly enter into an amendment to this Agreement solely for the purpose of amending the terms of Section 2.4(a) to reflect the new agreed upon percentage for each of the remaining Contract Years for which the Rolling Target List has not been designated.

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 Target Discovery Plan and the Antibody Discovery Plan consistent with Sections 2.3 and 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 Target Discovery Plan and the Antibody Discovery Plan, including information concerning new Program Targets, Lead Candidates and Product Candidates. 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 (other than with respect to the identity and progress of Targets in the Target Discovery Plan which are not Program Targets) and any other data and any other information it reasonably requests with respect to the conduct of the Target Discovery Plan and the Antibody Discovery Plan.

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, until the end of the Term, neither Party nor any of their respective Affiliates will either directly, or with any Third Party, work to discover Antibodies against, or develop or commercialize Antibodies against, Program Targets in the Territory, except pursuant to this Agreement or the License and Collaboration Agreement. Furthermore, subject to the other subparagraphs in this Section 2.8, until the earlier to occur of (A) the Discovery Expiration Date, and (B) the effective termination of this Agreement, neither Regeneron nor any of its Affiliates will, either directly or with any Third Party, work to discover, develop or commercialize Antibodies in the Territory, except pursuant to this Agreement or the License and Collaboration Agreement. Solely as used in this Section 2.8(a) and in Section 2.8(b), the terms "develop," "developing" or "development" shall mean any and all activities related to Antibody discovery and Antibody preclinical and clinical development. In the event this Agreement is terminated early pursuant to Sections 12.2, 12.3, 12.4, 12.5, or 12.11, the obligations stated in this Section 2.8(a) shall also terminate as of the effective date of such early termination.

(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.

(i) Excluded Candidates. Each Party (and its Affiliates) shall have the right to develop and commercialize Excluded Candidates either on its own or with Third Parties outside the Discovery Program without restriction under this Agreement; provided that Sanofi shall have no rights under this Agreement to any Excluded Candidates developed under the Discovery Program. Regeneron shall have and retain exclusive rights to any such Excluded Candidates developed in the Discovery Program against such Excluded Target without restrictions under this Agreement, subject to the royalty obligations set forth in Section 4.5. Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any such MTCs or other Antibodies (or any Acquired Antibodies of Regeneron) against Excluded Targets and may practice and use any Regeneron Intellectual Property, including, without limitation, the Mice, in connection with the development of Antibodies against Excluded Targets.

(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, *****.

(iii) Sanofi Acquired Antibodies. Sanofi and its Affiliates shall have the right to develop and commercialize Acquired Antibodies

, whether such acquisition is by direct acquisition, by license or through acquisition of a Third Party) (a “Sanofi Acquired Antibody”),
even if such Sanofi Acquired Antibodies are against Program Targets. Sanofi shall promptly notify Regeneron of any such acquisition or license (including the
identity of the Program Target), and may continue the development of such Sanofi Acquired Antibody without restriction outside the Discovery Program and this
Agreement. In the event of such an acquisition or license, unless otherwise agreed to by the Parties, the applicable Program Target shall be considered an Excluded
Target and Sanofi shall no longer have any rights to any Excluded Candidates against such Excluded Target developed under this Agreement (such Antibodies being
referred to herein as “Sanofi Divested Antibodies”). Regeneron may develop and commercialize (on its own or with one or more Third Parties) any Sanofi Divested
Antibodies or other Excluded Candidates against such Excluded Targets, and may practice and use any Regeneron Intellectual Property, including, without
limitation, the Mice, in connection with such activities without restrictions under this Agreement, subject to the royalty obligations set forth in Section 4.5. Until the
time of IND filing for a Sanofi Divested Antibody, Regeneron shall have the right to consider development of Sanofi Divested Antibodies against the applicable
Excluded Target as development under the Discovery Program solely for purposes of seeking reimbursement of Discovery Program Costs pursuant to Section 4.2.

(iv) Company Acquisitions. For clarification, where a Party or its Affiliate acquires rights to an Acquired Antibody by the acquisition of a Third Party or
part or the whole of its business, the applicable acquiring Party may as an alternative to any obligations herein, divest such Acquired Antibody (by sale or license)
*****.

(v) 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 a Program Target, then Sanofi
shall have the right to exclude such Program Target from the Discovery Program, and develop and commercialize such Acquired Antibodies against such Program
Target outside the Discovery Program and the terms of this Agreement. Sanofi shall no longer have any rights to any Antibodies, including MTCs, against such
Program Target under this Agreement (“Sanofi Regulatory Divested Antibodies”) *****. ***** Either Party shall
have the right to develop and commercialize Antibodies against Target(s) of the Sanofi Regulatory Divested Antibodies outside the Discovery Program and the
terms of this Agreement, and Regeneron shall have and retain exclusive rights to any Antibodies, including MTCs, discovered under the Discovery Program against
such Program Target(s) without restrictions under this Agreement.

(vi) *****.

(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, 2017 (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, 2017. 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. All Program Targets not listed in this notice shall be considered Excluded Targets as of January 1, 2018. 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 or Sanofi Regulatory 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, Sanofi Divested Antibody, or Sanofi Regulatory Divested Antibody, as the case may be. Where such Licensed Refused Sanofi Candidate is an Immunoconjugate, *****.

2.13 Non-Exclusive License to Sanofi. Regeneron hereby grants Sanofi and its Affiliates a perpetual, 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. On August 4, 2008, Regeneron and sanofi-aventis U.S. Inc. entered into a Mouse Purchase Agreement pursuant to which Regeneron is using its proprietary technology for the production of genetically modified mouse embryonic stem cell lines and mice derived from the corresponding mouse stem cell lines.

2.16 Option for VelocImmune® License. At Sanofi's request within sixty (60) days of the Discovery Expiration Date, 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 Additional Technologies. To the extent that Regeneron decides to license either ***** (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, during the one hundred eighty (180) day period 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. The Parties have established 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 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 Target Discovery Plan and the Antibody Discovery Plan;

(iii) exchange and review scientific information and data relating to the Target List and activities being conducted under, and the then-current progress of, the Target Discovery Plan and the Antibody Discovery Plan, and establish processes for the exchange of information relating to the progress of the activities under the Target Discovery Plan and the Antibody Discovery Plan (subject to the limitations concerning the identification of Targets in the Target Discovery Plan as set forth in Section 2.3(a));

(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 Target Discovery Plan and the Antibody Discovery Plan;

(vi) evaluate and prioritize Program Targets;

(vii) discuss the use of *****with regard to Program Targets;

(viii) discuss whether an Antibody, including any MTC, satisfies the criteria of Lead Candidates attached in Schedule 4;

(ix) review and prioritize Lead Candidates;

(x) maintain the Rolling Target List, Immunized Target List, and the list of Excluded Targets as provided in this Agreement;

(xi) conduct the Special JRC Meeting and Annual Draft Meetings;

(xii) consider and act upon such other matters as specified in this Agreement or as otherwise agreed to by the Parties, including, without limitation, any requests for Sanofi to perform activities under the Discovery Program costs for which to be treated as Discovery Program Costs in accordance with the last paragraph of Section 4.2;

(xiii) 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 (i) 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, (ii) decisions concerning whether Sanofi shall perform any activities under the Discovery Program, which shall require a joint decision of both Parties' Executive Officers, (iii) any decision of the Executive Officers pursuant to Section 2.4(d), and (iv) any decision of the Executive Officers pursuant to Section 4.4.

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; Reimbursement Payments for Manufacturing Expansion. Within five (5) Business Days of the Original Agreement Effective Date, Sanofi paid to Regeneron a non-refundable, non-creditable amount of US \$85,000,000 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. Regeneron plans to expand its facilities in Rensselaer, New York (the "Expansion Plans") to help provide an adequate and timely supply of Formulated Bulk Product for Clinical Supply Requirements (as those terms are defined in the License Agreement) of Licensed Products. The Parties have agreed on the general description, plan and budget of the Expansion Plans as set forth in Schedule 7. Sanofi shall reimburse Regeneron for up to US\$30,000,000 of costs incurred by Regeneron to implement the Expansion Plans (the "Maximum Reimbursable Amount"). Within forty-five (45) days following the end of each calendar quarter, until Regeneron has been reimbursed for the Maximum Reimbursable Amount under this Section 4.1, Regeneron shall provide to Sanofi a detailed report of the costs incurred by it in such calendar quarter to implement the Expansion Plans, together with an invoice therefor. Sanofi shall reimburse Regeneron for all costs set forth in such report and invoice within thirty (30) days after its receipt thereof. Regeneron shall not be entitled to include depreciation for equipment and other items included in the Expansion Plan as Development Costs (as defined in the License Agreement) under the License Agreement to the extent Sanofi has reimbursed Regeneron for such equipment and other items pursuant to this Section 4.1, and shall provide evidence of the same. Regeneron may only use the production suites identified in Schedule 7 to manufacture products other than Licensed Products if the production of such other products does not interfere with the production of Formulated Bulk Product for Clinical Supply Requirements (as those terms are defined in the License Agreement) of Licensed Products.

4.2 Discovery Program Costs. Commencing on the Original Agreement 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 and in Section 4.10, the total annual Discovery Program Costs to be paid by Sanofi in each of the first ten (10) years of the Discovery Program (the “Maximum Annual Discovery Program Costs”) shall not exceed the following amounts (as calculated for each Contract Year):

<u>Contract Year</u>	<u>Maximum Annual Discovery Program Costs</u>
1 (ending December 31, 2008)	US \$75,000,000
2	US \$100,000,000
3	US \$160,000,000
4	US \$160,000,000
5	US \$160,000,000
6	US \$160,000,000
7	US \$160,000,000
8	US \$160,000,000
9	US \$160,000,000
10 (ending December 31, 2017)	US \$160,000,000

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 10, 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 ***** Opt-in Payment. (a) In the event that Sanofi exercises its Opt-In Rights in accordance with Section 5.1 with regard to *****, then Sanofi shall, on an Opt-In Notice by Opt-In Notice basis, make a US \$10,000,000 payment to Regeneron with the applicable Opt-In Notice or, in the case of a dispute under this Section 4.4(a), upon the resolution of the dispute hereunder. Regeneron shall indicate in the Opt-In Report *****. Sanofi shall indicate in the Opt-In Notice for such a Product Candidate whether it, in good faith, agrees or disagrees with Regeneron, including any supporting information supporting its belief. In the event of a disagreement between the Parties as to *****, the matter shall be referred to the Executive Officers for a joint decision in accordance with Section 3.3. In the event the Executive Officers are unable to reach agreement with respect to the matter in accordance with Section 3.3, then the dispute shall be referred to an independent Third Party expert (the "Expert"). The Parties shall alternate having the right to select an Expert to resolve disputes in accordance with this Section 4.4, with Sanofi selecting the Expert for the first such dispute and neither Party selecting an Expert that was used previously by either Party without the written consent of the other Party. Each Expert shall be selected by the applicable Party within thirty (30) days of the end of the thirty (30) day period referred to in Section 3.3. Each Expert must be a person selected in good faith who is knowledgeable in the field of Antibodies, possessing senior executive experience in the biotechnology or pharmaceutical industry, and has no known prior, current, or planned future association (by contract, employment, or otherwise) with the selecting Party, any of its Affiliates, or any officer, director, or employee of such Party or any of its Affiliates. The Parties will both enter into a consulting agreement with each Expert and will share equally in all fees charged by each Expert. Each Expert shall be instructed in the consulting agreement to make his decision as to ***** within two (2) weeks of his selection. The Expert's decision shall be final and binding upon the Parties. For the avoidance of doubt, any dispute under this Section 4.4(a) shall not delay the development of the applicable Licensed Product.

(b) *****.

4.5 Royalty Payments for Royalty Products. 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.

4.6 Royalty Term and Reporting. The royalties payable under Sections 4.5 (i), 4.5(iii), and 4.5(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) ***** (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 4.5 (ii), 4.5 (iv), 4.5(vi), and 4.5(vii) 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.

4.7 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.

4.8 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, plus two percent (2%) (such sum being referred to as the "Default Interest Rate").

4.9 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).

4.10 Special Adjustment. If ***** , the Maximum Annual Discovery Program Costs set forth in Section 4.1 shall be reduced to US\$120,000,000 for each of Contract Years 7, 8, 9, and 10 (the "Special Adjustment"). Notwithstanding the foregoing, ***** . If Sanofi exercises its option for the Special Adjustment following the occurrence of the conditions set forth above, then Regeneron shall have the right (the "Catch Up Right"), in its sole discretion, to fund up to US\$40,000,000 of Discovery Program Costs on its own for each of the remaining Contract Years through the Discovery Expiration Date (the actual aggregate amount of such Discovery Program Costs funded by Regeneron on its own during Contract Years 7, 8, 9, and 10 being referred to as the "Catch-Up Amount"). Regeneron shall have sixty (60) days from the date of the Special Adjustment to exercise the Catch Up Right and shall notify Sanofi promptly in writing of such exercise. Regeneron shall provide Sanofi within sixty (60) days of the beginning of each subsequent Contract Year with a written report setting forth in reasonable detail the calculation of the Catch-Up Amount. If Regeneron exercises this Catch Up Right, then ***** , then Sanofi shall be required to make a payment to Regeneron equal to the Catch-Up Amount within forty-five (45) days after receipt of a written report setting forth in reasonable detail the calculation of the Catch-Up Amount. Effective upon the occurrence of the Special Adjustment, unless Regeneron exercises the Catch Up Right, the annual Collaboration Objectives shall be adjusted as follows:

ARTICLE 5

OPT-IN RIGHTS TO LICENSE PRODUCT CANDIDATES

5.1 Opt-In Rights to License Product Candidates. Subject to the penultimate 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 ten (10) years of the Discovery Program, 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 Program Targets properly identified by Sanofi in its notice to extend the Discovery Program through the Tail Period provided under Section 2.9. For the avoidance of doubt, Sanofi shall have no Opt-In Rights to Excluded Candidates owned or licensed by Regeneron or its Affiliates.

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 *****.

5.5 Dl14 and REGN 88. Sanofi exercised its Opt-In Rights to REGN 88 as of the Original Agreement Effective Date and was deemed to have exercised its Opt-In Rights with respect to the MTC against Delta-like ligand 4 (Dl14) as of the Original Agreement Effective Date.

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, otherwise it shall be considered an Excluded Target.

(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 B, 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.

(e) Each Party shall have the right to invoke the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. 103(c)(2)-(c)(3) (the "CREATE Act") with respect to Joint Inventions, without the prior written consent of the other Party. In the event that a Party intends to invoke the CREATE Act, as permitted by the preceding sentence, it shall notify the other Party and the Parties shall reasonably cooperate and coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act. For the avoidance of doubt, nothing in this Section 6.2(e) shall amend or modify the determination of ownership of intellectual property as set forth in Section 6.1.

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; and

(i) 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.

*****.

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 Indemnitee 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 Indemnitee 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. In the event of a Force Majeure, the performance of the Party giving such notification shall be abated and any time deadlines shall be extended for so long as the performance is prevented by Force Majeure. In no event will any Force Majeure extend beyond one hundred eighty (180) days. In the event of a Force Majeure affecting satisfaction of the criteria set forth in Section 4.10, the applicable time deadline set forth in Section 4.10 shall be extended for so long as such Force Majeure continues, but in no event shall such extension period exceed one hundred eighty (180) days.

ARTICLE 12

TERM AND TERMINATION

12.1 Term. The "Term" of this Agreement commenced on the Original Agreement Effective Date and shall end upon the end 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 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 of this Agreement pursuant to this Section 12.4.

12.5 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.

12.6 Effect of Termination by Sanofi for Breach. In addition to the provisions of Section 12.8 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 eleven (11) years from the Original Agreement 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 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 effective time of termination (and for no other uses);

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

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

12.7 Effect of Termination by Regeneron for Breach. In addition to the provisions of Sections 12.8 and 12.10 below, notwithstanding anything herein to the contrary, in the event that Regeneron terminates this Agreement pursuant to Section 12.2 or 12.4 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 2.16 and 2.17 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 effective time of termination (and for no other uses).

12.8 Survival of Obligations. Subject to Sections 12.6, 12.7, and 12.11 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:

(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;

(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 12.6 above), 2.13 (except as set forth in Section 12.7 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 licenses granted in Sections 2.11(b)(3), 2.11(c), 2.12, and 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.

12.9 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 12.9 within ten (10) days of a written request by the Disclosing Party.

12.10 Special Damages. If Regeneron terminates this Agreement pursuant to Section 12.2 or 12.4, 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.

12.11 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 12.11, 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 12.8, the following shall apply:

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

(b) Regeneron shall be granted a non-exclusive, non-transferable, royalty bearing (in accordance with Section 4.5) 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 existence and included in the Discovery Program at the effective time of termination.

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) 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 determination 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 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) *****: 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 10 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 12.10, 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/ John M. Spinnato
Name: John M. Spinnato
Title: VP & General Counsel, US Legal

By /s/ Christian Blin
Name: Christian Blin
Title: VP, R&D Finance

REGENERON PHARMACEUTICALS, INC.

By /s/ Murray Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance &
Administration and Chief Financial Officer

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

SCHEDULE 1

SCHEDULE 2

Excluded Targets

SCHEDULE 3

Initial Immunized Target List

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

SCHEDULE 4

Lead Candidate Criteria

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

SCHEDULE 5

Manufacturing Cost

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

SCHEDULE 6

Initial Rolling Target List

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

SCHEDULE 7

Expansion Plan

Technical Appendices 1 through 4 describe the general capacity expansion plans for Regeneron's Rensselaer Operations in Rensselaer, New York. The "IN" items described in appendices 1 and 2 will be initiated immediately.

SCHEDULE 8

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

SCHEDULE 9

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

SCHEDULE 10

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

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

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 Amended and Restated 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:

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

EXHIBIT B

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

AMENDED AND RESTATED
LICENSE AND COLLABORATION AGREEMENT

By and Among

AVENTIS PHARMACEUTICALS INC.,
SANOFI-AVENTIS AMERIQUE DU NORD

and

REGENERON PHARMACEUTICALS, INC.

Dated as of November 10, 2009

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AMENDED AND RESTATED
LICENSE AND COLLABORATION AGREEMENT

THIS AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT (this "Agreement"), dated as of November 10, 2009 (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, the Parties previously entered into a License and Collaboration Agreement (the "Original Agreement"), dated as of November 28, 2007, whereby, pursuant to the terms and conditions set forth therein, the Parties agreed to collaborate on the Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory (each capitalized term not previously defined being defined below);

WHEREAS, concurrently with the execution and delivery of the Original Agreement, the Parties entered into a Discovery and Preclinical Development Agreement (the "Original Discovery Agreement") whereby, upon the terms and conditions set forth therein, Regeneron agreed to use its proprietary VelocImmune[®] technology and related suite of technologies with the objective of discovering Product Candidates (as defined below) which Sanofi may have elected, 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, concurrently with the execution and delivery of this Agreement, the Parties have entered into an agreement amending and restating the Original Discovery Agreement (such amended and restated agreement, the "Discovery Agreement");

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 continue to collaborate on the Development, Manufacture and Commercialization of Licensed Products (each as defined below) in the Field in the Territory (each as defined below) upon the terms and conditions set forth herein (the "Collaboration");

WHEREAS, Regeneron and Sanofi now desire to amend the Original Agreement in accordance with Section 20.5 of the Original Agreement as set forth in this Agreement.

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 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 "Antibody," shall have the meaning ascribed to such term in the Discovery Agreement.

1.5 "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.

1.6 "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.

1.7 "Aventis LLC" shall mean sanofi-aventis US LLC (successor in interest under the Aventis Collaboration Agreement to Aventis Pharmaceuticals Inc.).

1.8 "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.

1.9 "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, and as may be further amended from time to time.

1.10 "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.

1.11 "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.

1.12 "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.

1.13 "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.

1.14 "Co-Commercialize" or "Co-Commercialization" shall mean the act of Co-Promoting in a Co-Commercialization Country.

1.15 "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.

1.16 "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.

1.17 "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.

1.18 "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.

1.19 "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.

1.20 "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 *****.

1.21 "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).

1.22 "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).

1.23 "Competing Opt-Out Product" shall mean any Opt-Out Product having the same Target as a Licensed Product.

1.24 "Competing Product" shall mean, with respect to a Licensed Product, *****.

1.25 "Confidentiality Agreements" shall mean the confidentiality agreements between Regeneron and Sanofi Parent dated February 1, 2007 and October 23, 2007, respectively.

1.26 "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.

1.27 "Contract Sales Force" shall mean sales representatives employed by a Third Party.

1.28 "Contract Year" shall mean the period beginning on the Original 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.

1.29 "Controlling Party" shall mean *****.

1.30 "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.

1.31 "Country/Region Commercialization Budget" shall mean the budget for a particular calendar year approved by the JCC for the applicable Country/Region Commercialization Plan.

1.32 "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.

1.33 "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.

1.34 "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.).

1.35 "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.

1.36 "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 Sections 13.3(d) and 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.

1.37 "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.

1.38 "Development FTE Rate" shall mean ***** in the Contract Year ending December 31, 2009 and ***** in the Contract Year ending December 31, 2010, such amount to be adjusted as of January 1, 2011 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.

1.39 "Development Plan" shall mean a Global Development Plan or an Initial Development Plan, as the context requires.

1.40 "Discovery Program" shall have the meaning set forth in the Discovery Agreement.

1.41 "EMEA" shall mean the European Medicines Evaluation Agency or any successor agency thereto.

1.42 "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.

1.43 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

1.44 "Field" shall mean the treatment, prevention, palliation and/or diagnosis of any disease.

1.45 "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.

1.46 "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.

1.47 "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.

1.48 "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.

1.49 "GAAP" shall mean generally accepted accounting principles as applicable in the United States.

1.50 "Global Commercialization Budget" shall mean the budget(s) for a particular Contract Year approved by the JCC for the applicable Global Commercialization Plan.

1.51 "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.

1.52 "Global Development Budget" shall mean the budget(s) for a particular Contract Year approved by the JSC for the applicable Global Development Plan.

1.53 "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.

1.54 "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.

1.55 "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.

1.56 "IAS/IFRS" shall mean International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board.

1.57 "ICH" shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.58 "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.

1.59 "Indication" means any disease.

1.60 "Initial Development Plan" shall have the meaning set forth in the Discovery Agreement.

1.61 "Initial IND Filing Date" means, with respect to a Licensed Product, the date an IND for such Licensed Product is first filed.

1.62 "Investor Agreement" means the Investor Agreement, dated as of December 20, 2007, by and among Sanofi Parent, Sanofi, Aventis LLC, Sanofi Amerique and Regeneron, as amended as of the Effective Date, and as the same may be amended from time to time.

1.63 "Joint Patent Rights" shall mean Patent Rights that cover a Joint Invention.

1.64 "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.

1.65 "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

1.66 "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.

1.67 "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.

1.68 "License" shall mean any license or other agreement to acquire rights from a Third Party, which license or other agreement has been approved by the JSC required for the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.

1.69 "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-114) and (iv) ***** (as defined in the Discovery Agreement) once included in the Collaboration pursuant to Section 2.11(b) of the Discovery Agreement.

1.70 "Major Market Country," shall mean any of the following: *****.

1.71 "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.

1.72 "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.

1.73 "Manufacturing Plan" shall mean the manufacturing plan as prepared by the JMC as described in Section 8.5.

1.74 "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.

1.75 "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.

1.76 "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.

1.77 "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.

1.78 "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).

1.79 "Opt-In Right" shall have the meaning set forth in the Discovery Agreement.

1.80 "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.

1.81 "Original Effective Date" shall mean November 28, 2007.

1.82 "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), 17.1(c), and 17.1(d).

1.83 "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.

1.84 "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.

1.85 "Patent Application" shall mean any application for a Patent.

1.86 "Patent Rights" shall mean unexpired Patents and Patent Applications.

1.87 "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.

1.88 "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.

1.89 "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.

1.90 "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.

1.91 "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.

1.92 "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 *****.

1.93 "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.

1.94 "Product Candidate" shall have the meaning set forth in the Discovery Agreement.

1.95 "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.

1.96 "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.

1.97 "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.

1.98 "Regeneron Intellectual Property" shall mean the Regeneron Patent Rights and any Know-How of Regeneron or any of its Affiliates.

1.99 "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.

1.100 "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.

1.101 "Region" shall mean such countries or group of countries as determined by the JCC.

1.102 "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.

1.103 "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.

1.104 "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.

1.105 "Rest of World" or "ROW" shall mean all Rest of World Countries.

1.106 "Rest of World Country" shall mean any country in the Territory other than the United States.

1.107 "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.

1.108 "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)*****. For the avoidance of doubt, the activities of contract personnel, including contract Sales Force, shall be charged as Out-of-Pocket Costs.

1.109 "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.

1.110 "Sanofi Intellectual Property," shall mean the Sanofi Patent Rights and the Sanofi Know-How.

1.111 "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.

1.112 "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.

1.113 "Sanofi Stock Purchase Agreement" means the Stock Purchase Agreement dated as of the Effective Date by and between Sanofi Amerique, Aventis LLC and Regeneron.

1.114 "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.

1.115 "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.

1.116 "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.

1.117 "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.

1.118 "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.

1.119 "Termination Notice Period" shall mean the Sanofi Termination Notice Period or the Regeneron Termination Notice Period, as applicable.

1.120 "Territory" shall mean all the countries and territories of the world.

1.121 "Third Party" shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.

1.122 "United States," "US" or "U.S." shall mean the United States of America (including its territories and possessions) and Puerto Rico.

1.123 "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).

1.124 "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).

1.125 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)
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)

<u>DEFINITION</u>	<u>SECTION/SCHEDULE</u>
Maximum Regeneration 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
Regeneration	Preamble
Regeneration Commitment Level	6.5(e)(i)
Regeneration Early Development Opt-Out Right	5.6
Regeneration Early Opt-Out Notice	5.6
Regeneration Indemnitees	17.1(a)
Regeneration Profit Split	SCHEDULE 2
Regeneration Reimbursement Amount	SCHEDULE 2
Regeneration Sole Inventions	12.1(a)
Regeneration 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)

<u>DEFINITION</u>	<u>SECTION/SCHEDULE</u>
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") or 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.

(d) Required Divestiture of Licensed Product. Notwithstanding any of the foregoing in this Section 2.6(d), 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(d), with regards to the Competing Licensed Product, or transfer its interest in the Acquired Competing 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(d), 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). 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).

(f) Sanofi Rights. Notwithstanding Section 2.6(a), if Sanofi or its Affiliate wishes to acquire or license rights to a Competing Product other than through the acquisition of a Third Party (which is covered in Section 2.6(c) above), and the applicable Licensed Product against the same Target as such Competing Product has not yet commenced Development in any Phase 3 Trial in any indication, then during the Sanofi Termination Notice Period following Regeneron's receipt of Sanofi's termination notice for such Licensed Product under Section 19.2(a), Sanofi or its Affiliate shall have the right to acquire, license, Develop and Commercialize a Competing Product, either alone or through any Third Party, and the provisions of Section 19.2(a), 19.7, 19.8, and Schedule 4 shall then apply with respect to such Licensed Product.

**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. It is understood that the Parties may wish to establish multiple Committees reporting to the JSC, JDC, and JCC with responsibility for different Licensed Products. 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 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) 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 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);

(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) 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 forec 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 char 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. 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) ***** . 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 *****. 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 (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 *****. 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 *****, 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 exercises 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 practice 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 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 the 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 representative 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. For the avoidance of doubt, nothing in this Section 8.1 shall require Regeneron to expand its manufacturing capacity or use any manufacturing capacity acquired or constructed by Regeneron in the future to satisfy its obligations under this Section 8.1 other than those Regeneron manufacturing facilities in Rensselaer, New York that will be constructed pursuant to the Expansion Plan annexed to the Discovery Agreement. *****
***** , Sanofi will make capacity at this facility available to provide Formulated Bulk Product for Phase 3 Trials of Licensed Products on Regeneron's behalf as set forth in the Manufacturing Plan in the event that the requirements for Formulated Bulk Product for Phase 3 Trials exceed Regeneron's capacity at its Manufacturing facilities.

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 three (3) years prior to the Anticipated First Commercial Sale of each Licensed Product. ***** . 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 *****. 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, ***** (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 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 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 Indemnatee 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 Indemnatee; 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 Indemnatee 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 Indemnatee; 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 commenced on the Original 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 (12th) 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 Regeneration. Regeneration 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 Regeneration 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 "Regeneration 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 Regeneration 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 Regeneration Termination Notice Period, to the extent set forth or requested in one or more written notices from Sanofi to Regeneration hereunder and in any event upon the expiration of the Regeneration Termination Notice Period, whether or not any such notice is given by Sanofi, (i) the licenses and rights granted by Sanofi to Regeneration 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 Regeneration Termination Notice Period), (ii) the licenses and rights granted by Regeneration to Sanofi hereunder with respect to the Opt-Out Product(s) shall terminate, and (iii) Regeneration will promptly take the actions required by Schedule 5 and Sanofi will reasonably cooperate with Regeneration (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 Regeneration 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 Regeneration 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 Regeneration 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 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 12.4 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.

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 14.4 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/ John M. Spinnato
Name: John M. Spinnato
Title: VP & General Counsel, US Legal

By /s/ Christian Blin
Name: Christian Blin
Title: VP, R&D Finance

SANOFI-AVENTIS AMERIQUE DU NORD
(solely for purposes of Section 15.1, 15.2 and 20.11).

By /s/ Jose Ferrer
Name: Jose Ferrer
Title: VP, Legal Operations

By /s/ Christian Blin
Name: Christian Blin
Title: VP, R&D Finance

REGENERON PHARMACEUTICALS, INC.

By /s/ Murray Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance &
Administration and Chief Financial Officer

EXHIBIT A

Royalties For Opt-Out Products

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:

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 (a) fifty percent (50%) of the aggregate amount of Development Costs incurred by both Parties under the Global Development Plans for all Licensed Products from the Effective Date through the close of such Quarter, excluding any Shared Phase 3 Trial Costs, plus (b) thirty percent (30%) of the aggregate amount of Shared Phase 3 Trial Costs incurred by both Parties under the Global Development Plans for all Licensed Products from the Effective Date through the close of such Quarter, less (c) the aggregate amount of Development Compensation Payments included in the calculation of the Quarterly True-Up in all prior Quarters.

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) ten percent (10%) of the Regeneron Profit Split for the Quarter 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	900
U.S. Profit Split payable to Regeneron	350
Rest of World Profit Split payable to Regeneron	380
Regeneron Profit Split	730
10% of the Regeneron Profit Split	73
Development Compensation Payment	73

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 (a) aggregate Shared Commercial Expenses incurred by Regeneron in the U.S. and ROW in the Quarter for all Licensed Products, plus (b) aggregate Other Shared Expenses incurred by Regeneron in the U.S. and ROW in the Quarter for all Licensed Products, plus (c) Development Costs incurred by Regeneron under a Global Development Plan in the Quarter for all Licensed Products, other than Shared Phase 3 Trial Costs, plus (d) aggregate Shared Phase 3 Trial Costs incurred by Regeneron under a Global Development Plan in the Quarter for all Licensed Products minus twenty percent (20%) of the aggregate Shared Phase 3 Trial Costs incurred by both Sanofi and Regeneron under a Global Development Plan in the Quarter for all Licensed Products (with the amount so calculated in this clause (d) called the "Shared Phase 3 Trial Costs Balance"). For clarity, if the Shared Phase 3 Trial Costs Balance is negative, it shall be subtracted from the amount otherwise payable to Regeneron as a Regeneron Reimbursement Amount, and if the total Regeneron Reimbursement Amount is negative, it shall be a negative number in the calculation of the Quarterly True-Up.

An example of a calculation of the Regeneron Reimbursement Amount in a Quarter would be:

Regeneron Shared Commercial Expenses in the U.S.	50
Regeneron Shared Commercial Expenses in ROW	100
Regeneron Other Shared Expenses in the U.S.	10
Regeneron Other Shared Expenses in ROW	10
Regeneron Development Costs under a Global Development Plan	80
Shared Phase 3 Trial Costs Balance	0
Regeneron Reimbursement Amount	250

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	350
ROW Profit Split Payable to Regeneron	380
Development Compensation Payment	(73)
Regeneron Reimbursement Amount	250
<hr/>	
Quarterly True-Up	907

In this example, Sanofi would pay Regeneron 907 in accordance with the terms set forth in Article 9.

SCHEDULE 3

Sales Milestones

Aggregate annual Net Sales
of all Licensed Products
in Rest of World Countries

Sales Milestone

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 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 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 Licenses and 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 Licenses and 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.

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, 31st Floor
Boston, Massachusetts 02108
Attention: Kent A. Coit

First Amendment to the Investor Agreement
dated as of December 20, 2007

This Amendment (“Amendment”), dated as of November 10, 2009, is by and among sanofi-aventis (“sanofi-aventis”), a company organized under the laws of France, with its principal headquarters at 174, avenue de France, 75013 Paris, France, sanofi-aventis US LLC (“Sanofi US”), a Delaware limited liability company with its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807, Aventis Pharmaceuticals Inc. (“Aventis”), a Delaware corporation with its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807, sanofi-aventis Amérique du Nord (the “Investor”), a *société en nom collectif* organized under the laws of France, with its principal headquarters at 174, avenue de France, 75013 Paris, France, 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, sanofi-aventis, Sanofi US, Aventis, the Investor, and the Company (collectively, the “Parties”) entered into an Investor Agreement, dated as of December 20, 2007 (the “Investor Agreement”); and

WHEREAS, the Parties now desire to amend the Investor Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the premises and mutual agreements set forth in the Investor Agreement and this Amendment and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions. Capitalized terms used herein and not otherwise defined in this Amendment shall have the meanings ascribed to them in the Investor Agreement.
2. Changes to the definition of “Lock-Up Term”. The definition of “Lock-Up Term” in the first sentence of Section 4.1 of the Investor Agreement is hereby amended by replacing the words “fifth (5th) anniversary” therein with the words “tenth (10th) anniversary.”
3. Continuing Effect. Except as specifically modified in this Amendment, all of the provisions of the Investor Agreement shall remain in full force and effect.
4. Counterparts. This Amendment may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed and delivered this Amendment in accordance with Section 7.5 of the Investor Agreement as of the date first above written.

SANOFI-AVENTIS

By: /s/ José Ferrer
Name: José Ferrer
Title: VP, Legal Operations

By: /s/ Christian Blin
Name: Christian Blin
Title: VP, R&D Finance

SANOFI-AVENTIS US LLC

By: /s/ John M. Spinnato
Name: John M. Spinnato
Title: VP & General Counsel, US Legal

By: /s/ Christian Blin
Name: Christian Blin
Title: VP, R&D Finance

AVENTIS PHARMACEUTICALS INC.

By: /s/ John M. Spinnato
Name: John M. Spinnato
Title: VP & General Counsel, US Legal

By: /s/ Christian Blin
Name: Christian Blin
Title: VP, R&D Finance

SANOFI-AVENTIS AMÉRIQUE DU NORD

By: /s/ José Ferrer
Name: José Ferrer
Title: VP, Legal Operations

By: /s/ Christian Blin
Name: Christian Blin
Title: VP, R&D Finance

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance &
Administration and Chief Financial Officer

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-50480, 333-85330, 333-97176, 333-33891, 333-80663, 333-61132, 333-97375, 333-119257 and 333-151941) and on Form S-3 (No. 333-121225) of Regeneron Pharmaceuticals, Inc., of our report dated February 18, 2010 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 18, 2010

**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 report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 18, 2010

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 report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 18, 2010

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, 2009 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 18, 2010

/s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Chief Financial Officer
February 18, 2010
