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, 2012

OR

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

Commission file number 000-12477

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**95-3540776**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive,	**91320-1799**
Thousand Oaks, California	(Zip Code)
(Address of principal executive offices)	

(805) 447-1000

(Registrant's telephone number, including area code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common stock, $0.0001 par value	The 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 Section 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 Section 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 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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $56,028,159,915 as of June 30, 2012(A)

(A) Excludes 771,532 shares of common stock held by directors and executive officers at June 30, 2012. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

748,430,018

(Number of shares of common stock outstanding as of February 19, 2013)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2013 Annual Meeting of stockholders to be held May 22, 2013, are incorporated by reference into Part III of this annual report.

INDEX

PART I

Item 1. BUSINESS

Overview

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. Our medicines help millions of patients in the fight against cancer, kidney disease, rheumatoid arthritis (RA), bone disease, and other serious illnesses. We operate in one business segment: human therapeutics.

We were incorporated in 1980 and organized as a Delaware corporation in 1987. Our public website is www.amgen.com. On our website, investors can find press releases, financial filings and other information about the Company. The U.S. Securities and Exchange Commission (SEC) website, www.sec.gov, also offers access to reports and documents we have electronically filed with or furnished to the SEC. These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.

Our principal products are Neulasta® (pegfilgrastim), a pegylated protein, based on the Filgrastim molecule, and NEUPOGEN® (Filgrastim), a recombinant-methionyl human granulocyte colony-stimulating factor (G-CSF), both of which stimulate the production of neutrophils (a type of white blood cell that helps the body fight infection); Enbrel® (etanercept), an inhibitor of tumor necrosis factor (TNF), a substance that plays a role in inflammatory diseases; Aranesp® (darbepoetin alfa) and EPOGEN® (epoetin alfa), erythropoiesis-stimulating agents (ESAs) that stimulate the production of red blood cells; and XGEVA®/Prolia® (denosumab), two products that contain the same active ingredient but which are approved for different indications, patient populations, doses and frequencies of administration. Denosumab is a human monoclonal antibody that specifically targets RANKL, an essential regulator of osteoclasts (the cells that break down bone). Our principal products represented 89%, 90% and 92% of our sales in 2012, 2011 and 2010, respectively. Our other marketed products include primarily Sensipar®/Mimpara® (cinacalcet), a small molecule calcimimetic that lowers serum calcium levels; Vectibix® (panitumumab), a monoclonal antibody that binds specifically to the epidermal growth factor receptor (EGFr); and Nplate® (romiplostim), a thrombopoietin (TPO) receptor agonist that mimics endogenous TPO, the primary driver of platelet production.

We maintain sales and marketing forces primarily in the United States, Europe and Canada. We have also entered into agreements with third parties to assist in the commercialization and marketing of certain of our products in specified geographic areas. (See Business Relationships.) Together with our partners, we market our products to healthcare providers, including physicians or their clinics, dialysis centers, hospitals and pharmacies.

In addition to our marketed products, we have various product candidates in mid- to late-stage development in a variety of therapeutic areas, including oncology, hematology, inflammation, bone health, nephrology, cardiovascular and general medicine, which includes neuroscience. Our research and development (R&D) organization has expertise in multiple treatment modalities, including large molecules (such as proteins, antibodies and peptibodies) and small molecules.

Our manufacturing operations consist of bulk manufacturing, formulation, fill and finish and distribution activities for all of our principal products as well as most of our product candidates. We operate a number of commercial and/or clinical manufacturing facilities, and our primary manufacturing facilities are located in the United States, Puerto Rico and the Netherlands. See Item 2. Properties.

Drug development in our industry is complex, challenging and risky; and failure rates are high. Product development cycles are very long — approximately 10 to 15 years from discovery to market. A potential new medicine must undergo many years of preclinical and clinical testing to establish its safety and efficacy for use in humans at appropriate dosing levels and with an acceptable benefit-risk profile. Biological products, which are produced in living systems, are inherently complex due to naturally occurring molecular variations. Highly specialized knowledge and extensive process and product characterization are required to transform laboratory-scale processes into reproducible commercial manufacturing processes. Upon approval, marketed products in our industry generally face substantial competition.

Our industry is highly regulated, and various U.S. and foreign regulatory bodies have substantial authority over how we conduct our business. Government authorities in the United States and other countries regulate the manufacturing and marketing of our products as well as our ongoing R&D activities. In recent years, regulators have placed a greater scrutiny on drug safety. This has led to, and may in the future lead to: fewer products being approved by the U.S. Food and Drug Administration (FDA) or other regulatory bodies; delays in receiving approvals; additional safety-related requirements; restrictions on the use of products, including expanded safety labeling, or required risk management activities.

Significant Developments

Following is a summary of significant developments that occurred in 2012 affecting our business.

Products/Pipeline

AMG 145

- In November 2012, we presented data from four phase 2 studies evaluating AMG 145 as monotherapy, in combination with statin therapy, in heterozygous familial hypercholesterolemia, and in statin-intolerant subjects. In each of these studies, treatment with AMG 145 resulted in statistically significant reductions in low-density lipoprotein cholesterol compared to the control arms at 12 weeks. Based on the study results, phase 3 enrollment is underway in these populations.

Sensipar®/Mimpara®

- In November 2012, we presented at American Society of Nephrology's (ASN) Kidney Week the results of the phase 3 E.V.O.L.V.E™ (EValuation Of Cinacalcet HCl Therapy to Lower CardioVascular Events) trial. As previously reported, the primary analysis showed that the trial did not reach its primary endpoint (time to composite event comprising all-cause mortality or first non-fatal cardiovascular event, including myocardial infarction, hospitalization for unstable angina, heart failure or peripheral vascular event) in the intent-to-treat analysis. See Significant Developments in our Quarterly Report on Form 10-Q for the period ended June 30, 2012.

Rilotumumab

- In November 2012, we initiated a phase 3 study for the treatment of gastric cancer.

Brodalumab (AMG 827)

- In October 2012, we announced the start of a phase 3 program in moderate-to-severe psoriasis. The program consists of three phase 3 studies, with ustekinumab and/or placebo controls. Brodalumab is one of five inflammation monoclonal antibodies being jointly developed in the collaboration with AstraZeneca Plc. (AstraZeneca).

XGEVA®

- In April 2012, we announced that the FDA issued a Complete Response Letter for the supplemental Biologics License Application (sBLA) for XGEVA® to treat men with castration-resistant prostate cancer at high risk of developing bone metastases. The Complete Response Letter states that the FDA cannot approve the application in its present form. The FDA determined that the effect on bone metastases-free survival was of insufficient magnitude to outweigh the risks (including osteonecrosis of the jaw) of XGEVA® in the intended population.

Romosozumab (AMG 785)

- In April 2012, we along with our partner UCB announced the start of two phase 3 clinical studies in postmenopausal osteoporosis (PMO). The registrational study is a placebo-controlled trial that will evaluate incidence of new vertebral fractures at 12 and 24 months in 6,000 patients. We are also conducting an active-controlled trial versus alendronate that will evaluate the incidence of clinical fracture and new vertebral fracture at 12 and 24 months in 4,000 patients.

Acquisitions/Collaborations

- In June 2012, we acquired substantially all of the outstanding stock of Mustafa Nevzat Pharmaceuticals (MN), a privately held company that is a leading supplier of pharmaceuticals to the hospital sector and a major supplier of injectable medicines in Turkey. The acquisition provides us with the opportunity to expand our presence in Turkey and the surrounding region.

- In March 2012, we entered into a collaboration agreement with AstraZeneca to jointly develop and commercialize certain monoclonal antibodies from Amgen's clinical inflammation portfolio including brodalumab, AMG 139, AMG 157, AMG 181 and AMG 557. The agreement covers the worldwide development and commercialization except for certain Asian countries for brodalumab and Japan for AMG 557, which are licensed to other third parties.

- In March 2012, we acquired Micromet, Inc. (Micromet), a publicly held biotechnology company focused on the discovery, development and commercialization of innovative antibody-based therapies for the treatment of cancer.

Marketed Products

We market our principal products, Neulasta®, NEUPOGEN®, ENBREL, Aranesp®, EPOGEN®, XGEVA® and Prolia®, in supportive cancer care, inflammation, nephrology and bone disease. Certain of our marketed products face — and our product candidates, if approved, are also expected to face — substantial competition. Our products' competitive positions among other biological and pharmaceutical products may be based on, among other things, safety, efficacy, reliability, availability, patient convenience/delivery devices, price, reimbursement, timing of market entry and patent position and expirations.

Over the next several years, certain of the existing patents on our principal products will expire, and we expect to face increasing competition thereafter, including from biosimilars. A biosimilar is another version of a biological product for which marketing approval is sought or has been obtained based on a demonstration that it is "biosimilar" to the original reference product. This demonstration will typically consist of comparative analytical, preclinical and clinical data from the biosimilar to show that it has similar safety and efficacy as the reference product. The 2010 U.S. healthcare reform legislation authorized the FDA to approve biosimilars under a new, abbreviated pathway. In February 2012, the FDA released three draft guidance documents that provide insight into the FDA's current thinking on the development of biosimilars and broad parameters for the scientific assessment of biosimilar applications. The FDA guidance documents leave room for the FDA to consider, on a case-by-case basis, the specifics of what evidence would be required for a biosimilar to gain approval. (See Government Regulation.) In the European Union (EU), there is already an established regulatory pathway for biosimilars and we are facing increasing competition from biosimilars. In the United States after patent expiration, we expect to face greater competition than today, including from manufacturers with biosimilars approved in Europe, that may seek to obtain U.S. approval. In some cases we may experience additional competition prior to the expiration of our patents as a result of agreements we have made in connection with the settlement of patent litigation with companies developing potentially competing products. See the discussions of Neulasta®/NEUPOGEN® and Aranesp® later in this section.

Further, the introduction of new products or the development of new processes or technologies by competitors or new information about existing products may result in increased competition for our marketed products, even for those protected by patents, or in a reduction of price that we receive from selling our products. In addition, the development of new treatment options or standards of care may reduce the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates.

In addition to the challenges presented by competition, our existing products and product candidates are also subject to increasing regulatory compliance requirements that could be imposed as conditions of approval or after a product has been approved. This is increasingly true of new therapies with novel mechanisms of action. While such therapies may offer important benefits and/or better treatment alternatives, they may also involve relatively new or higher levels of scientific complexity and may therefore generate increased safety concerns. We design and implement comprehensive proactive pharmacovigilance programs for all of our products to help ensure the detection, assessment and communication of adverse effects. When deemed necessary and appropriate, additional measures for risk communication and mitigation are designed and implemented in consultation with regulatory agencies. As a condition of approval or due to safety concerns after a product has been approved, we may be required to perform additional clinical trials or studies, including postmarketing requirements (PMRs) and postmarketing commitments (PMCs). A PMR is a trial or study that a sponsor company is required by statute or regulation to conduct. A PMC is a trial or study that a sponsor company agrees to in writing, but is not required by law, to conduct. In addition, we may be required to implement risk management plans for our products in the various regions in which they are approved. The FDA requires risk evaluation and mitigation strategies (REMS) for various approved products to ensure that the benefits of the drugs outweigh the risks. A REMS may also be imposed as a condition of approval or after a product has been on the market. A REMS may include a medication guide or a patient package insert, a healthcare provider communication plan or elements to assure safe use that the FDA deems necessary. While the elements of REMS may vary, all REMS require the sponsor company to submit periodic assessment reports to the FDA to demonstrate that the goals of the REMS are being met. The FDA evaluates such assessments and may require additional modifications to the REMS elements. REMS may also be modified as the FDA and companies gain more experience with REMS and how they are implemented, operated and monitored. We currently have REMS for a number of our marketed products. See discussion on PMRs, PMCs and REMS in Government Regulation.

Most patients receiving our principal products for approved indications are covered by either government or private payer healthcare programs, which influence demand. The reimbursement environment continues to evolve with greater emphasis on both cost containment and demonstration of the economic value of products. In addition, the current worldwide economic conditions have also contributed to increasing pressures on cost containment.

Neulasta® (pegfilgrastim)/NEUPOGEN® (Filgrastim)

We were granted an exclusive license to manufacture and market Neulasta® and NEUPOGEN® in the United States, Europe, Canada and Australia under a licensing agreement with Kirin-Amgen, Inc. (K-A), a joint venture between Kirin Holdings Company, Limited (Kirin), and Amgen. See Business Relationships — Kirin-Amgen, Inc.

Neulasta® and NEUPOGEN® stimulate production of neutrophils, a type of white blood cell important in the body's fight against infection. Both the treatments for various diseases and the diseases themselves can result in extremely low numbers of neutrophils, a condition called neutropenia. Myelosuppressive chemotherapy, one treatment option for individuals with certain types of cancers, targets cell types that grow rapidly, such as tumor cells. Normal cells that divide rapidly, such as those in the bone marrow that become neutrophils, are also vulnerable to the cytotoxic effects of myelosuppressive chemotherapy, resulting in neutropenia with an increased risk of severe infection. NEUPOGEN® is our registered trademark for Filgrastim, our recombinant-methionyl human G-CSF. Neulasta® is our registered trademark for pegfilgrastim, a pegylated protein based on the Filgrastim molecule. A polyethylene glycol molecule is added to the Filgrastim molecule to make pegfilgrastim. Because pegfilgrastim is eliminated from the body through binding to its receptor on neutrophils and neutrophil precursor cells, pegfilgrastim remains in circulation in the body until neutrophil recovery has occurred. This neutrophil-mediated clearance allows for administration as a single dose per chemotherapy cycle, compared with NEUPOGEN®, which requires more frequent dosing.

We market Neulasta® and NEUPOGEN® primarily in the United States and Europe. Neulasta® was launched in the United States and Europe in 2002 and is indicated to decrease the incidence of infection associated with chemotherapy-induced febrile neutropenia in cancer patients with non-myeloid malignancies. Administration of Neulasta® in all cycles of chemotherapy is approved for patients receiving myelosuppressive chemotherapy associated with a clinically significant risk of febrile neutropenia. NEUPOGEN® was launched in the United States and Europe in 1991. NEUPOGEN® is indicated for reducing the incidence of infection as manifested by febrile neutropenia for patients with non-myeloid malignancies undergoing myelosuppressive chemotherapy associated with a significant incidence of severe neutropenia with fever; reducing the duration of neutropenia and neutropenia-related consequences for patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation; reducing the incidence and duration of neutropenia-related consequences in symptomatic patients with congenital neutropenia, cyclic neutropenia or idiopathic neutropenia (collectively, severe chronic neutropenia); mobilizing peripheral blood progenitor cells (PBPC) in cancer patients who have undergone myeloablative chemotherapy for stem cell transplantation; and reducing the recovery time of neutrophils and the duration of fever following induction or consolidation chemotherapy treatment in adult patients with acute myeloid leukemia (AML).

Total Neulasta®/NEUPOGEN® sales were as follows (in millions):

	2012	2011	2010
Neulasta® — U.S.	$ 3,207	$ 3,006	$ 2,654
Neulasta® — rest-of-the-world (ROW)	885	946	904
Total Neulasta®	4,092	3,952	3,558
NEUPOGEN® — U.S.	1,007	959	932
NEUPOGEN® — ROW	253	301	354
Total NEUPOGEN®	1,260	1,260	1,286
Total Neulasta®/NEUPOGEN®	$ 5,352	$ 5,212	$ 4,844

Our outstanding material patents for pegfilgrastim are described in the following table.

Territory	General Subject Matter	Expiration
U.S.	Pegylated G-CSF	10/20/2015
Europe[(1)]	Pegylated G-CSF	2/8/2015

(1) This European patent is also entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary by country. For example, supplementary protection certificates covering pegfilgrastim have issued in France, Germany, Italy, Spain, and the United Kingdom, and will expire in 2017.

Our outstanding material patents for Filgrastim are described in the following table.

Territory	General Subject Matter	Expiration
U.S.	G-CSF polypeptides	12/3/2013
U.S.	Methods of treatment using G-CSF polypeptides	12/10/2013

Our principal European patent related to G-CSF expired in August 2006. Upon expiration of that patent, some companies received approval to market products, including biosimilars, that compete with NEUPOGEN® and Neulasta® in Europe, as further discussed below.

Our outstanding material U.S. patents for Filgrastim (NEUPOGEN®) expire in December 2013. We expect to face competition in the United States beginning in the fourth quarter of 2013, which may have a material adverse impact over time on future sales of NEUPOGEN® and, in turn, Neulasta®. See discussion of Teva below.

Any products or technologies that are directly or indirectly successful in treating neutropenia associated with chemotherapy, for bone marrow and PBPC transplant patients, severe chronic neutropenia and AML could negatively impact Neulasta® and/or NEUPOGEN® sales. Neulasta® and/or NEUPOGEN® sales may also be impacted by increases or decreases in the use of myelosuppressive chemotherapy, which may result from changes in the number of patients being treated, changes to treatment protocols or the introduction of new cancer treatments that may not be myelosuppressive. Further, NEUPOGEN® competes with Neulasta® in the United States and Europe, and NEUPOGEN® sales have been adversely impacted by conversion to Neulasta®, which we believe is substantially complete.

The following table reflects companies and their currently marketed products that compete with Neulasta® and/or NEUPOGEN® in the United States and Europe in the supportive cancer care setting. The table below and the following discussion of competitor marketed products and products in development may not be exhaustive.

Territory	Competitor Marketed Product	Competitor
U.S.	Leukine®	Bayer HealthCare Pharmaceuticals (Bayer)
Europe	Granocyte®	Chugai Pharmaceuticals Co., Ltd./Sanofi-Aventis (Sanofi)
Europe	Ratiograstim®(1)/Biograstim®(1)	ratiopharm GmbH (ratiopharm)(2)/CT Arzneimittel GmbH (CT Arzneimittel)
Europe	Tevagrastim®(1)	Teva Pharmaceutical Industries Ltd. (Teva Pharmaceutical)
Europe	Zarzio®(1)/Filgrastim Hexal®(1)	Sandoz GmbH (Sandoz)/Hexal Biotech Forschungs GmbH (Hexal)
Europe	Nivestim®(1)	Hospira Inc. (Hospira)

(1) Approved via the EU biosimilar regulatory pathway.
(2) A subsidiary of Teva Pharmaceutical.

In August 2012, the FDA approved Sicor Biotech's (Teva Corporation) tbo-filgrastim product to reduce the time that certain patients receiving cancer chemotherapy experience severe neutropenia. The approval was on the basis of a full BLA rather than under the FDA's new biosimilar approval pathway. This drug may compete with NEUPOGEN® subject to the terms of the injunction and settlement agreement discussed below.

In November 2009, Teva Pharmaceutical filed a declaratory judgment action against us alleging that certain of our NEUPOGEN® patents are invalid and not infringed by its tbo-filgrastim product, and in January 2010, we filed an answer and counterclaims seeking a declaratory judgment that our patents are valid and infringed. In July 2011, we announced that the U.S. District Court in Pennsylvania entered final judgment and a permanent injunction against Teva Pharmaceutical and Teva Pharmaceuticals USA, Inc. (together defined as Teva) prohibiting them from infringing our patents relating to human G-CSF polypeptides and methods of treatment. The court’s injunction extends until November 10, 2013, after which date Teva will no longer be prohibited by the injunction from selling its tbo-filgrastim product in the United States. Teva also agreed not to sell balugrastim, a long-acting product candidate, in the United States before November 10, 2013, unless it first obtains a final court decision that our patents are not infringed by balugrastim. Pursuant to the parties’ settlement, the launch date for either product could be sooner if certain unexpected events occur: a third party launches a similar G-CSF polypeptide product and we fail to sue that third party, or the patents are held invalid or unenforceable in a final court decision in an action brought by a third party.

Several companies have short-acting filgrastim product candidates in phase 3 clinical development, including:

- Merck & Company, Inc. (Merck) (MK-4214)
- Intas/Apotex Inc. (Neukine)
- Reliance Life Sciences Pvt. Ltd. (ReliGrast)
- Biocon Ltd./Celgene Corporation (Celgene) (Nufil)

In addition, several companies have long-acting filgrastim product candidates in phase 3 clinical development, including:

- Teva Pharmaceutical (balugrastim and Lonquex)
- Sandoz (LA-EP2006)
- Intas/Apotex Inc. (Neupeg)

Enbrel® (etanercept)

ENBREL is our registered trademark for etanercept, our TNF receptor fusion protein that inhibits the binding of TNF to its receptors, which can result in a significant reduction in inflammatory activity. TNF is one of the chemical messengers that help regulate the inflammatory process. When the body produces too much TNF, it overwhelms the immune system's ability to control inflammation of the joints or of psoriasis-affected skin areas. ENBREL binds certain TNF molecules before they can trigger inflammation.

ENBREL was launched in the United States in November 1998 and in Canada in March 2001. ENBREL is indicated for the treatment of adult patients with the following conditions: moderate to severe active RA; chronic moderate to severe plaque psoriasis patients who are candidates for systemic therapy or phototherapy; active psoriatic arthritis; and active ankylosing spondylitis. It is also indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages two and older.

We market ENBREL under a collaboration agreement with Pfizer Inc. (Pfizer) in the United States and Canada, which expires October 31, 2013. (See Business Relationships — Pfizer Inc.) The rights to market and sell ENBREL outside the United States and Canada are reserved to Pfizer.

Total ENBREL sales were as follows (in millions):

	2012	2011	2010
Total ENBREL	$ 4,236	$ 3,701	$ 3,534

Our outstanding material patents for etanercept are described in the following table.

Territory	General Subject Matter	Expiration
U.S.	Methods of treating psoriasis	8/13/2019
U.S.	Aqueous formulation and methods of treatment using the formulation[(1)]	6/8/2023
U.S.	Fusion protein, and pharmaceutical compositions	11/22/2028
U.S.	DNA encoding fusion protein, and methods of making fusion protein	4/24/2029

[(1)] This formulation patent relates to the currently approved liquid formulation of ENBREL, which formulation accounts for the majority of ENBREL sales in the United States. However, ENBREL is also sold as an alternative lyophilized formulation that requires reconstituting before it can be administered to the patient.

Any products or technologies that are directly or indirectly successful in treating rheumatologic conditions, which includes moderate to severe RA; moderate to severe polyarticular juvenile idiopathic arthritis; ankylosing spondylitis and psoriatic arthritis; and dermatologic conditions, which includes moderate to severe plaque psoriasis, could negatively impact ENBREL sales. Certain of the treatments for these indications include generic methotrexate and other products.

The following table reflects companies and their currently marketed products that compete with ENBREL in the United States and Canada in the inflammatory disease setting. The table below and the following discussion of competitor marketed products and products in development may not be exhaustive.

Territory	Therapeutic Area	Competitor Marketed Product	Competitor
U.S. & Canada	Rheumatology & Dermatology	REMICADE®	Janssen Biotech, Inc. (Janssen)[(1)]/Merck
U.S. & Canada	Rheumatology & Dermatology	HUMIRA®	Abbott Laboratories (Abbott) [(2)]
U.S. & Canada	Rheumatology & Dermatology	Simponi®	Janssen [(1)]
U.S. & Canada	Rheumatology	Cimzia®	UCB/Nektar Therapeutics (Nektar)
U.S. & Canada	Rheumatology	Orencia®	Bristol-Myers Squibb Company (BMS)
U.S. & Canada	Rheumatology	Rituxan®	F. Hoffmann-La Roche Ltd (Roche)
U.S.	Rheumatology	Actemra®	Roche
U.S. & Canada	Dermatology	Stelara®	Janssen [(1)]
U.S.	Rheumatology	Xeljanz®	Pfizer

(1) A subsidiary of Johnson & Johnson (J&J).

(2) In January 2013, Abbott announced that it completed the separation of its research-based pharmaceuticals business, which became AbbVie, Inc. (AbbVie), a new independent biopharmaceutical company which now owns the rights to this product.

In November 2012, the FDA approved Pfizer's Xeljanz® (tofacitinib), an oral treatment for patients with moderate to severe RA who have had an inadequate response or intolerance to methotrexate. In addition, a number of companies have product candidates in phase 3 clinical development which may compete with ENBREL in the future, including:

- Celgene (apremilast), in both psoriasis and psoriatic arthritis
- AstraZeneca and Rigel Pharmaceuticals Inc. (fostamatinib) in RA
- Eli Lilly and Company (Eli Lilly) (ixekizumab) for moderate to severe plaque psoriasis
- UCB/Nektar's Cimzia® in psoriatic arthritis
- Janssen's Simponi® IV in RA and Stelara® in psoriatic arthritis
- Roche's Actemra® SC in RA

ESAs

Aranesp® and EPOGEN® are our registered trademarks for darbepoetin alfa and epoetin alfa, respectively, both of which are proteins that stimulate red blood cell production in a process known as erythropoiesis. Red blood cells transport oxygen to all cells of the body. Without adequate amounts of a protein called erythropoietin, the red blood cell count is reduced. A deficient red blood cell count can result in anemia, a condition in which insufficient oxygen is delivered to the body's organs and tissues. Anemia can be associated with chronic kidney disease (CKD) in patients either on or not on dialysis. Individuals with CKD may suffer from anemia because they do not produce sufficient amounts of erythropoietin, which is normally produced in healthy kidneys and stimulates erythropoiesis. Anemia can also result from chemotherapy treatments for patients with non-myeloid malignancies.

ESAs, including ours, have faced and continue to face challenges. For example, based on adverse safety results observed beginning in late 2006 in various studies, performed by us and by others, that explored the use of ESAs in settings different from those outlined in the FDA approved label, the product labeling of our ESAs in the United States and the EU has been updated several times to reflect those safety concerns. In addition, due in part to certain of these developments, reimbursement of our ESAs in the United States was also revised. These regulatory and reimbursement changes have led to changes in the way ESAs are used in clinical practice, including by decreasing the number of patients treated with ESAs as well as the average dose and duration of ESA therapy.

In 2010 and 2011, the FDA and Centers for Medicare & Medicaid Services (CMS) took a number of actions with respect to the label for and the reimbursement of ESAs:

- Effective January 1, 2011, CMS implemented the Final Rule on Bundling in Dialysis, providing a single payment for all dialysis services (with the exception of oral drugs without intravenous equivalents).
- In June 2011, the FDA approved ESA label changes impacting both patients on dialysis and those not on dialysis. While the previous label language specified a hemoglobin (Hb) target range of 10-12 grams per deciliter (g/dL) for patients in both populations, the new label advises physicians treating patients on dialysis to initiate ESA therapy when the Hb level is less than 10 g/dL and to reduce or interrupt the dose when the Hb approaches or exceeds 11 g/dL. For CKD patients not on dialysis receiving ESA treatment, the new label advises physicians to initiate ESA therapy when the Hb level is less than 10 g/dL and to reduce or interrupt the dose when the Hb exceeds 10 g/dL.
- In November 2011, CMS finalized a rule to update various provisions of its bundled-payment system for dialysis services and the related end stage renal disease (ESRD) Quality Incentive Program (QIP). The final rule eliminated for payment year 2013 and beyond the QIP's measure that tracks the percent of a provider's Medicare patients with a Hb level below 10 g/dL.
- In June 2010, CMS opened a National Coverage Analysis (NCA) to examine the use of ESAs to manage anemia in patients with CKD and dialysis-related anemia. Following further analysis, in June 2011, CMS issued a Final Decision Memorandum (FDM) in which it determined that it would not issue a National Coverage Determination (NCD) at that time for ESAs for treatment of anemia in adults with CKD. In the absence of an NCD, Local Coverage Determinations (LCDs) may be made by regional contractors called Medicare Administrative Contractors (MACs). Since CMS issued their FDM, three MACs have issued a revised LCD relating to anemia in patients with CKD not on dialysis. These three MACs provide ESA coverage no more restrictive than the revised label.

Certain of these developments have had a material adverse impact on sales of our ESAs.

In addition, in November 2011, we entered into a seven-year supply agreement with DaVita Inc. (DaVita), commencing January 1, 2012, to supply EPOGEN® in amounts necessary to meet no less than 90% of DaVita's and its affiliates' requirements for ESAs used in providing dialysis services in the United States and Puerto Rico.

We have an ongoing oncology pharmacovigilance program in place for Aranesp®. The five clinical trials originally included in the program explored the use of ESAs in settings different from those outlined in the FDA approved label and were designated by the FDA as PMCs. Of the five studies, one was sponsored by Amgen while the other four were investigator-sponsored. Four of the studies are complete and analysis of the results from the fifth study is currently ongoing. The results of certain of those studies contributed to safety-related product labeling changes for our ESAs and changes in reimbursement, as noted above. In addition, Janssen Research & Development, LLC (JRD), a subsidiary of J&J, and/or its investigators have conducted numerous studies that contribute to the understanding of ESA safety. Results of the JRD studies were submitted to the FDA.

Additionally, based on discussions with the FDA, we and JRD have carefully considered potential new study designs to determine the effects of ESAs on survival and tumor outcomes in anemic patients with metastatic cancer receiving concomitant myelosuppressive chemotherapy. Based on those discussions, we are conducting a randomized, double-blind, placebo-controlled, phase 3 non-inferiority study evaluating overall survival when comparing advanced non small cell lung cancer (NSCLC) patients on Aranesp® to patients receiving placebo (Study '782) as part of our Aranesp® pharmacovigilance program. In addition, JRD's EPO-ANE-3010 study in breast cancer is ongoing. Both studies are designated by the FDA as PMR clinical trials. For the nephrology setting, we have been engaged in ongoing discussions with the FDA regarding additional PMRs to explore alternative ESA dosing strategies in CKD patients on dialysis and not on dialysis. In July 2012 we initiated study '226 to evaluate Aranesp® use in CKD patients not on dialysis. We expect to discuss further with the FDA a potential study in CKD patients on dialysis.

In January 2013, we announced the top-line results of the phase 3 Aranesp® RED-HF® (Reduction of Events With Darbepoetin Alfa in Heart Failure) Trial. The trial was initiated in 2006, and a total of 2,278 patients with symptomatic systolic heart failure and anemia (Hb levels ranging from 9.0-12.0 g/dL) were randomized to receive either treatment with Aranesp® to achieve a target Hb of at least 13.0 g/dL (not to exceed 14.5 g/dL), or placebo. The study did not meet its primary endpoint of reducing the composite endpoint of time to death from any cause or first hospital admission for worsening heart failure. There were no new safety findings identified in the study. These summary results will be followed by full efficacy and safety analyses, which will be shared and discussed with global regulatory agencies and submitted for presentation at an upcoming medical meeting.

Adverse events or results of any of these studies could further affect product labeling, healthcare provider prescribing behavior, regulatory or private healthcare organization medical guidelines and/or reimbursement practices related to Aranesp® or EPOGEN®.

Aranesp® (darbepoetin alfa)

We were granted an exclusive license by K-A to manufacture and market Aranesp® in the United States, all European countries, Canada, Australia, New Zealand, Mexico, all Central and South American countries and certain countries in Central Asia, Africa and the Middle East.

We market Aranesp® primarily in the United States and Europe, and it was launched in 2001 in both regions. It is indicated for the treatment of anemia associated with CKD (in both patients on dialysis and patients not on dialysis) and also for the treatment of anemia due to concomitant chemotherapy in patients with non-myeloid malignancies.

Total Aranesp® sales were as follows (in millions):

	2012	2011	2010
Aranesp® — U.S.	$ 782	$ 986	$ 1,103
Aranesp® — ROW	1,258	1,317	1,383
Total Aranesp®	$ 2,040	$ 2,303	$ 2,486

Our outstanding material patents for darbepoetin alfa are described in the following table.

Territory	General Subject Matter	Expiration
U.S.	Glycosylation analogs of erythropoietin proteins	5/15/2024
Europe[(1)]	Glycosylation analogs of erythropoietin proteins	8/16/2014

(1) This European patent is also entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary by country. For example, supplementary protection certificates covering darbepoetin alfa have issued in France, Germany, Italy, Spain, and the United Kingdom, and will expire in 2016.

Our principal European patent related to epoetin alfa expired in December 2004. Although we do not market EPOGEN® in Europe, upon expiration of this patent, some companies received approval to market products, including biosimilars, that compete with Aranesp® in Europe, as further discussed below.

Any products or technologies that are directly or indirectly successful in addressing anemia associated with chemotherapy and/or renal failure could negatively impact Aranesp® sales. In the United States, Aranesp® competes with EPOGEN®, primarily in the U.S. hospital dialysis clinic setting.

The following table reflects companies and their currently marketed products that compete with Aranesp® in the United States and Europe in the supportive cancer care and nephrology segments, unless otherwise indicated. The table below and the following discussion of competitor products in development may not be exhaustive.

Territory	Competitor Marketed Product	Competitor
U.S.	PROCRIT®(1)	Janssen(2)
Europe	EPREX®/ERYPO®	Janssen-Cilag(2)
Europe	NeoRecormon®	Roche
Europe	Retacrit™(3)/Silapo®(3)	Hospira/Stada Arzneimittel AG
Europe	Binocrit®(3)/epoetin alfa Hexal®(3)/Abseamed®(3)	Sandoz/Hexal/Medice Arzneimittel Pütter GmbH & Co. KG
Europe	MIRCERA®(4)	Roche
Europe	Eporatio®/Biopoin®	ratiopharm (5)/CT Arzneimittel

(1) PROCRIT® competes with Aranesp® in the supportive cancer care and pre-dialysis settings.

(2) A subsidiary of J&J.

(3) Approved via the EU biosimilar regulatory pathway.

(4) Competes with Aranesp® in the nephrology segment only. Pursuant to a December 2009 settlement agreement between Amgen and Roche, Roche is allowed to begin selling MIRCERA® in the United States in mid-2014 under terms of a limited license agreement. MIRCERA® has been approved by the FDA for the treatment of anemia associated with chronic renal failure (CRF) in patients on and not on dialysis.

(5) A subsidiary of Teva Pharmaceutical.

Several companies have short-acting ESA candidates in late stage clinical development, some of which may be pursued as biosimilars with U.S.-sourced epoetin alfa as the comparator product, including:

- APOTEX Inc. (APO-EPO)
- Hospira (Retacrit)
- Sandoz (HX-575)

EPOGEN® (epoetin alfa)

We were granted an exclusive license to manufacture and market EPOGEN® in the United States under a licensing agreement with K-A. We have retained exclusive rights to market EPOGEN® in the United States for dialysis patients. We granted Ortho Pharmaceutical Corporation, a subsidiary of J&J (which has assigned its rights under the Product License Agreement to Janssen), a license to commercialize recombinant human erythropoietin as a human therapeutic in the United States in all indications other than dialysis.

We market EPOGEN® in the United States and it was launched in 1989. EPOGEN® is indicated to treat a lower than normal number of red blood cells (anemia) caused by CKD in patients on dialysis to lessen the need for red blood cell transfusions.

Total EPOGEN® sales were as follows (in millions):

	2012	2011	2010
EPOGEN® — U.S.	$ 1,941	$ 2,040	$ 2,524

Our outstanding material patents for epoetin alfa are described in the following table.

Territory	General Subject Matter	Expiration
U.S.	Product claims to erythropoietin	8/20/2013
U.S.	Pharmaceutical compositions of erythropoietin	8/20/2013
U.S.	Pharmaceutical erythropoietin formulation with certain stabilizers	9/24/2014
U.S.	Cells that make certain levels of erythropoietin	5/26/2015

Any products or technologies that are directly or indirectly successful in addressing anemia associated with renal failure could negatively impact EPOGEN® sales. In the United States, as noted above, EPOGEN® and Aranesp® compete with each other, primarily in the U.S. hospital dialysis clinic setting.

In March 2012, the FDA approved OMONTYS® (peginesatide), a synthetic, PEGylated peptidic compound that binds to and stimulates the erythropoietin receptor and thus acts as an ESA. OMONTYS® was co-developed by Affymax, Inc. and Takeda Pharmaceutical Company Limited (Takeda) and competes with EPOGEN® in the United States in the nephrology segment in patients with CKD who are on dialysis. On February 23, 2013, Affymax, Inc. and Takeda announced that they had decided to voluntarily recall all lots of OMONTYS® Injection to the user level as a result of new postmarketing reports regarding serious hypersensitivity reactions, including anaphylaxis, which can be life-threatening or fatal.

XGEVA®/Prolia® (denosumab)

In 2010, we launched XGEVA® and Prolia®, both of which contain the same active ingredient but which are approved for different indications, patient populations, doses and frequencies of administration. We have a collaboration agreement with Glaxo Group Limited (Glaxo), a wholly owned subsidiary of GlaxoSmithKline plc (GSK), for the commercialization of denosumab in certain countries. See Business Relationships — Glaxo Group Limited.

Total XGEVA® and Prolia® sales were as follows (in millions):

	2012	2011	2010
XGEVA® — U.S.	$ 644	$ 343	$ 8
XGEVA® — ROW	104	8	—
Total XGEVA®	748	351	8
Prolia® — U.S.	292	130	26
Prolia® — ROW	180	73	7
Total Prolia®	472	203	33
Total XGEVA®/Prolia®	$ 1,220	$ 554	$ 41

XGEVA®

In November 2010, the FDA approved XGEVA® for the prevention of skeletal-related events (SREs) (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumors. XGEVA® is not indicated for the prevention of SREs in patients with multiple myeloma.

In July 2011, we announced that the European Commission (EC) granted marketing authorization for XGEVA® for the prevention of SREs in adults with bone metastases from solid tumors. The EC also granted XGEVA® an additional year of data and market exclusivity in the EU since the indication was considered new for denosumab and based on the significant clinical benefit of XGEVA® in comparison with existing therapies.

Any products or technologies that are directly or indirectly successful in treating for the prevention of SREs in patients with bone metastases from solid tumors could negatively impact XGEVA® sales.

The following table reflects currently marketed products that compete with XGEVA®. The table below and the following discussion of competitor products in development may not be exhaustive.

Territory	Competitor Marketed Product	Competitor
U.S. & Europe	Zometa®(1)	Novartis AG (Novartis)
U.S. & Europe	Aredia®(2)	Novartis

(1) Novartis has indicated that patent protection on the active ingredient for Zometa® will expire in 2013 in the United States. At such time, we expect that generic forms of zoledronic acid may become commercially available and compete with Zometa® and XGEVA®. Generic forms of zoledronic acid became available in other major markets in 2012.

(2) This product has lost its patent protection and generic versions of this product are available.

In addition, Bayer has filed with the FDA for approval of alpharadin for the treatment of castration-resistant prostate cancer patients with bone metastases, that may compete with XGEVA® in the future.

Prolia®

In June 2010, the FDA approved Prolia® for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In September 2011, we announced that the FDA approved two additional indications for Prolia® as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer and as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. In September 2012, the FDA approved Prolia® for a treatment to increase bone mass in men with osteoporosis at high risk for fracture.

In May 2010, the EC granted marketing authorization for Prolia® for the treatment of osteoporosis in postmenopausal women at increased risk of fractures and for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures.

Any products or technologies that are directly or indirectly successful in treating osteoporosis in patients at high risk for fracture could negatively impact Prolia® sales.

The following table and discussion reflect other companies and their currently marketed products that compete with Prolia®. The table below and the following discussion of competitor marketed products and products in development may not be exhaustive.

Territory	Competitor Marketed Product	Competitor
U.S. & Europe	FOSAMAX®(1)	Merck
U.S. & Europe	Actonel®/Atelvia™	Warner Chilcott PLC
U.S. & Europe	Boniva®(1)/Bonviva®(1)	Roche
U.S. & Europe	Evista®	Eli Lilly
U.S. & Europe	Forteo®/Forsteo™	Eli Lilly
U.S. & Europe	Miacalcin®	Novartis
U.S. & Europe	Aclasta®(1)/Reclast®	Novartis
Europe	Conbriza®	Pfizer
Europe	Fablyn®	Pfizer

(1) This product has lost its patent protection and generic versions of this product are available.

We expect several additional marketed products noted above to lose patent protection over the next several years.

Merck (odanacatib) and Radius Health, Inc. (BA058) have product candidates in phase 3 clinical development for PMO.

Our outstanding material patents for denosumab are described in the following table.

Territory	General Subject Matter	Expiration(1)
U.S.	RANKL antibodies; and methods of use	12/22/2017
U.S.	Methods of treatment	11/11/2018
U.S.	RANKL antibodies including sequences	2/19/2025
U.S.	Nucleic acids encoding RANKL antibodies, and methods of producing RANKL antibodies	11/30/2023
Europe	RANKL antibodies	12/22/2017
Europe	Medical use of RANKL antibodies	4/15/2018
Europe	RANKL antibodies including epitope binding	2/23/2021
Europe	RANKL antibodies including sequences	6/25/2022

(1) In some cases, these patents may be entitled to patent term extension in the United States or supplemental protection in one or more countries in Europe and the length of any such extension will vary by country. For example, supplementary protection certificates covering denosumab have issued in France, Italy and Spain, and will expire in 2025.

Other Marketed Products

Our other marketed products include Sensipar®/Mimpara® (cinacalcet), Vectibix® (panitumumab) and Nplate® (romiplostim).

Sensipar®/Mimpara® (cinacalcet)

Sensipar® is our registered trademark in the United States and Mimpara® is our registered trademark in Europe for cinacalcet, our small molecule medicine used in treating CKD patients on dialysis who produce too much parathyroid hormone (PTH), a condition known as secondary hyperparathyroidism. In 2004, Sensipar®/Mimpara® was approved in the United States and Europe for the treatment of secondary hyperparathyroidism in CKD patients on dialysis and for the treatment of hypercalcemia in patients with parathyroid carcinoma. In 2008, Mimpara® was approved in Europe for the reduction of hypercalcemia in patients with primary hyperparathyroidism (PHPT) where a parathyroidectomy is not clinically appropriate or is contraindicated. In 2011, Sensipar® was approved in the United States for the treatment of severe hypercalcemia in patients with PHPT who are unable to undergo parathyroidectomy. We market Sensipar® primarily in the United States and Mimpara® primarily in Europe.

As previously discussed, CMS's Final Rule on Bundling in Dialysis became effective on January 1, 2011, and provides a single payment for all dialysis services. Oral drugs without intravenous equivalents, such as Sensipar® and phosphate binders, will continue to be reimbursed separately under the Medicare Part D benefit until they are included in the bundled-payment system, which was delayed by Congress from 2014 to 2016 in connection with the passage in January 2013 of the American Taxpayer Relief Act (ATRA). Inclusion in the bundled-payment system may reduce utilization of these oral drugs and have an adverse impact on our sales. See Reimbursement.

In November 2012, we presented at ASN's Kidney Week the results of the phase 3 E.V.O.L.V.E™ trial. As previously reported, the primary analysis showed that the trial did not reach its primary endpoint (time to composite event comprising all-cause mortality or first non-fatal cardiovascular event, including myocardial infarction, hospitalization for unstable angina, heart failure or peripheral vascular event) in the intent-to-treat analysis. See Significant Developments in our Quarterly Report on Form 10-Q for the period ended June 30, 2012.

Total Sensipar®/Mimpara® sales were as follows (in millions):

	2012	2011	2010
Total Sensipar®/Mimpara®	$ 950	$ 808	$ 714

Our outstanding material patents for cinacalcet are described in the following table.

Territory	General Subject Matter	Expiration
U.S.	Calcium receptor-active molecules including species	10/23/2015
U.S.	Calcium receptor-active molecules	3/8/2018
U.S.	Methods of treatment	12/14/2016
Europe[1]	Calcium receptor-active molecules	10/23/2015

(1) This European patent is also entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary by country. For example, supplementary protection certificates covering cinacalcet have issued in France, Germany, Italy, Spain, and the United Kingdom, and will expire in 2019.

Any products or technologies that are directly or indirectly successful in treating secondary hyperparathyroidism in patients with CKD on dialysis and/or hypercalcemia in patients with parathyroid carcinoma could negatively impact Sensipar®/Mimpara® sales.

The following table reflects companies and their currently marketed products that compete with Sensipar® in the United States and with Mimpara® in Europe in the nephrology segment for patients with CKD on dialysis and may not be exhaustive.

Territory	Competitor Marketed Product	Competitor
U.S.	Hectorol®	Genzyme Corporation (Genzyme)
U.S.	Rocaltrol®	Roche
U.S.	Calcijex®	Abbott [1]
U.S.	Calcium Acetate®	Roxane Laboratories/Sandoz
U.S. & Europe	Zemplar®	Abbott [1]
U.S. & Europe	Renagel®	Genzyme
U.S. & Europe	Renvela®	Genzyme
U.S. & Europe	PhosLo®/Rephoren®	Fresenius Medical Care AG & Co. KGaA (Fresenius Medical Care)
U.S. & Europe	OsvaRen®	Fresenius Medical Care
U.S. & Europe	Fosrenol®	Shire Pharmaceuticals Group Plc

(1) In January 2013, Abbott announced that it completed the separation of its research-based pharmaceuticals business, which became AbbVie, a new independent biopharmaceutical company which now owns the rights to this product.

In July 2008, we filed a lawsuit against Teva and Barr Pharmaceuticals Inc. (Barr) for infringement of four Sensipar® patents. The lawsuit was based on Abbreviated New Drug Applications (NDA) filed by Teva and Barr that sought approval to market generic versions of Sensipar®. Following trial, in January 2011, the U.S. District Court for the District of Delaware granted an injunction prohibiting Teva and Barr from commercializing generic versions of Sensipar® in the United States until expiration of three of those patents. These generic versions could compete with Sensipar® in the future.

Vectibix® (panitumumab)

Vectibix® is our registered trademark for panitumumab, our monoclonal antibody for the treatment of patients with EGFr expressing metastatic colorectal cancer (mCRC) after disease progression on, or following fluoropyrimidine-, oxaliplatin- and irinotecan- containing chemotherapy regimens. EGFr is a protein that plays an important role in cancer cell signaling and is over-expressed in many human cancers. Vectibix® binds with high affinity to EGFrs and interferes with signals that might otherwise stimulate growth and survival of the cancer cell. In September 2006, Vectibix® received FDA accelerated approval in the United States, based upon clinical trial data from a study demonstrating a statistically significant improvement in progression-free survival and with the condition that Amgen conduct a confirmatory trial to verify the clinical benefit of panitumumab through demonstration of an improvement in overall survival. (See discussion of the '181 trial below.) In the EU, the conditional approval of Vectibix® as monotherapy, for the treatment of patients with EGFr expressing metastatic colorectal carcinoma with non-mutated (wild-type) *KRAS* genes after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens, was received in December 2007 and is reviewed annually by the Committee for Medicinal Products for Human Use (CHMP). Each year thereafter, the EU conditional marketing authorization was renewed with an additional specific obligation to conduct a clinical trial in the approved monotherapy indication. In 2010, we began enrollment for this additional clinical trial which compares the effect of Vectibix® versus Erbitux® (cetuximab) on overall survival for chemorefractory mCRC patients with wild-type *KRAS* genes. *KRAS*

is a protein found in all human cells. Some colorectal cancers have mutations in the *KRAS* gene. Vectibix® has been shown to be ineffective in people whose tumors had *KRAS* mutations in codon 12 or 13.

In 2009, we announced results from the ‘203 and ‘181 pivotal phase 3 trials evaluating Vectibix® in combination with chemotherapy (FOLFOX or FOLFIRI) as a first- and second-line treatment for mCRC, respectively. Both studies demonstrated that Vectibix® administered with chemotherapy significantly improved progression-free survival in patients with wild-type *KRAS* mCRC. Additionally, both studies showed numeric improvements in median overall survival in the same patient population. The numeric improvements in median overall survival failed to achieve statistical significance. It was previously agreed with the FDA that the '181 study would serve as the confirmatory trial for establishing full approval for the mCRC indication.

In July 2011, we announced that we received Complete Response Letters from the FDA on the first- and second-line mCRC sBLAs that we filed in late 2010. The FDA did not ask for new clinical studies but did request an updated safety analysis and additional analyses of the overall survival data in the ’181 and ’203 studies using more mature data sets. The FDA has also informed us that approval for the first- and second-line mCRC indications will be contingent upon approval of the companion diagnostic device being developed in collaboration with QIAGEN N.V. (QIAGEN), which identifies a patient’s *KRAS* gene status. We are currently working on addressing the FDA’s requests in the Complete Response Letters.

In November 2011, the EC approved a variation to the marketing authorization for Vectibix® to include indications for the treatment of patients with wild-type *KRAS* mCRC in first- and second-line in combination with chemotherapy.

Total Vectibix® sales were as follows (in millions):

	2012	2011	2010
Total Vectibix®	$ 359	$ 322	$ 288

Our outstanding material patents for panitumumab are described in the following table.

Territory	General Subject Matter	Expiration
U.S.	Human monoclonal antibodies to EGFr	4/8/2020
U.S.	Human monoclonal antibodies to EGFr	5/5/2017
Europe	Fully human antibodies that bind EGFr	12/3/2017
Europe[(1)]	Human monoclonal antibodies to EGFr	5/5/2018

(1) This European patent is also entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary by country. For example, supplementary protection certificates covering panitumumab have issued in France, Italy, Spain, and the United Kingdom, and will expire in 2022.

Any products or technologies that are directly or indirectly successful in treating mCRC after disease progression either on or following fluoropyrimidine-, oxaliplatin- and irinotecan-containing chemotherapy regimens could negatively impact Vectibix® sales.

The following table reflects companies and their currently marketed products that compete with Vectibix® in the United States and Europe and may not be exhaustive.

Territory	Competitor Marketed Product	Competitor
U.S.	Erbitux®	Eli Lilly/BMS
U.S.	Zaltrap®	Sanofi
U.S.	Avastin®	Genentech, Inc. (Genentech)
U.S.	Stivarga®	Bayer
Europe	Erbitux®	Merck KGaA

Nplate® (romiplostim)

In August 2008, the FDA approved Nplate® for the treatment of thrombocytopenia in splenectomized (spleen removed) and non-splenectomized adults with chronic immune thrombocytopenic purpura (ITP). Nplate® works by raising and sustaining platelet counts. We were granted an exclusive license by K-A to manufacture and market Nplate® in the United States, all European countries, Canada, Australia, New Zealand, Mexico, all Central and South American countries and certain countries in Central Asia, Africa and the Middle East. In February 2009, we announced that the EC had granted marketing authorization for Nplate®

for the treatment of splenectomized adult chronic ITP patients who are refractory to other treatments (e.g., corticosteroids, immunoglobulins). In the EU, Nplate® may also be considered as second-line treatment for adult non-splenectomized ITP patients where surgery is contraindicated.

Total Nplate® sales were as follows (in millions):

	2012	2011	2010
Total Nplate®	$ 368	$ 297	$ 229

Our outstanding material patents for romiplostim are described in the following table.

Territory	General Subject Matter	Expiration
U.S.	Thrombopoietic compounds	1/19/2022
U.S.	Thrombopoietic compounds	10/22/2019
Europe[(1)]	Thrombopoietic compounds	10/22/2019

(1) This European patent is also entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary by country. For example, supplementary protection certificates covering romiplostim have issued in France, Italy, Spain, and the United Kingdom, and will expire in 2024.

Any products or technologies that are directly or indirectly successful in treating thrombocytopenia in splenectomized and non-splenectomized adults with chronic ITP could negatively impact Nplate® sales.

The following table reflects companies and their currently marketed products that compete with Nplate® in the United States and Europe and may not be exhaustive.

Territory	Competitor Marketed Product	Competitor
U.S.	Promacta®	GSK
Europe	Revolade®	GSK

Marketing and Distribution

We maintain sales and marketing forces primarily in the United States, Europe and Canada to support our currently marketed products. We have also entered into agreements with third parties to assist in the commercialization and marketing of certain of our products in specified geographic areas. (See Business Relationships.) Together with our partners, we market our products to healthcare providers, including physicians or their clinics, dialysis centers, hospitals and pharmacies. We also market certain products directly to consumers through direct-to-consumer print and television advertising, as well as through the Internet. In addition, for certain of our products, we promote programs to increase public awareness of the health risks associated with the diseases these products treat and we provide support for various patient education and support programs in the related therapeutic areas. See Government Regulation — FDA Regulation of Product Marketing and Promotion for a discussion of government regulation of product marketing and promotion.

In the United States, we sell primarily to pharmaceutical wholesale distributors. We utilize those wholesale distributors as the principal means of distributing our products to healthcare providers. In Europe, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country. We monitor the financial condition of our larger customers, and we limit our credit exposure by setting credit limits and, for certain customers, by requiring letters of credit.

Our product sales to three large wholesalers, AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc., each accounted for more than 10% of total revenues for each of the years ended December 31, 2012, 2011 and 2010. On a combined basis, these wholesalers accounted for approximately 94%, 90% and 88% of our gross product sales in the United States, respectively and approximately 76%, 72% and 71% of our total worldwide gross revenues, respectively in 2012, 2011 and 2010.

Reimbursement

Sales of all of our principal products are dependent in large part on the availability and extent of coverage and reimbursement from third-party payers, including government and private insurance plans. Most patients receiving our products are covered by government healthcare programs or private insurers. Governments may regulate coverage, reimbursement and/or pricing of our products to control costs or to affect levels of use of our products; and private insurers may adopt or be influenced by government

coverage and reimbursement methodologies. Worldwide use of our products may be affected by cost containment pressures and cost shifting from governments and private insurers to healthcare providers or patients in response to ongoing initiatives to reduce or reallocate healthcare expenditures. An increasing worldwide focus on patient access controls and cost containment by public and private insurers has resulted, and may continue to result, in reduced reimbursement rates for our products. In addition, healthcare reforms enacted in the United States have made substantial long-term changes to the reimbursement of our products, and those changes have had, and are expected to continue to have, a material adverse impact on our business.

U.S. Reimbursement System

Our principal products are sold primarily in the United States, and healthcare providers, including doctors, hospitals and other healthcare professionals and providers, are reimbursed by the government through Medicare, Medicaid and other government healthcare programs as well as through private payers for covered services and products they use. Government healthcare programs are funded primarily through the payment of taxes by individuals and businesses. The public and private components of this multi-payer system are described below.

Medicare and Other Forms of Public Health Insurance

Medicare is a federal program administered by the federal government that covers individuals 65 years or older as well as those with certain disabilities or ESRD regardless of their age. The primary Medicare programs that affect reimbursement for our products are Medicare Part B, which covers physician services and outpatient care, and Medicare Part D, which provides a voluntary outpatient prescription drug benefit. CMS is the federal agency responsible for administering Medicare (as well as Medicaid, described below) and, among its responsibilities, has authority to promulgate regulations and policies, as well as issue reimbursement codes for drugs, all of which can determine how medical items and services are covered and reimbursed by Medicare. CMS can also issue Medicare NCDs, which are national policy determinations granting, limiting or excluding Medicare coverage for specific medical items or services applicable throughout the United States. In the absence of a relevant NCD, Medicare coverage determinations for a particular medical item or service are left to MACs, who issue LCDs, which are binding on providers within their respective jurisdictions. CMS sometimes uses advisory committees of external experts in order to obtain independent expert advice on scientific, technical and policy matters. For example, the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) was established to provide independent guidance and expert advice for CMS on specific clinical topics. The MEDCAC reviews and evaluates medical literature and technology assessments and examines data and information on the effectiveness and appropriateness of medical items and services that are covered under Medicare or that may be eligible for coverage under Medicare.

Medicare Part B Coverage of Drugs. Medicare Part B provides limited coverage of outpatient drugs and biologicals that are reasonable and necessary for a medically accepted diagnosis or treatment of an illness or injury and that fall into a statutory benefit category. One such category relevant to our products covers drugs and biologicals furnished incident to a physician’s services. Generally, incident-to drugs and biologicals are covered if they satisfy certain criteria, including that they are of the type that are not usually self-administered by the patient. Medicare Part B also covers certain drugs pursuant to specific statutory benefit categories, such as blood-clotting factors and certain immunosuppressive drugs, erythropoietin and certain oral cancer drugs. Many of our principal products are currently covered under Medicare Part B (as well as other government healthcare programs).

Medicare Part D Coverage of Drugs. Medicare Part D provides a voluntary prescription drug benefit for Medicare eligible beneficiaries. The coverage is available through private plans that provide insurance coverage for prescription drugs for a monthly premium and with patient cost sharing. The list of prescription drugs covered by Medicare Part D plans varies by plan, but drug lists maintained by individual plans must cover certain classes of drugs and biologicals; specifically the statute stipulates that Medicare Part D plans have at least two drugs in each unique therapeutic category or class, subject to certain exceptions.

Medicare ESRD Program. Most patients with ESRD, regardless of age, are eligible for coverage of dialysis treatment through Medicare's ESRD Program. Because Medicare is the primary payer for dialysis treatment in the United States, reimbursement for products, such as EPOGEN®, that are typically administered in dialysis centers and other settings is particularly sensitive to changes in Medicare coverage and reimbursement policy. Since January 1, 2011, dialysis treatment under the ESRD Program has been reimbursed under a bundled-payment system described in more detail below. See Dialysis Reimbursement.

Medicaid. Medicaid is a joint federal and state program administered by individual states for low-income and disabled eligible beneficiaries. CMS also has responsibility for federal administration of the Medicaid program. Under federal law, states must cover low-income adults and children, pregnant women, disabled individuals and seniors, and states have the option of expanding eligibility beyond those groups of beneficiaries. Medicaid is financed jointly by the states and the federal government through taxes. Medicaid offers a broad set of benefits, including prescription drugs, although coverage varies by state. Medicaid includes the Drug Rebate Program, which requires that manufacturers provide rebates for the states for products covered and reimbursed by state Medicaid programs.

See Item 1A. Risk Factors — Our sales depend on coverage and reimbursement from third-party payers.

Private Health Insurance

Employer-sponsored insurance. Employer-sponsored insurance currently represents the main pathway by which Americans receive private health insurance. Many employers provide health insurance as part of employees' benefit packages. Insurance plans are administered by private companies — both for-profit and not-for-profit — and some companies are self-insured (i.e., they pay directly through a plan administered by a third party for all healthcare costs incurred by employees). Generally, employer-sponsored insurance premiums are paid primarily by employers and secondarily by employees.

Individual market. The individual market covers part of the population that is self-employed or retired. In addition, it covers some people who are unable to obtain insurance through their employers. The plans are administered by private insurance companies. Individuals pay out-of-pocket insurance premiums for coverage, and the benefits vary widely according to plan specifications.

Efforts to reduce health care costs are being made in the private sector, notably by health care payers and providers, which have instituted various cost reduction and containment measures. Amgen expects insurers and providers to continue attempts to reduce the cost and/or utilization of healthcare products including our products.

Reimbursement of Our Principal Products

Neulasta®, NEUPOGEN®, Aranesp®, Prolia® and XGEVA®. Medicare and Medicaid payment policies for drugs and biologicals are subject to various laws and regulations. The Medicare program covers our principal products Neulasta®, NEUPOGEN®, Aranesp®, Prolia® and XGEVA® (as well as certain of our other products, including Vectibix® and Nplate®) primarily under Part B, when administered in the physician clinic setting and the hospital outpatient setting. Healthcare providers are reimbursed for these products under a buy-and-bill process whereby providers purchase the product in advance of treatment and then submit a reimbursement claim to Medicare following administration of the product. Medicare reimburses providers by using a payment methodology based on a fixed percentage of each product's average sales price (ASP). ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. A product's ASP is calculated and reported to CMS on a quarterly basis and therefore may change each quarter. The ASP in effect for a given quarter (the Current Period) is based on certain historical sales and sales incentive data covering a defined period of time preceding the Current Period. CMS publishes the ASPs for products in advance of the quarter in which they go into effect so healthcare providers will know the applicable reimbursement rates. In the calculation of ASP, CMS currently allows manufacturers to make reasonable assumptions consistent with the general requirements and the intent of the Medicare statute and regulations and their customary business practices; in the future, CMS may provide more specific guidance. Any changes to the ASP calculations directly affect the Medicare reimbursement for our products administered in the physician clinic setting, hospital outpatient setting and, to a lesser extent, the dialysis facility setting. (See Dialysis Reimbursement.) Our ASP calculations are reviewed quarterly for completeness, and based on such review, we have on occasion restated our reported ASPs to reflect calculation changes both prospectively and retroactively. See Items 1A. Risk Factors — Our sales depend on coverage and reimbursement from third-party payers.

In general, drugs and biologicals provided in the physician clinic setting and in the hospital outpatient setting are reimbursed under Medicare Part B at a certain percentage of their ASP (sometimes referred to as "ASP +X%"). The 2013 reimbursement rates in both settings will be ASP +6%. The rate for the physician clinic setting is set by statute, but CMS has authority to adjust the rate for the hospital outpatient setting annually. Commercial payers may use the government's ASP data in setting their payment methodologies for drugs and biologicals provided in the physician clinic and hospital outpatient settings. The extent to which commercial payers rely on the government's ASP data and the specific ASP +X% used is often based on the contractual relationship between the provider and the insurer.

For fiscal years 2013-21, Medicare payment rates are scheduled to be affected by across-the-board budget cuts (referred to commonly as "sequestration") mandated under the Budget Control Act (the BCA) and revised by the ATRA, as explained more fully below in Impact of Budget Control Act on U.S. Reimbursement. Under sequestration, CMS can reduce Medicare payments to providers, including ASP-based reimbursement, by up to 2% per fiscal year.

Dialysis Reimbursement. Currently, dialysis providers in the United States are reimbursed for EPOGEN® primarily by Medicare through the ESRD Program, which is established by federal law and implemented by CMS. Historically, the ESRD Program reimbursed Medicare providers for 80% of allowed dialysis costs; the remainder was paid by other sources, including patients, state Medicaid programs, private insurance, and to a lesser extent, state kidney patient programs. Until January 1, 2011, Medicare reimbursed for separately billable dialysis drugs (including Aranesp® and EPOGEN®) administered in both freestanding and hospital-based dialysis centers, at ASP +6%, by using the same payment amount methodology used in the physician clinic setting under Part B. On January 1, 2011, CMS's bundled-payment system went into effect for dialysis providers by establishing a single payment for all dialysis services, including drugs, supplies and non-routine laboratory tests that had previously been reimbursed separately. ESRD providers receive a designated payment for each dialysis treatment and can be paid for up to three treatments per week unless medical necessity justifies more frequent treatments. Oral drugs without intravenous equivalents, such

as Sensipar® and phosphate binders, will continue to be reimbursed separately under the Medicare Part D benefit until they are included in the bundled-payment system in 2016. Inclusion in the bundled-payment system may reduce utilization of these oral drugs and have an adverse impact on our sales.

To encourage dialysis providers to continue to provide quality dialysis treatment under the new bundled-payment system, CMS also implemented the ESRD QIP. Under the QIP, beginning in 2012, ESRD facilities are subject to a payment penalty of up to 2% of amounts reimbursed for failure to meet or exceed CMS's quality performance standards, including performance standards related to anemia management and dialysis adequacy. In November 2011, following our June 2011 announcement of changes to the labels for the use of ESAs in patients with CKD, CMS finalized a rule to update various provisions of its bundled-payment system for dialysis services and the related ESRD QIP. The final rule eliminated for payment year 2013 and beyond one of the QIP's measures that tracks the percent of a provider's Medicare patients with a Hb level below 10 g/dL. CMS indicated that removal of this quality measure from the QIP was being done in response to the June 2011 ESA label changes. We believe that the implementation of these various changes in the dialysis setting has resulted and could result in a material adverse impact on the reimbursement, use and sales of EPOGEN® and on our business and results of operations. Data available through October 2012 indicates a stabilization of Hb levels.

ENBREL Reimbursement. The majority of prescription claims for ENBREL are paid through private insurance companies. Under Medicare, ENBREL is reimbursed through the Part D program, although less than 10% of all ENBREL U.S. prescriptions are reimbursed by Medicare.

Mandatory Government Rebates and Discounts

Since 1991, we have participated in the Medicaid drug rebate program established in Section 1927 of the Social Security Act by the Omnibus Budget Reconciliation Act of 1990 and subsequent amendments of that law. Under the Medicaid drug rebate program, we pay a rebate to the states for each unit of our product reimbursed by state Medicaid programs. The amount of the rebate for each of our products is currently set by law as a minimum of 23.1% of the Average Manufacturer Price (AMP) of that product, or if it is greater, the difference between AMP and the best price available from us to any non-government customer. The rebate amount is determined for each quarter based on our reports to CMS of the quarter's AMP and best price for each of our products. The rebate amount also includes an inflation adjustment if AMP increases faster than inflation. The statutory definition of AMP changed in 2010 as a result of the U.S. healthcare reform law, and in January 2012, CMS issued a proposed rule further defining the new AMP definition. Until that rule is finalized, we are required to make reasonable assumptions when calculating AMP. Once CMS's proposed rule is finalized, we will have to determine whether our calculations should be amended and whether we will need to restate our prior AMPs. The terms of our participation in the Medicaid drug rebate program impose an obligation to correct the prices reported in previous quarters, as may be necessary. Any such corrections could result in an overage or underage in our rebate liability for past quarters, depending on the direction of the correction. In addition to retroactive rebates, if we were found to have knowingly submitted false information to the government, in addition to other penalties available to the government, the statute provides for civil monetary penalties in the amount of $100,000 per item of false information.

Related to our participation in the Medicaid drug rebate program is a requirement that we extend comparable discounts under the Public Health Service (PHS) drug pricing program to eligible community health clinics and other entities that receive health services grants from the PHS, as well as hospitals that serve a disproportionate share of Medicare and Medicaid beneficiaries.

We also make our products available to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration. Since 1993, as a result of the Veterans Health Care Act of 1992 (VHC Act), federal law has required that we offer deeply discounted FSS contract pricing for purchases by the Department of Veterans Affairs, the Department of Defense, the Coast Guard and the PHS (including the Indian Health Service) in order for federal funding to be available for reimbursement of our products under the Medicaid program or purchase of our products by those four federal agencies and certain federal grantees. FSS pricing to those four federal agencies must be equal to or less than the Federal Ceiling Price (FCP), which is 24% below the Non-Federal Average Manufacturer Price (Non-FAMP) for the prior fiscal year. The accuracy of our reported Non-FAMPs, FCPs and our FSS contract prices may be audited by the government under applicable federal procurement laws and the terms of our FSS contract. Among the remedies available to the government for inaccuracies in calculation of Non-FAMPs and FCPs is recoupment of any overcharges to the four specified federal agencies based on those inaccuracies. Also, if we were found to have knowingly reported a false Non-FAMP, in addition to other penalties available to the government, the VHC Act provides for civil monetary penalties of $100,000 per item that is incorrect. Finally, we are required to disclose in our FSS contract proposal all commercial pricing that is equal to or less than our proposed FSS pricing, and subsequent to award of an FSS contract, we are required to monitor certain commercial price reductions and extend commensurate price reductions to the government, under the terms of the FSS contract price reductions clause. Among the remedies available to the government for any failure to properly disclose commercial pricing and/or to extend FSS contract price reductions is recoupment of any FSS overcharges that may result from such omissions.

U.S. Healthcare Reform. In March 2010, the Patient Protection and Affordable Care Act (PPACA) and the companion Health Care and Education Reconciliation Act, which made certain changes and adjustments to the PPACA, primarily with respect to the PPACA's financial and budgetary impacts, were signed into law. We refer to those two laws collectively as the "U.S. healthcare reform law." The U.S. healthcare reform law imposes additional costs on and reduces the revenue of companies in the biotechnology and pharmaceutical industries. The following paragraphs describe certain provisions of the healthcare reform law that are affecting and will affect our business.

The U.S. healthcare reform law also imposed a new fee (the U.S. healthcare reform federal excise fee) on manufacturers and importers of "branded prescription drugs," which includes drugs approved under section 505(b) of the Federal Food, Drug and Cosmetic Act (FDCA) or biological products licensed under section 351(a) of the Public Health Service Act. The U.S. healthcare reform law set an aggregate annual fee, to be paid by these manufacturers and importers, totaling $28 billion over 10 years beginning in 2011. This annual fee is apportioned among the participating companies, including us, based on each company's sales of qualifying products to, and utilization by, certain U.S. government programs during the preceding calendar year. The additional fee is not deductible for U.S. federal income tax purposes. Manufacturers and importers of generic or biosimilar drugs are not subject to the fee.

Other changes under the U.S. healthcare reform law that became effective in 2010 include: (i) an increase in the rebates we pay to the states for our products that are covered and reimbursed by state Medicaid programs, (ii) the extension of the Medicaid drug rebate program to patients in Medicaid managed care insurance plans for whom rebates were not previously required and (iii) the expansion of the list of provider institutions to which we must extend discounts under the PHS 340B drug-pricing program.

When the Medicare Part D drug benefit took effect in 2006, standard benefit Part D plan enrollees were required to pay 100% of their prescription drug costs after their total drug spending exceeded an initial coverage limit and until they qualified for catastrophic coverage. This coverage gap is sometimes referred to as the Part D "doughnut hole." Then the PPACA directed CMS to phase out up to 50% of this coverage gap from 2011 to 2020. Under the standard benefit, cost sharing for both brand and generic drugs will be reduced each year until 2020, when the coverage gap will be eliminated and beneficiaries will pay 25% cost sharing for all drugs until they reach the out-of-pocket threshold. Manufacturers like Amgen are presently required to provide a 50% cost sharing discount for beneficiaries in the doughnut hole.

The U.S. healthcare reform law also expands Medicaid eligibility to include those with incomes up to 133% of the federal poverty level (FPL), from 100% of the FPL. This provision becomes effective January 1, 2014.

Impact of Budget Control Act on U.S. Reimbursement

The Budget Control Act of 2011, signed into law in the United States in August 2011, mandated a 2% reduction in government payments for all Medicare services (including the administration of separately billable drugs and payment for drugs in all Medicare programs) for federal fiscal years 2013-21. The impact of sequestration remains subject to administrative implementation of the Budget Control Act, as updated by the more recent ATRA, or future statutory revision by Congress, which could block, limit or otherwise modify the automatic spending cuts. Several alternative deficit reduction proposals have been put forth by President Obama and/or congressional committees, including proposals designed to further limit federal healthcare expenditures. We cannot predict whether any deficit reduction actions will be approved by Congress and/or whether a budget sequestration will ultimately occur for Medicare services. A reduction in reimbursement for drugs and biologics for U.S. healthcare programs as a result of changes such as those that have been proposed or as a result other changes designed to achieve similar federal budget savings could have a material adverse effect on the sales of our products, our business and results of operations.

Reimbursement Outside the United States

Generally, in Europe and other countries outside the United States, government-sponsored healthcare systems have traditionally been the primary payers of all healthcare costs, including payment for drugs and biologicals. Over the past several years, the reimbursement environment in Europe has become very challenging. The proliferation of Health Technology Assessment (HTA) organizations (e.g., National Institute for Health and Clinical Excellence (NICE) in the UK and the German Institute for Quality and Efficiency in Health Care (IQWiG) in Germany) has led to recommendations and/or determinations of coverage and reimbursement based on both the clinical as well as the economic value of a product. Although the methods employed by different HTA agencies vary from country to country, the use of formal economic metrics has been increasing across Europe as well as in several emerging markets throughout the world. In addition to determining whether or not a new product will be reimbursed, these agencies are becoming increasingly involved in setting the maximum price at which the product will be reimbursed - the "value-based" price for a product.

With increased budgetary constraints, payers in many countries employ a variety of measures to exert downward price pressure. Mandatory price controls continue to be a significant aspect of business for the pharmaceutical and biotechnology industries in most countries outside the United States. In some countries, international price referencing is the primary mechanism for price control, whereby the ceiling price of a pharmaceutical or biological product is set based on prices in particular benchmark

countries. These price-referencing rules are increasing in complexity as payers seek lower-price benchmarks against which to compare themselves. Trends across Europe are also leading toward increased price transparency, with the development of databases to include prices across Europe and requests from specific national payers that manufacturers provide commercially confidential net price information. Additional cost-containment measures can include therapeutic reference pricing (e.g., setting the reimbursement rate for a given class of agents at the lowest price within the class), increasing mandates or incentives for generic substitution and biosimilar usage, and government-mandated price cuts. In addition, healthcare reform and related legislative proposals in such countries as France, Germany, and Poland, as well as austerity plans in a number of countries, including Spain, Greece, Italy, Ireland and Portugal, have targeted the pharmaceutical sector with multiple mechanisms to reduce government healthcare expenditures. We expect that countries will continue to take aggressive actions to reduce expenditures on drugs and biologics, including mandatory price reductions, clawbacks of payments made to companies when drug spending thresholds are exceeded, preferences for biosimilars, changes in international price referencing, price transparency to achieve prices similar to those in lower-priced countries, and reductions in the amount of reimbursement, sometimes with the imposition of patient copayments. Similarly, fiscal constraints may also impact the extent to which countries are willing to reward new innovative therapies and/or allow access to new technologies. This could impact coverage, price, time to achieve reimbursement, and ultimate level of reimbursement.

In many countries, the influence of regional and hospital payers also contributes to whether patients have access to certain products. For example, a product may be listed successfully on a national formulary, but may also be subject to further evaluations or competitive bidding by payers at a regional or hospital level. The impact of multiple layers of assessment can result in delay or failure to secure access and/or net price pressure.

Payers in some countries are using and others are beginning to experiment with alternative payment mechanisms (e.g., payment caps, risk sharing) as a means to achieve or maintain access to innovative therapies while increasing their budget certainty. Requirements for such payment mechanisms can adversely impact Amgen’s business through increased net price concessions and added administrative burden.

While we cannot fully predict either the extent of further price reductions and/or reimbursement restrictions taken by governmental payers outside the United States or the impact such actions will have on our business, such reductions in price and/or the coverage and reimbursement for our products could have a material adverse effect on the sales of our products, our business and results of operations.

Fraud and Abuse Regulations Related to Reimbursement

As participants in government reimbursement programs, we are subject to various U.S. federal and state laws, as well as foreign laws, pertaining to healthcare “fraud and abuse,” including anti-kickback laws and false claims laws. (See Government Regulation — Other.) Violations of fraud and abuse laws can result in stringent enforcement penalties up to and including complete exclusion from federal healthcare programs (including Medicare and Medicaid).

Manufacturing, Distribution and Raw Materials

Manufacturing

Biological products, which are produced in living systems, are inherently complex due to naturally-occurring molecular variations. Highly specialized knowledge and extensive process and product characterization are required to transform laboratory-scale processes into reproducible commercial manufacturing processes. Our manufacturing operations consist of bulk manufacturing, formulation, fill and finish and distribution activities. Bulk manufacturing includes fermentation and/or cell culture — processes by which our proteins are produced — and also includes purification of the proteins to a high quality. The proteins are then formulated into stable forms. The fill process dispenses the formulated bulk protein into vials or syringes. Finally, in the finish process, our products are packaged for distribution.

We operate a number of commercial and/or clinical manufacturing facilities, and our primary facilities are located in the United States, Puerto Rico and the Netherlands. (See Item 2. Properties.) We also use and expect to continue to use third-party contract manufacturers to produce or assist in the production of certain of our large molecule marketed products as well as a number of our clinical product candidates. Manufacturing of Sensipar®/Mimpara®, our small molecule product, is currently performed by third-party contract manufacturers, except for certain fill and finish activities performed by us in Puerto Rico.

The global supply of our products depends on actively managing the inventory produced at our facilities and by third-party contract manufacturers and the uninterrupted and efficient operation of these facilities. During the manufacturing scale-up process, and even after achieving sustainable commercial manufacturing, we may encounter difficulties or disruptions due to defects in raw materials or equipment, contamination or other factors that could impact product availability. See Item 1A. Risk Factors — Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales and — We rely on third-party suppliers for certain of our raw materials, medical devices and components.

Commercial Bulk Manufacturing

We operate commercial bulk manufacturing facilities in Puerto Rico and in several locations throughout the United States for most of our products. (See Item 2. Properties.) We have the option to supplement commercial bulk manufacturing for ENBREL, Prolia®, XGEVA® and Vectibix® with a third-party contract manufacturer.

Commercial Formulation, Fill and Finish Manufacturing

We perform most of our commercial protein formulation, fill and finish manufacturing in our Puerto Rico facility. Formulation, fill and finish manufacturing for Nplate® and Vectibix® is performed by third-party contract manufacturers. In addition to the formulation, fill and finish of ENBREL performed by us in Puerto Rico, fill and finish of a certain portion of ENBREL is also performed by third-party contract manufacturers. We also conduct finish activities in the Netherlands. See Item 2. Properties.

Clinical Manufacturing

Clinical bulk, formulation, fill and finish manufacturing facilities are operated primarily in our Thousand Oaks, California, location. We also utilize third-party contract manufacturers for certain clinical products.

See Item 1A. Risk Factors — We perform a substantial amount of our commercial manufacturing activities at our Puerto Rico manufacturing facility and a substantial amount of our clinical manufacturing activities at our Thousand Oaks, California manufacturing facility; if significant natural disasters or production failures occur at the Puerto Rico facility, we may not be able to supply these products or, at the Thousand Oaks facility, we may not be able to continue our clinical trials.

Distribution

We operate distribution centers in the United States, principally in Kentucky, California and the Netherlands for worldwide distribution of the majority of our commercial and clinical products. In addition, we also use third-party distributors to supplement distribution of our commercial and clinical products in certain areas of the world.

Other

In addition to the manufacturing and distribution activities noted above, our operations in the United States, Puerto Rico and the Netherlands perform key manufacturing support functions, including quality control, process development, procurement, distribution and production scheduling. Certain of those manufacturing and distribution activities are highly regulated by the FDA as well as other international regulatory agencies. See Government Regulation — FDA Regulation of Manufacturing Standards.

Manufacturing Initiatives

We have multiple ongoing initiatives that are designed to optimize our manufacturing network and/or mitigate risks while continuing to ensure adequate supply of our commercial products. The facilities impacted by each of these initiatives will require qualification and licensure by various regulatory authorities. These initiatives include the construction of a formulation and fill facility at our Puerto Rico site; and as part of a risk mitigation strategy, we plan modification and expansion of our recently acquired formulation, fill and finish site in Ireland to manufacture our products.

In addition to these initiatives, we have projects designed to operate our facilities at appropriate production capacity over the next few years, further optimize manufacturing asset utilization, continue our use of third-party contract manufacturers and maintain a state of regulatory compliance. See Item 1A. Risk Factors — Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

Raw Materials and Medical Devices

Certain raw materials necessary for the commercial and clinical bulk manufacturing of our products are provided by unaffiliated third-party suppliers, certain of which may be our only sources for such materials. Also, certain medical devices and components necessary for the formulation, fill and finish of our products are provided by unaffiliated third-party suppliers, certain of which may be the sole sources. Certain of the raw materials, medical devices and components are the proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug application with regulatory agencies so that they must be obtained from the specific sole source or sources and could not be obtained from another supplier unless and until the regulatory agency approved such supplier. We currently attempt to manage the risk associated with such suppliers by inventory management, relationship management and evaluation of alternative sources when feasible. We also monitor the financial condition of certain suppliers and their ability to supply our needs.

Certain of the raw materials required in the commercial and clinical manufacturing of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues. In addition, one of our marketed products also uses bovine serum and human serum albumin. Some countries in which we market our products may restrict the use of certain

biologically derived substances in the manufacture of drugs. We continue to investigate alternatives to certain biological sources and alternative manufacturing processes that do not require the use of certain biologically derived substances because such raw materials may be subject to contamination and/or recall. A material shortage, contamination, recall and/or restriction of the use of certain biologically derived substances or other raw materials that may be sourced from other countries and that are used in the manufacture of our products could adversely impact or disrupt the commercial manufacturing of our products or could result in a mandated withdrawal of our products from the market. See Item 1A. Risk Factors — We rely on third-party suppliers for certain of our raw materials, medical devices and components.

We perform various procedures to assist in authenticating the source of raw materials, including intermediary materials used in the manufacture of our products, which include verification of the country of origin. These procedures are incorporated into the manufacturing processes we and our third-party contract manufacturers perform.

Government Regulation

Regulation by government authorities in the United States and other countries is a significant factor in the production and marketing of our products and our ongoing R&D activities.

In order to clinically test, manufacture and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. In the United States, the Public Health Service Act, the FDCA and the regulations promulgated thereunder, as well as other federal and state statutes and regulations govern, among other things, the raw materials and components used in the production, research, development, testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising and promotion, and distribution of our products. Failure to comply with the applicable regulatory requirements may subject us to a variety of administrative and/or judicially imposed sanctions. The sanctions could include the FDA's refusal to approve pending applications, withdrawals of approvals, delay or suspension of clinical trials, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties and/or criminal prosecution.

Clinical Development. We must conduct extensive clinical trials designed to establish the safety and efficacy of product candidates in order to file for regulatory approval to market a product. Product development and approval within that regulatory framework take a number of years and involve our expenditure of substantial resources, and any approval we obtain remains costly for us to maintain. After laboratory analysis and preclinical testing in animals, we file an Investigational New Drug Application (IND) with the FDA to begin human testing. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions. In such a case, we and the FDA must resolve any outstanding concerns before the clinical trial can begin.

Typically, we undertake a three-phase human clinical testing program. In phase 1, we conduct small clinical trials to investigate the safety and proper dose ranges of our product candidates in a small number of human subjects. In phase 2, we conduct clinical trials to investigate side effect profiles and the efficacy of our product candidates in a larger number of patients who have the disease or condition under study. In phase 3, we conduct clinical trials to investigate the safety and efficacy of our product candidates in a large number of patients who have the disease or condition under study. The time and expense required for us to perform this clinical testing are substantial and may vary by product. For example, the phase 3 ongoing clinical trials for AMG 145 are large and require substantial time and resources to recruit patients and significant expense to execute. Foreign studies performed under an IND must meet the same requirements that apply to U.S. studies. The FDA will accept a foreign clinical study not conducted under an IND only if the study is well-designed, well-conducted, performed by qualified investigators and conforms to good clinical practice. Phase 1, 2 and 3 testing may not be completed successfully within any specified time period, if at all. (See Item 1A. Risk Factors — We may not be able to develop commercial products.) The FDA monitors the progress of each trial conducted under an IND and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based on the data accumulated to that point and the FDA's risk/benefit assessment with regard to the patients enrolled in the trial. See Item 1A. Risk Factors — We must conduct clinical trials in humans before we can commercialize and sell any of our product candidates or existing products for new indications.

Applications. The results of preclinical and clinical trials are submitted to the FDA in the form of a BLA for biologic products subject to the Public Health Service Act or an NDA for drugs subject to the approval provisions of the FDCA. Submission of the application is no guarantee that the FDA will find it complete and accept it for filing. If an application is accepted for filing, following the FDA's review, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. We cannot take any action to market any new drug or biologic product in the United States until our appropriate marketing application has been approved by the FDA.

Post-approval Phase. After we have obtained approval to market our products, we monitor adverse events from the use of our products and report such events to regulatory agencies, along with information from post marketing surveillance or studies. We may utilize other research approaches to learn or confirm information about our marketed products, including observational

studies and patient registries, and may engage in risk management activities such as physician education initiatives and patient advocacy group initiatives. We may also conduct or be required by regulatory agencies to conduct further clinical trials to provide additional information on our marketed products' safety and efficacy. Those additional trials may include studying doses or schedules of administration different from those used in previous studies, use in other patient populations or other stages of the disease or use over a longer period of time. Additional trials of this nature are sometimes required by regulatory agencies as a condition of their approval to market our products, and they might also request or require that we conduct specific studies, including observational epidemiological studies, in order to identify or assess possible safety risks of our marketed products that are observed or suggested by available scientific data and such trials are sometimes referred to as PMCs or PMRs. In the United States, if the FDA becomes aware of new safety information after approval of a product, it may require us to conduct further clinical trials to assess a known or potential serious risk. If we are required to conduct such a post-approval study, periodic status reports must be submitted to the FDA. Failure to conduct such post-approval studies in a timely manner may result in substantial civil or criminal penalties. Data resulting from these clinical trials may result in expansions or restrictions to the labeled indications for which our products have already been approved and to the reimbursement provided by government and commercial payers for our products.

The FDA also has the authority to require companies to implement a REMS for a product to ensure that the benefits of the drug outweigh the risks. The FDA may require the submission of a REMS before a product is approved or after approval based on new safety information, including new analyses of existing safety information. In determining whether a product will require a REMS before the product is approved, the FDA may consider a number of factors.

Each REMS is unique and varies depending on the specific factors required. While the elements of REMS may vary, all REMS require the sponsor to submit periodic assessment reports to the FDA to demonstrate that the goals of the REMS are being met. Failure to comply with a REMS, including submission of a required assessment or any modification to a REMS, may result in substantial civil or criminal penalties and can result in additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market. We currently have approved REMS for our ESAs, Prolia® and Nplate®. The FDA and sponsor companies continue to learn how best to implement, operate and monitor the effectiveness of REMS, and the requirements of our REMS and those of other companies may change over time. The FDA published guidance intended to limit or remove REMS requirements for certain products. The FDA will also be looking at ways to standardize REMS programs, with the intent to make the establishment, review and assessment of these programs less burdensome on the agency and the sponsor. The FDA will hold a series of public meetings on REMS over the next several years and will solicit stakeholder feedback in an effort to continue to focus and improve their risk management oversight.

Adverse events that are reported after marketing approval also can result in additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market. The FDA has authority to mandate labeling changes to products at any point in a product's lifecycle based on new safety information or as part of an evolving label change to a particular class of products.

The FDA also uses various advisory committees of external experts to assist in its mission to protect and promote the public health and to obtain independent expert advice on scientific, technical and policy matters. The committees are generally advisory only and FDA officials are not bound to or limited by their recommendations. We have participated in meetings of the Oncology Drug Advisory Committee, the Cardiovascular and Renal Drug Advisory Committee and the Advisory Committee for Reproductive Health Drugs, among others, to address certain issues related to our products, including Aranesp®, EPOGEN®, Prolia® and XGEVA®.

FDA Approval of Biosimilars. The PPACA authorizes the FDA to approve biosimilars via a separate, abbreviated pathway. The law establishes a period of 12 years of data exclusivity for reference products in order to preserve incentives for future innovation and outlines statutory criteria for science-based biosimilar approval standards that take into account patient safety considerations. Under this framework, data exclusivity protects the data in the innovator's regulatory application by prohibiting others, for a period of 12 years, from gaining FDA approval based in part on reliance on or reference to the innovator's data in their application to the FDA. The new law does not change the duration of patents granted on biologic products. In February 2012, the FDA released three draft guidance documents as part of the implementation of the abbreviated approval pathway for biosimilars. While the FDA guidance documents are not legally binding on the public or on the FDA, they indicate the FDA's current thinking on the development of biosimilars. The draft guidance documents provide insight on a range of technical, scientific and regulatory issues. The guidance documents generally provide that, for approval, a sponsor must demonstrate that the proposed product is "biosimilar" (a term defined by statute) to a single reference product already licensed by the FDA. In assessing biosimilarity, the FDA indicated that it intends to use a risk-based "totality of the evidence" approach to evaluate all available data submitted by the applicant. Generally, a biosimilar application must include a clinical study or studies sufficient to demonstrate safety, purity and potency in one or more indications for which the reference product is licensed and the biosimilar applicant seeks approval. The scope and magnitude of clinical data needed will depend on the extent of uncertainty about the biosimilarity of the product as well as the frequency and severity of safety risks associated with the reference product. The FDA indicated that it is still

evaluating a number of relevant issues, and additional guidance documents are expected to be released, including guidance on the criteria for interchangeability (which the FDA has indicated would be a “higher standard” than biosimilarity).

FDA Regulation of Product Marketing and Promotion. The FDA closely reviews and regulates the marketing and promotion of products. We are required to obtain the FDA approval before marketing or promoting a product as a treatment for a particular indication. Our product promotion for approved product indications must comply with the statutory standards of the FDCA, and the FDA’s implementing regulations and standards. The FDA’s review of marketing and promotional activities encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving the Internet. The FDA may also review industry-sponsored scientific and educational activities. The FDA may take enforcement action against a company for promoting unapproved uses of a product or for other violations of its advertising and labeling laws and regulations. Enforcement action may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with the FDA’s regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators.

FDA Regulation of Manufacturing Standards. The FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of products prior to providing approval to market products. If after receiving approval from the FDA, we make a material change in manufacturing equipment, location or process, additional regulatory review may be required. We also must adhere to current Good Manufacturing Practice regulations and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA also conducts regular, periodic visits to re-inspect our equipment, facilities, laboratories and processes following an initial approval. If, as a result of those inspections, the FDA determines that our equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal or administrative sanctions and/or remedies against us, including suspension of our manufacturing operations. Such issues may also delay the approval of new products undergoing FDA review.

Regulation of Combination Products. When our products are used with medical devices, they may be considered combination products, which are defined by the FDA to include products comprised of two or more regulated components or parts (e.g., a biologic and a device). When regulated independently, biologics and devices each have their own regulatory requirements. However, the regulatory requirements for a combination product comprised of a biologic administered with a delivery device are more complex, as in addition to the individual regulatory requirements for each component, additional combination product regulatory requirements may apply. We expect that in the future a number of our pipeline products may meet this definition and be evaluated for regulatory approval under this framework. In addition, due to regional differences in regulation structures and systems outside the United States, the definition and regulatory requirements for combination products may differ significantly depending on the region.

New Innovation Provisions Available to Regulatory Agencies Reviewing Drug Applications. In the United States, the FDA may grant accelerated approval status to products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments. Under accelerated approval regulations, the FDA may approve a product based on a surrogate endpoint that is reasonably likely to predict clinical benefit or based on an effect on a clinical endpoint other than survival or irreversible morbidity. The sponsor/marketing applicant will then be required to conduct additional, post-approval confirmatory trials to verify and describe clinical benefit, and the product may have certain post-marketing restrictions as necessary to assure safe use. The FDA is also given greater flexibility to withdraw approval granted under accelerated approval, if it is warranted. Additional legislation has been approved in 2012 that could further expand the FDA's authority. For example, the FDA may consider ways to more greatly use the accelerated approval pathway for rare or very rare diseases, and a new review designation was created to help foster the innovation of promising new therapies with the potential to shorten the timeframe for conducting pivotal trials and speed up patient access to the approved product.

In Europe, the preexisting conditional approval pathway provides for the European Medicines Agency (EMA) to apply greater flexibility in terms of their benefit/risk evaluation in order to promote innovation. While no plans to revise or add to this statutory provision have been announced, there are on-going discussions at the EMA to consider so-called “adaptive licensing”. It is not clear at this stage whether such proposals will result in meaningful changes to the EU regulatory approval pathway.

Approval and Post-Approval Regulation Outside the United States. In the EU countries, Switzerland, Canada and Australia, regulatory requirements and approval processes are similar in principle to those in the United States. Additionally, depending on the type of drug for which approval is sought, there are currently two potential tracks for marketing approval in the EU, including a centralized procedure. In the centralized procedure, which is required of all products derived from biotechnology, a company submits a single marketing authorization application to the EMA which conducts a thorough evaluation, drawing from its scientific resources across Europe. If the drug product is proven to fulfill the requirements for quality, safety and efficacy, the CHMP adopts a positive opinion, which is transmitted to the EC for final approval of the marketing authorization. While the EC generally follows the CHMP's opinion, it is not bound to do so. In the EU, biosimilars have been approved under a sub-pathway of the centralized procedure since 2006. The pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on the

clinical trial data of an originator product to which the biosimilar has been demonstrated to be "similar." In many cases, this allows biosimilars to be brought to market without conducting the full suite of clinical trials typically required of originators. After evaluation and marketing authorization, various parties, including the national competent authorities, the EMA, the EC and the marketing authorization holders share pharmacovigilance responsibilities regarding the detection, assessment and prevention of adverse effects and other medicine-related problems. Healthcare professionals and patients are also encouraged to report adverse effects and other medicine-related problems. This process includes the collection of adverse drug reaction reports as part of the follow-up on any side effects of a product, and upon assessment, the authorities can decide to demand that product labels be updated with safety data or warnings, that safety data or warnings be provided to healthcare professionals, or recommend the temporary suspension or complete withdrawal of a product from the market. In 2012, new pharmacovigilance legislation became effective in the EU that contains new and revised requirements for conducting pharmacovigilance, as well as codifying various existing requirements previously set out as guidance. The new legislation enhanced the authority of European regulators to require pharmaceutical companies to conduct post-authorization efficacy and safety studies, both at the time of approval and at any time afterwards in light of scientific developments. There are also additional requirements to include statements in product labeling with regard to adverse drug reaction reporting and additional monitoring of products. There also is expected to be significantly greater transparency of the safety review process as a result of the new legislation.

Other countries such as those in Latin America, Mexico, Brazil, Russia, Turkey and the Middle East have a less comprehensive review process in terms of data requirements and for the most part rely on prior marketing approval (as demonstrated by a certificate of pharmaceutical product) from a foreign regulatory authority in the United States or EU. The regulatory process in these countries is less well defined than in the United States and frequently includes manufacturing/testing facility inspections, testing of drug product on importation and other domestic requirements.

Other. We are also subject to various federal and state laws, as well as foreign laws, pertaining to healthcare "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for or to induce the referral of business, including the purchase or prescription of a particular drug that is reimbursed by a state or federal program. The federal government and the states have published regulations that identify "safe harbors" or exemptions for certain arrangements that do not violate the anti-kickback statute. We seek to comply with the safe harbors whenever possible. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit knowingly and willingly presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid) any claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Our activities related to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). On December 19, 2012, Amgen announced that it had finalized a settlement agreement with the U.S. government, 49 states and the District of Columbia regarding allegations that Amgen's promotional, contracting, sales and marketing activities and arrangements caused the submission of various false claims under the Federal Civil False Claims Act and various State False Claims Acts. In connection with entering into the settlement agreement, Amgen also entered into a corporate integrity agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services that requires Amgen to maintain its corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years. See Note 18, Contingencies and commitments, to the Consolidated Financial Statements for further information. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of those laws and the increasing attention being given to them by law enforcement authorities.

We are also subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other current and potential future federal, state or local laws, rules and/or regulations. Our R&D activities involve the controlled use of hazardous materials, chemicals, biological materials and various radioactive compounds. We believe our procedures comply with the standards prescribed by federal, state or local laws, rules and/or regulations; however, the risk of injury or accidental contamination cannot be completely eliminated. While we are not required to do so, we strive to conduct our research and manufacturing activities in a manner that meets the intents and purposes of the National Institutes of Health Guidelines for Recombinant DNA Research.

Additionally, the U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

Our present and future business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or regulations.

Research and Development and Selected Product Candidates

We focus our R&D on novel human therapeutics for the treatment of grievous illness in the areas of oncology, hematology, inflammation, bone health, nephrology, cardiovascular and general medicine, which includes neuroscience. We take a modality-independent approach to R&D with a focus on biologics. Our discovery research programs may therefore yield targets that lead to the development of human therapeutics delivered as large molecules, small molecules, or other combination or new modalities.

We have major R&D centers in several locations throughout the United States and in the United Kingdom, as well as smaller research centers and development facilities globally. See Item 2. Properties.

We conduct clinical trial activities using both our internal staff and third-party contract clinical trial service providers. To increase the number of patients available for enrollment in our clinical trials, we have opened clinical sites and will continue to open clinical sites and to enroll patients in a number of geographic locations. See Item 1A. Risk Factors — We must conduct clinical trials in humans before we can commercialize and sell any of our product candidates or existing products for new indications.

Some of our competitors are actively engaged in R&D in areas where we have products or where we are developing product candidates or new indications for existing products. For example, we compete with other clinical trials for eligible patients, which may limit the number of available patients who meet the criteria for certain clinical trials. The competitive marketplace for our product candidates is significantly dependent on the timing of entry into the market. Early entry may have important advantages in gaining product acceptance, thereby contributing to the product's eventual success and profitability. Accordingly, we expect that in some cases, the relative speed with which we can develop products, complete clinical testing, receive regulatory approval and supply commercial quantities of the product to the market will be important to our competitive position.

In addition to product candidates and marketed products generated from our internal R&D efforts, we acquire companies, acquire and license certain product and R&D technology rights and establish R&D arrangements with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. Those licenses and arrangements generally provide for non-refundable, upfront license fees, R&D and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing.

Various public and privately owned companies, research organizations, academic institutions and government agencies conduct a significant amount of R&D in the biotechnology industry. In pursuing R&D arrangements and licensing or acquisition activities, we face competition from other pharmaceutical and biotechnology companies that also seek to license or acquire technologies, product candidates or marketed products from those entities. Accordingly, we may have difficulty entering into R&D arrangements and licensing or acquiring technologies, product candidates and marketed products on acceptable terms.

See Government Regulation — Clinical Development for a discussion of government regulation over clinical development.

The following table is a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 11, 2013, unless otherwise indicated. Each disease or condition for our product candidates in phase 3 is listed separately. Additional product candidate (pipeline) information can be found on our website at http://www.amgen.com. (This website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.) The information in this section does not include other, non-registrational clinical trials, such as the Pegfilgrastim and Anti-VEGF Evaluation Study (PAVES) trial evaluating Neulasta® (pegfilgrastim) use in patients receiving chemotherapy and bevacizumab for the first-line treatment of locally-advanced or metastatic colorectal cancer, that we may conduct for purposes other than for submission to regulatory agencies for their approval of a new product indication. We may conduct non-registrational clinical trials for various reasons including to evaluate real-world outcomes or to collect additional safety information with the use of our products. See, for example, the discussion of our ESA pharmacovigilance trials under — Marketed Products — ESAs.

Molecule	Disease/Condition
Phase 3 Programs	
AMG 145	Hyperlipidemia
Aranesp® (darbepoetin alfa)	Myelodysplastic syndromes
Brodalumab (AMG 827)	Psoriasis
Prolia® (denosumab)	Glucocorticoid-induced osteoporosis
Prolia® (denosumab) - EU	Male osteoporosis
Rilotumumab	Gastric cancer
Romosozumab (AMG 785)	PMO
Sensipar®/Mimpara® (cinacalcet)	Post renal transplant
Talimogene laherparepvec	Melanoma
Trebananib (AMG 386)	Ovarian cancer
Vectibix® (panitumumab) - U.S.	First- and second-line colorectal cancer
XGEVA® (denosumab)	Delay or prevention of bone metastases in breast cancer
XGEVA® (denosumab) - EU	Delay or prevention of bone metastases in prostate cancer
XGEVA® (denosumab)	Cancer-related bone damage (SREs) in patients with multiple myeloma
Phase 2 Programs	
AMG 151	Type 2 diabetes
AMG 181	Inflammatory bowel disease
AMG 416	Secondary hyperparathyroidism in patients with CKD receiving dialysis
AMG 747	Schizophrenia
Blinatumomab (AMG 103)	Acute lymphoblastic leukemia (ALL)
Blinatumomab	Non-Hodgkin's Lymphoma (NHL)
Brodalumab	Inflammatory diseases
Omecamtiv mecarbil	Heart failure
Prolia® (denosumab)	RA
Trebananib	Various cancer types
Vectibix® (panitumumab)	Squamous cell head and neck cancer
XGEVA® (denosumab)	Giant cell tumor of the bone (GCTB)
XGEVA® (denosumab)	Hypercalcemia of malignancy
Phase 1 Programs	
AMG 110	Various cancer types
AMG 139	Inflammatory diseases
AMG 157	Asthma
AMG 167	Bone-related conditions
AMG 172	Various cancer types
AMG 208	Various cancer types
AMG 232	Various cancer types
AMG 319	Hematologic malignancies
AMG 334	Migraine
AMG 337	Various cancer types
AMG 357	Autoimmune diseases
AMG 557	Systemic lupus erythematosus
AMG 595	Glioblastoma
AMG 729	Autoimmune diseases
AMG 780	Various cancer types
AMG 811	Systemic lupus erythematosus
AMG 820	Various cancer types
AMG 876	Type 2 diabetes
AMG 900	Various cancer types

Phase 1	clinical trials investigate safety and proper dose ranges of a product candidate in a small number of human subjects.
Phase 2	clinical trials investigate side effect profiles and efficacy of a product candidate in a large number of patients who have the disease or condition under study.
Phase 3	clinical trials investigate the safety and efficacy of a product candidate in a large number of patients who have the disease or condition under study.

The following text provides additional information about selected product candidates that have advanced into human clinical trials.

AMG 145

AMG 145 is a human monoclonal antibody that inhibits Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9). It is being investigated as a treatment for hyperlipidemia.

Phase 2 study results evaluating AMG 145 were reported at a medical meeting in November 2012 in the following four areas: as monotherapy, in combination with statin therapy, in heterozygous familial hypercholesterolemia, and in statin-intolerant subjects. Based on the study results, phase 3 enrollment is underway in these populations.

Aranesp® (darbepoetin alfa)

Aranesp® is a recombinant human protein agonist of the erythropoietin receptor.

The phase 3 study of Aranesp® for the treatment of low risk myelodysplastic syndromes is ongoing.

Brodalumab

Brodalumab is a human monoclonal antibody that inhibits the interleukin-17 receptor. It is being investigated as a treatment for a variety of inflammatory diseases. Brodalumab is one of five inflammation monoclonal antibodies being jointly developed in collaboration with AstraZeneca.

In 2012, we initiated three phase 3 studies for the treatment of psoriasis. We completed our phase 2 study in psoriatic arthritis in 2012. Brodalumab is also being evaluated for the treatment of asthma.

Denosumab

Denosumab is a human monoclonal antibody that specifically targets a ligand known as RANKL (that binds to a receptor known as RANK) which is a key mediator of osteoclast formation, function, and survival. It is being investigated across a range of conditions including osteoporosis, treatment-induced bone loss, RA and numerous tumor types across the spectrum of cancer-related bone diseases, including hypercalcemia of malignancy.

Prolia® (denosumab)

In September 2012, Prolia® was approved by the FDA for the treatment to increase bone mass in men with osteoporosis at high risk for fracture in the US. A phase 3 study of Prolia® for the treatment of glucocorticoid-induced osteoporosis was initiated in 2012.

XGEVA® (denosumab)

In June 2012, we submitted a marketing application to the EMA for XGEVA® to treat men with castration-resistant prostate cancer at high risk of developing bone metastases.

In December 2012, we submitted marketing applications to the FDA and EMA for XGEVA® for the treatment of GCTB in adults or skeletally mature adolescents.

Phase 3 studies for the delay or prevention of bone metastases in patients with adjuvant breast cancer and prevention of SRE in patients with multiple myeloma are ongoing.

Rilotumumab

Rilotumumab is a human monoclonal antibody that inhibits the action of hepatocyte growth factor/scatter factor. It is being investigated as a cancer treatment.

In 2012, we initiated a phase 3 study for the treatment of gastric cancer.

Romosozumab

Romosozumab is a humanized monoclonal antibody that inhibits the action of sclerostin. Romosozumab is being developed in collaboration with UCB for PMO.

In 2012, we initiated two phase 3 studies for the treatment of PMO in women.

After reviewing the 52-week tibia data and recent regulatory guidance that deemed acceleration of fracture healing a non-viable endpoint for a phase 3 program, it was determined that we would not pursue this indication. This decision is based on the regulatory guidance and on the efficacy results from the acceleration of fracture healing endpoint in the tibia trial, not on safety. The safety profile remains consistent with what has been seen in the PMO program.

Sensipar®/Mimpara® (cinacalcet)

Sensipar®/Mimpara® is an orally-administered small molecule that lowers PTH levels in blood by increasing sensitivity of the calcium-sensing receptor (CaSR) to extracellular calcium. It is being evaluated in post renal transplant patients.

Talimogene laherparepvec

Talimogene laherparepvec is an oncolytic immunotherapy derived from HSV-1. It is being investigated as a cancer treatment.

The phase 3 study for the treatment of melanoma is ongoing.

Trebananib

Trebananib is a peptibody that inhibits the interaction between the endothelial cell-selective Tie2 receptor and its ligands Ang1 and Ang2. It is being investigated as a cancer treatment.

Phase 3 studies of trebananib for the treatment of first-line and recurrent ovarian cancer are ongoing. Phase 2 studies of trebananib for treatment of renal cell carcinoma, hepatocellular carcinoma and NSCLC are ongoing.

Vectibix® (panitumumab)

Vectibix® is a human monoclonal antibody antagonist of the EGFr pathway. It is being investigated as a cancer treatment.

In July 2011, we announced that we received Complete Response Letters from the FDA on the first- and second-line line mCRC sBLAs requesting additional information from the '181 and '203 studies. We are currently working on addressing the FDA's requests in the Complete Response Letters.

AMG 151

AMG 151 is a small molecule glucokinase activator. It is being investigated as a treatment for type 2 diabetes. We completed our phase 2 study in 2012.

AMG 181

AMG 181 is a human monoclonal antibody that inhibits the action of alpha4/beta7. It is being investigated as a treatment for ulcerative colitis and Crohn's disease, with phase 2 studies initiated in 2012. AMG 181 is one of five inflammation monoclonal antibodies being jointly developed in collaboration with AstraZeneca.

AMG 416

AMG 416 is a peptide agonist of the human cell surface CaSR. It is being investigated as a treatment for secondary hyperparathyroidism in patients with CKD receiving dialysis.

We completed two phase 2 studies in 2012. Phase 3 initiation is planned in 2013.

AMG 747

AMG 747 is a small molecule inhibitor of glycine transporter type-1 (GlyT-1). It is being investigated as a treatment for negative symptoms and cognitive deficits associated with schizophrenia, with two phase 2 studies initiated in 2012.

Blinatumomab

Blinatumomab is an anti-CD19 x anti-CD3 (BiTE®) bispecific antibody. It is being investigated as a cancer treatment.

In December 2012, we reported the results from a phase 2 adult ALL relapsed refractory study at a medical meeting. Phase 2 studies in adult patients with relapsed/refractory and minimal residual disease of ALL and a phase 2 study in adult patients with NHL are ongoing.

Omecamtiv mecarbil

Omecamtiv mecarbil is a small molecule activator of cardiac myosin. It is being investigated for the treatment of heart failure. We are developing this product in collaboration with Cytokinetics, Inc.

A phase 2 study of an intravenous formulation of omecamtiv mecarbil in patients with left ventricular systolic dysfunction, who are hospitalized with acute heart failure, is ongoing.

Amgen Development of Biosimilars

As previously announced, we are collaborating with Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.) to develop and commercialize, on a worldwide basis, several oncology antibody biosimilar medicines. The products our collaboration is pursuing include biosimilar versions of bevacizumab (sold by Genentech/Roche under the brand name Avastin®), trastuzumab (sold by Genentech/Roche under the brand names Herceptin®/Herclon®), rituximab (sold by Roche under the brand names Rituxan®/Mabthera®) and cetuximab (sold by Eli Lilly/BMS under the brand name Erbitux®).

We are also working to develop biosimilar versions of adalimumab (sold by AbbVie under the brand name HUMIRA®) and infliximab (sold by Janssen/Merck under the brand name REMICADE®).

Our biosimilar product candidates are in varying stages of regulatory development. We expect that any revenue contribution from these biosimilar programs, if successful, would not occur for a number of years.

Phase 3 Product Candidate Program Changes

As of February 10, 2012, we had 12 phase 3 programs. As of February 11, 2013, we had 14 phase 3 programs, as six programs had advanced into phase 3 trials, three programs had concluded and all rights to one program were out-licensed. These changes are set forth in the following table:

Molecule	Disease / Condition	Program Change
AMG 145	Hyperlipidemia	Advanced to phase 3
Aranesp®	Anemia in heart failure	Concluded - failed to meet primary endpoint(s)
Brodalumab (AMG 827)	Psoriasis	Advanced to phase 3
Ganitumab	Pancreatic cancer	Concluded - failed to meet primary endpoint(s)
Prolia® (denosumab)	Glucocorticoid-induced osteoporosis	Advanced to phase 3
Sensipar®/Mimpara® (cinacalcet)	Cardiovascular disease in patients with secondary hyperparathyroidism and CKD undergoing maintenance dialysis	Concluded - failed to meet primary endpoint(s)
Rilotumumab	Gastric cancer	Advanced to phase 3
Romosozumab (AMG 785)	PMO	Advanced to phase 3
Motesanib	First-line NSCLC	Licensed all rights to this program to Takeda[(1)]
XGEVA® (denosumab)	Cancer-related bone damage (SREs) in patients with multiple myeloma	Advanced to phase 3

(1) See Business Relationships.

Phase 3 Product Candidate Patent Information

The following table describes our outstanding composition of matter patents that have issued thus far for our product candidates in phase 3 development that have yet to be approved for any indication. Patents for products already approved for one or more indications but currently undergoing phase 3 clinical trials for additional indications are previously described. See Marketed Products.

Molecule	Territory	General Subject Matter	Estimated Expiration*
AMG 145	U.S.	Polypeptides	2029
Brodalumab (AMG 827)	U.S.	Polynucleotides and polypeptides	2027
Romosozumab (AMG 785)	U.S.	Polypeptides	2026
Talimogene laherparepvec	U.S.	Modified HSV1 compounds and strains	2021
	Europe	Modified HSV1 compounds and strains	2021
Trebananib (AMG 386)	U.S.	Polynucleotides and polypeptides	2025
	Europe	Polynucleotides and polypeptides	2022

* Patent expiration estimates are based on issued patents which may be challenged, invalidated, or circumvented by competitors. The patent expiration estimates do not include any term adjustments, extensions or supplemental protection certificates that may be obtained in the future and extend these dates. Corresponding patent applications are pending in other jurisdictions. Additional patents may be filed or issued in the future and may provide additional exclusivity for the product candidate or its use.

Business Relationships

From time to time, we enter into business relationships, including joint ventures and collaborative arrangements, for the R&D, manufacture and/or commercialization of products and/or product candidates. In addition, we also acquire product and R&D technology rights and establish R&D collaborations with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. These arrangements generally provide for non-refundable, upfront license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. The activities under these collaboration agreements are performed with no guarantee of either technological or commercial success, and each is unique in nature.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require counterparties to execute confidentiality agreements upon the commencement of the business relationship with us. However, others could either develop independently the same or similar information or obtain access to our information.

Kirin-Amgen, Inc.

K-A is a 50-50 joint venture with Kirin. K-A develops and then out licenses to third parties certain product rights which have been transferred to this joint venture from Amgen and Kirin.

K-A has given us exclusive licenses to manufacture and market: (i) G-CSF and pegfilgrastim in the United States, Europe, Canada and Australia, (ii) darbepoetin alfa, romiplostim and brodalumab in the United States, Europe, Canada, Australia, New Zealand, Mexico, all Central and South American countries and certain countries in Central Asia, Africa and the Middle East, and (iii) recombinant human erythropoietin in the United States. We currently market pegfilgrastim, G-CSF, darbepoetin alfa, recombinant human erythropoietin and romiplostim under the brand names Neulasta®, NEUPOGEN®/GRANULOKINE®, Aranesp®, EPOGEN® and Nplate®, respectively. Under these agreements, we pay K-A royalties based on product sales. In addition, we also receive payments from K-A for milestones earned and for conducting certain R&D activities on its behalf. See Note 7, Related party transactions, to the Consolidated Financial Statements.

K-A has also given Kirin exclusive licenses to manufacture and market: (i) G-CSF and pegfilgrastim in Japan, Taiwan and South Korea, (ii) darbepoetin alfa, romiplostim and brodalumab in Japan, China, Taiwan, South Korea and in certain other countries and/or regions in Asia and (iii) recombinant human erythropoietin in Japan. K-A also gave Kirin and Amgen co-exclusive licenses to manufacture and market G-CSF, pegfilgrastim and recombinant human erythropoietin in China, which Amgen subsequently assigned to Kirin, and as a result, Kirin now exclusively manufactures and markets G-CSF and recombinant human erythropoietin in China. Kirin markets G-CSF, pegfilgrastim, darbepoetin alfa, romiplostim and recombinant human erythropoietin under the

brand names GRAN®/Grasin®, Neulasta®, NESP®, ROMIPLATE® and ESPO®, respectively. Under these agreements, Kirin pays K-A royalties based on product sales. In addition, Kirin also receives payments from K-A for conducting certain R&D activities on its behalf.

K-A has also given J&J exclusive licenses to manufacture and market recombinant human erythropoietin for all geographic areas of the world outside the United States, China and Japan. K-A has also given Roche exclusive licenses to market pegfilgrastim and G-CSF in all territories not licensed to Amgen and Kirin. Under these agreements, J&J and Roche pay royalties to K-A based on product sales.

Pfizer Inc.

We are in a collaboration with Pfizer to co-promote ENBREL in the United States and Canada. The rights to market ENBREL outside the United States and Canada are reserved to Pfizer. Under the agreement, a management committee comprised of equal representation from Amgen and Pfizer is responsible for overseeing the marketing and sales of ENBREL, including strategic planning, the approval of an annual marketing plan, product pricing and the establishment of a brand team. Amgen and Pfizer share in the agreed-upon selling and marketing expenses approved by the joint management committee. We currently pay Pfizer a percentage of annual gross profits on our ENBREL sales in the United States and Canada attributable to all approved indications on a scale that increases as gross profits increase; however, we maintain a majority share of ENBREL profits. After expiration of the co-promotion term on October 31, 2013, we will be required to pay Pfizer residual royalties based on a declining percentage of annual net ENBREL sales in the United States and Canada for three years, ranging from 12% to 10%. The amounts of such payments are anticipated to be significantly less than what would be owed based on the terms of the current ENBREL profit share. Effective November 1, 2016, there will be no further royalty payments.

Glaxo Group Limited

We are in a collaboration with Glaxo for the commercialization of denosumab for osteoporosis indications in Europe, Australia, New Zealand and Mexico (the Primary Territories). We have retained the rights to commercialize denosumab for all indications in the United States and Canada and for oncology indications in the Primary Territories. Under a related agreement, Glaxo will commercialize denosumab for all indications in countries, excluding Japan, where we did not have a commercial presence at the commencement of the agreement, including China, Brazil, India, Taiwan and South Korea (the Expansion Territories). In the Expansion Territories, Glaxo is responsible for all development and commercialization costs and will purchase denosumab from us to meet demand. We have the option of expanding our role in the commercialization of denosumab in the Primary Territories and certain of the Expansion Territories. In the Primary Territories, we share equally in the commercialization profits and losses related to the collaboration after accounting for expenses, including an amount payable to us in recognition of our discovery and development of denosumab. Glaxo is also responsible for bearing a portion of the cost of certain specified development activities in the Primary Territories.

Takeda Pharmaceutical Company Limited

In 2008, we entered into an arrangement with Takeda, that provided Takeda both: (i) the exclusive rights to develop and commercialize for the Japanese market up to 12 molecules from our portfolio across a range of therapeutic areas, including oncology and inflammation (collectively the “Japanese market products”) and (ii) the right to collaborate with us on the worldwide (outside Japan) development and commercialization of our product candidate, motesanib. The Japanese market products include Vectibix® and certain product candidates.

In 2011, we announced that the motesanib pivotal phase 3 trial (MONET1) did not meet its primary objective of demonstrating an improvement in overall survival.

In June 2012, the parties materially modified this arrangement such that Amgen licensed all of its rights to motesanib to Takeda which now has control over the worldwide development and commercialization of motesanib.

AstraZeneca Plc.

We are in a collaboration with AstraZeneca to jointly develop and commercialize certain monoclonal antibodies from Amgen's clinical inflammation portfolio, including brodalumab, AMG 139, AMG 157, AMG 181 and AMG 557. The agreement covers the worldwide development and commercialization, except for certain Asian countries for brodalumab and Japan for AMG 557, that are licensed to other third parties.

Under the terms of the agreement, approximately 65% of related development costs for the 2012-2014 periods will be funded by AstraZeneca; thereafter, the companies will share costs equally. If approved for sale, Amgen would receive a low-single-digit royalty rate for brodalumab and a mid-single-digit royalty rate for the rest of the portfolio, after which the worldwide commercialization profits and losses related to the collaboration products would be shared equally.

UCB

We are in a collaboration with UCB for the development and commercialization of romosozumab. We have the rights to commercialize romosozumab for all indications in the United States, Canada, Mexico and Japan. UCB has the rights for all EU members at the time of first regulatory approval, Australia and New Zealand. Prior to commercialization, countries that have not been initially designated will be designated to Amgen or UCB in accordance with the terms of the agreement.

Generally, development costs are shared equally and we will share equally in the worldwide commercialization profits and losses related to the collaboration after accounting for expenses.

DaVita Inc.

We are in a seven-year supply agreement with DaVita that commenced January 1, 2012. Pursuant to this agreement, we will supply EPOGEN® in amounts necessary to meet no less than 90% of DaVita's and its affiliates' requirements for ESAs used in providing dialysis services in the United States and Puerto Rico. The agreement may be terminated by either party before expiration of its term in the event of certain breaches of the agreement by the other party.

Human Resources

As of December 31, 2012, Amgen had approximately 18,000 staff members. We consider our staff relations to be good.

Executive Officers of the Registrant

The executive officers of the Company as of February 13, 2013, are as follows:

Mr. Robert A. Bradway, age 50, has served as a director of the Company since October 2011 and Chairman of the Board of Directors since January 1, 2013. Mr. Bradway has been the Company's President since May 2010 and Chief Executive Officer since May 2012. From May 2010 to May 2012, Mr. Bradway served as the Company's President and Chief Operating Officer. Mr. Bradway joined the Company in 2006 as Vice President, Operations Strategy, and served as Executive Vice President and Chief Financial Officer from April 2007 to May 2010. Prior to joining the Company, he was a Managing Director at Morgan Stanley in London where he had responsibility for the firm's banking department and corporate finance activities in Europe and focused on healthcare.

Mr. Madhavan (Madhu) Balachandran, age 62, became Executive Vice President, Operations in August 2012. Mr. Balachandran joined the Company in 1997 and has held leadership positions in engineering, information systems and operations. From October 2007 to August 2012, Mr. Balachandran was Senior Vice President, Manufacturing. From February 2007 to October 2007, Mr. Balachandran was Vice President, Site Operations. From May 2002 to February 2007, Mr. Balachandran was Vice President, Puerto Rico Operations. Prior to 2002, Mr. Balachandran served as Associate Director, Capital Projects, before his promotion to Director, Engineering, and then to Vice President, Information Management.

Dr. Sean E. Harper, age 50, became Executive Vice President, Research and Development in February 2012. Dr. Harper joined the Company in 2002 and has held leadership roles in early development, medical sciences and global regulatory and safety. Dr. Harper served as Senior Vice President, Global Development and Corporate Chief Medical Officer from March 2007 to February 2012. Prior to joining the Company, Dr. Harper worked for five years at Merck Research Laboratories.

Mr. Anthony C. Hooper, age 58, became Executive Vice President, Global Commercial Operations, in October 2011. From March 2010 to October 2011, Mr. Hooper was Senior Vice President, Commercial Operations and President, U.S., Japan and Intercontinental of BMS, a pharmaceutical company. From January 2009 to March 2010, Mr. Hooper was President, Americas of BMS. From January 2004 to January 2009, Mr. Hooper was President, U.S. Pharmaceuticals, Worldwide Pharmaceuticals Group, a division of BMS. Prior to that, Mr. Hooper held various senior leadership positions at BMS. In his roles at BMS, Mr. Hooper led commercial operations in mature and emerging markets. Prior to joining BMS, Mr. Hooper was Assistant Vice President of Global Marketing for Wyeth Laboratories.

Mr. Brian McNamee, age 56, became Senior Vice President, Human Resources in June 2001. From November 1999 to June 2001, Mr. McNamee served as Vice President of Human Resources at Dell Computer Corp. From 1998 to 1999, Mr. McNamee served as Senior Vice President, Human Resources for the National Broadcasting Corporation, a division of GE. From July 1988

to November 1999, Mr. McNamee held human resources positions at GE.

Ms. Cynthia M. Patton, age 51, became Senior Vice President and Chief Compliance Officer in October 2012. Ms. Patton joined the Company in 2005. From September 2010 to October 2012, Ms. Patton was Vice President, Law. From July 2005 to September 2010, Ms. Patton was Associate General Counsel. Previously, Ms. Patton served as Senior Vice President, General Counsel and Secretary of SCAN Health Plan from 1999 to 2005.

Mr. Jonathan M. Peacock, age 54, became Executive Vice President and Chief Financial Officer in September 2010. Prior to joining Amgen and beginning in 2005, Mr. Peacock served as Chief Financial and Administration Officer of Novartis Pharmaceuticals AG, a healthcare company based in Switzerland. From 1998 to 2005, Mr. Peacock was a partner at McKinsey and Co., where he co-led the firm's European Corporate Finance Practice. Mr. Peacock was also a partner at Price Waterhouse in London and New York from 1993 to 1998.

Mr. David J. Scott, age 60, became Senior Vice President, General Counsel and Secretary in March 2004. From May 1999 to February 2004, Mr. Scott served as Senior Vice President and General Counsel of Medtronic, Inc., and also as Secretary from January 2000. From December 1997 to April 1999, Mr. Scott served as General Counsel of London-based United Distillers & Vintners. Mr. Scott also served in executive roles at Grand Metropolitan plc and RJR Nabisco, Inc., and was an attorney in private practice.

Geographic Area Financial Information

For financial information concerning the geographic areas in which we operate, see Note 19, Segment information — Geographic information, to the Consolidated Financial Statements.

Investor Information

Financial and other information about us is available on our website (http://www.amgen.com) (This website address is not intended to function as a hyperlink, and the information contained in our website is not intended to be a part of this filing). We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and 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 filing or submitting such material electronically or otherwise furnishing it to the SEC. In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected, without charge, at the SEC’s public reference room at 100 F Street NE, Washington, DC 20549, or at the SEC’s internet address at http://www.sec.gov. (This website address is not intended to function as a hyperlink, and the information contained in the SEC’s website is not intended to be a part of this filing). Information related to the operation of the SEC’s public reference room may be obtained by calling the SEC at 800-SEC-0330 (800-732-0330).

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business or others on our behalf, our beliefs and our management's assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties facing our business. The risks described below are not the only ones facing us. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Our sales depend on coverage and reimbursement from third-party payers.

Sales of all of our principal products are dependent on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers may regulate prices, reimbursement levels and/or access to our products to control costs or to affect levels of use. We rely in large part on the reimbursement of our principal products through government programs such as Medicare and Medicaid in the United States and similar programs in foreign countries, and a reduction in the coverage and/or reimbursement for our products could have a material adverse effect on our product sales, business and results of operations.

In the United States, there is an increased focus by the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs. For example, the Budget Control Act of 2011 mandated a two percent reduction in government payments for all Medicare services (including the administration of separately-billable drugs and payment for drugs in all Medicare programs) for federal fiscal years 2013 through 2021. This payment “sequestration” is currently scheduled to begin in 2013 and continue through 2021. The sequestration remains subject to administrative implementation of the Budget Control Act or future statutory revision by Congress, who could block, limit or otherwise modify the automatic spending cuts. Several alternative deficit reduction proposals have been put forth by President Obama and/or Congressional committees, including proposals designed to further limit federal healthcare expenditures. While we cannot predict whether any deficit reduction actions will be approved by Congress and/or whether a budget sequestration will ultimately occur for Medicare services, a reduction in the availability or extent of reimbursement for drugs and biologics for U.S. healthcare programs as a result of changes such as those that have been proposed or from other changes designed to achieve similar federal budget savings could have a material adverse effect on the sales of our products, our business and results of operations.

In March 2010 the United States adopted significant healthcare reform through the enactment of the PPACA and the Healthcare and Education Reconciliation Act (See Item 1. Business — Reimbursement — U.S. Healthcare Reform.) A major goal of the healthcare reform law is to provide greater access to healthcare coverage for more Americans. Accordingly, the healthcare reform law requires individual U.S. citizens and legal residents to maintain qualifying health coverage, imposes certain requirements on employers with respect to offering health coverage to employees, amends insurance regulations regarding when coverage can be provided and denied to individuals, and expands existing government healthcare coverage programs to more individuals in more situations, with most of these changes going into effect by January 2014. We do not expect a significant increase in sales of our products as a result of the 2014 expansions in healthcare coverage. While we cannot fully predict the ultimate impact the healthcare reform law will have on us, or how the law may change due to statutory revision or judicial review, we expect that the new law will continue to have a material adverse effect on our business and results of operations.

Public and private insurers have pursued, and continue to pursue, aggressive cost containment initiatives, including increased focus on comparing the effectiveness, benefits and costs of similar treatments, which could result in lower reimbursement rates for our products. A substantial portion of our U.S. business relies on reimbursement from the U.S. federal government under Medicare Part B coverage. Any deterioration in the timeliness or certainty of payment by Medicare to physicians, including as a result of changes in policy or regulations, or as a result of operational difficulties, could negatively impact the willingness of physicians to prescribe our products for patients relying on Medicare for their medical coverage. Most of our products furnished to Medicare beneficiaries in both a physician office setting and hospital outpatient setting are reimbursed under the Medicare Part B ASP payment methodology. (See Item1. Business — Reimbursement — Reimbursement of Our Principal Products.) ASP- based reimbursements of products under Medicare may be below or could fall below the cost that some medical providers pay for such products, which could materially and adversely affect sales of our products. Private payers also continue to seek to reduce their costs. Insurance plans administered by private companies frequently adopt their own payment or reimbursement reductions. Consolidation among managed care organizations may increase the negotiating power of these entities, potentially resulting in lower reimbursement rates for our products. Private third-party payers increasingly employ formularies to control costs by

negotiating discounted prices in exchange for formulary inclusion and/or favorable formulary positioning. Private health insurance companies also are increasingly adopting utilization management tools, such as prior authorization in order to limit payment to uses of the product that are in accordance with the FDA approved labeling or step therapy to ensure that payment for a branded product is only made if the patient has first failed a cheaper generic product. Consistent with recent healthcare reforms, we anticipate that future trends will include greater reliance upon comparative effectiveness to make formulary decisions. Additionally, private payers are experimenting with new models of payment whereby reimbursement for health care providers may be linked to bundled or capitated payments. Under these payment systems, providers would get a fixed payment amount to cover a broad range of products and services provided to each patient and would be significantly incentivized to utilize the lowest cost product or service, regardless of its overall benefit to the patient, or to minimize the provision of services. To the extent that such changes affect the price we receive for our products or the level of coverage and reimbursement available when healthcare providers prescribe our products, they could have a material adverse effect on the sales of our products, our business and results of operations.

We also face risks relating to the reporting of pricing data that affects the U.S. reimbursement of and discounts for our products. ASP data are calculated by the manufacturer based on a formula defined by statute and regulation and are then submitted to CMS. CMS uses those ASP data to determine the applicable reimbursement rates for our products under Medicare Part B. However, the statute, regulations and CMS guidance do not define specific methodologies for all aspects of the reporting of ASP data. For example, CMS has not provided specific guidance regarding the treatment of “bundled sale arrangements” or administrative fees paid to Group Purchasing Organizations in the ASP calculation. CMS directs that manufacturers make “reasonable assumptions” in their calculation of ASP data in the absence of specific CMS guidance on a topic, and requires that any such reasonable assumptions be consistent with the general requirements and the intent of the Medicare statute, federal regulations and the manufacturer's customary business practices. As a result, we are required to apply our reasonable judgment to certain aspects of calculating ASP data. We also submit AMP and BP data to the government on a periodic basis. The formulas for those price figures also are defined by statute and regulation and CMS similarly has directed manufacturers to make reasonable assumptions in the absence of specific guidance on a topic relating to the calculation of those pricing figures. We are also required to pay rebates to state Medicaid programs, when our products are paid for by Medicaid, at a rate of 23.1% of the product's AMP, or if it is greater, the difference between the product's AMP and the BP, subject to various adjustments. The AMP and BP regulations require a manufacturer to update previously submitted data for a period not to exceed three years. Our ASP, AMP, and BP data calculations are reviewed on at least a quarterly basis, and based on such reviews we have on occasion restated previously reported ASP, AMP, and BP data to reflect changes in calculation methodology, reasonable assumptions, and/or underlying data. If our submitted ASP, AMP, or BP data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse impact on our business and results of operations. In addition, if our calculations of AMP and/or BP are incorrect, we also may be required to make additional rebate payments to state Medicaid programs. In addition, the PPACA revised the definition of AMP, effective with submissions for the fourth quarter 2010, and in February 2012 CMS issued a proposed rule further clarifying the new AMP definition and other aspects of the AMP and BP calculations, and subsequently accepted public comments on the proposed rule. Until that rule is final, which is expected to occur later in 2013, we will be required to apply our reasonable judgment in certain aspects of the AMP and BP calculations. A significant change in the final rule regarding the AMP definition or the AMP and BP calculations could require us to pay higher rebates to state Medicaid programs in the future, which could have a material adverse impact on our business and results of operations.

Other initiatives reviewing the coverage or reimbursement of our products could result in less extensive coverage or lower reimbursement rates. For example, in July 2007, CMS issued an NCD where it determined that ESA treatment was not reasonable and necessary for certain clinical conditions and established Medicare coverage parameters for the FDA-approved ESA use in oncology. Generally, an NCD is a national policy statement granting, limiting or excluding Medicare coverage or reimbursement for a specific medical item or service. We believe the restrictions in the 2007 NCD changed the way ESAs are used in clinical practice, for example, by decreasing the number of treated patients, the average ESA dose and the duration of ESA therapy in the oncology setting. As a result, we believe these restrictions have had a material adverse effect on the use, reimbursement and sales of Aranesp®, which in turn had a material adverse effect on our business and results of operations. The reimbursement of ESAs in the nephrology setting has also been reviewed by CMS. On June 16, 2010, CMS opened an NCA to examine the use of ESAs to manage anemia in patients with CKD and dialysis-related anemia. Following further analysis, on June 16, 2011, CMS issued a FDM in which it determined that it would not issue an NCD at that time for ESAs for treatment of anemia in adults with CKD. In the absence of an NCD, Medicare determinations are made by regional MACs, three of which have issued revised LCDs relating to anemia in patients with CKD not on dialysis. All of the revised LCDs restrict reimbursement of ESAs to use in accordance with the revised FDA label. Other MACs could also issue LCDs that similarly or further restrict reimbursement for ESAs in this setting, and physician behavior may change to be consistent with the revised label even before formal LCDs are implemented, all of which could have a further material adverse effect on the reimbursement, use and sales of Aranesp®. Additionally, CMS could still further review or change the reimbursement of ESAs in the nephrology setting at some point in the future and/or propose an NCD for ESAs or other drug topics that could result in less extensive coverage for our products. For example, CMS periodically identifies topics for potential future NCDs, and while there were no drug products included on the 2012 CMS topic list, in prior years that

list has included the category of thrombopoiesis stimulating agents (platelet growth factors), the category of drugs that includes Nplate®.

In the dialysis setting, the reimbursement rates for our products are also subject to downward pressure. In the United States, dialysis providers are reimbursed for EPOGEN® primarily by the federal government through Medicare's ESRD Program. (See Item 1. Business — Reimbursement — Reimbursement of Our Principal Products — Dialysis Reimbursement.) Until January 1, 2011, Medicare reimbursed for separately billable dialysis drugs (including Aranesp® and EPOGEN®) administered in both freestanding and hospital-based dialysis centers at ASP +6%, using the same ASP payment amount methodology used in the physician clinic setting under Part B. On January 1, 2011, CMS's bundled-payment system went into effect for dialysis providers which provides a single payment for all dialysis services including drugs, supplies, and non-routine laboratory tests that were previously reimbursed separately. On November 1, 2011, following our June 2011 announcement of changes to the labels for the use of ESAs in patients with CKD (See Item 1. Business — Marketed Products — ESAs), CMS finalized a rule to update various provisions of its bundled-payment system for dialysis services and the related ESRD QIP. The final rule eliminated for payment year 2013 and beyond one of the QIP's measures which tracks the percent of a provider's Medicare patients with an Hb level below 10 g/dL. (See Item 1. Business — Reimbursement - Reimbursement of Our Principal Products — Dialysis Reimbursement.) CMS indicated that removal of this quality measure from the QIP was being done in response to the June 2011 ESA label changes. We believe that the implementation of these various changes in the dialysis setting has resulted and may continue to result in a material adverse impact on the reimbursement, use and sales of EPOGEN® and on our business and results of operations. Under the ATRA enacted in January 2013, CMS was directed to reduce the ESRD payment bundle amount effective January 1, 2014 to account for changes in the utilization of drugs and biologics (including Aranesp® and EPOGEN®) since the bundle was first implemented in 2011. Oral drugs without intravenous equivalents, such as Sensipar® and phosphate binders, will continue to be reimbursed separately under the Medicare Part D benefit until they are included in the bundled-payment system in 2016. However, efforts are underway to get Congress to repeal the provision of the ATRA that postponed the entry of these oral-only drugs into the bundled-payment system; if such efforts are successful, these oral drugs could enter into the bundled-payment system before 2016. Inclusion in the bundled-payment system may reduce utilization of these oral drugs and have an adverse impact on our sales.

The government-sponsored healthcare systems in Europe and many other foreign countries are the primary payers for healthcare expenditures, including payment for drugs and biologics, in those regions. Mandatory price controls continue to be a significant aspect of business for the pharmaceutical and biotechnology industries outside the United States. Healthcare reform and related legislative proposals in France, Germany and Poland, as well as austerity plans in a number of countries, including Spain, Italy, Greece, Ireland and Portugal, have targeted the pharmaceutical sector with multiple mechanisms to reduce government healthcare expenditures. We expect that countries will continue to take aggressive actions to reduce expenditures on drugs and biologics, including mandatory price reductions, clawbacks of payments made to companies when drug spending thresholds are exceeded, preferences for biosimilars, changes in international price referencing, price transparency to achieve prices similar to those in lower-priced countries, and reductions in the amount of reimbursement, sometimes with the imposition of patient copayments. Similarly, fiscal constraints may also impact the extent to which countries are willing to reward new innovative therapies and/or allow access to new technologies or the speed with which they make approval or reimbursement decisions. The proliferation of HTA organizations (e.g., NICE in the UK and IQWiG in Germany) has led to determinations of coverage and reimbursement based on both the clinical as well as the economic value of a product; these agencies are also increasingly setting the maximum price at which products will be reimbursed. While we cannot fully predict the extent of further price reductions and/or reimbursement restrictions taken by governmental payers outside the United States or the impact such actions will have on our business, such reductions in price and/or the coverage and reimbursement for our products could have a material adverse effect on the sales of our products, our business and results of operations.

Additional initiatives addressing the coverage or reimbursement of our products could result in less extensive coverage or lower reimbursement, which could negatively affect sales of our products. If, for any of these or other reasons, reimbursement rates are reduced, or if healthcare providers anticipate reimbursement being reduced, providers may narrow the circumstances in which they prescribe or administer our products, which could reduce the use and/or sales of our products. A reduction in the use and sales of our products could have a material adverse effect on our business and results of operations.

Our current products and products in development cannot be sold if we do not maintain or gain regulatory approval.

Our business is subject to extensive regulation by numerous state and federal governmental authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in foreign countries to obtain approval from regulatory authorities before we can manufacture, market and sell our products. Once approved, the FDA and other U.S. and foreign regulatory agencies have substantial authority to require additional testing, perform inspections, change product labeling or mandate withdrawals of our products. Also, legislative bodies or regulatory agencies could enact new laws or regulations or change existing laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products. For example, the 2007 creation of the Food and Drug Administration Amendments Act of 2007 (FDAAA)

significantly added to the FDA's authority, allowing the FDA to (i) require sponsors of marketed products to conduct post-approval clinical studies; (ii) mandate labeling changes to products and (iii) require sponsors to implement a REMS for a product. Failure to comply with FDAAA requirements could result in significant civil monetary penalties, reputational harm and increased product liability risk. In 2012, new pharmacovigilance legislation became effective in the EU that enhanced the authority of European regulatory authorities to require companies to conduct additional post-approval clinical efficacy and safety studies and increased the burden on sponsor companies in terms of adverse event management and reporting and safety data analyses. As with FDAAA, failure to comply with the new EU pharmacovigilance legislation could result in significant monetary penalties as well as reputational and other harms. We are unable to predict when and whether any further changes to laws or regulatory policies affecting our business could occur, such as efforts to reform medical device regulation or the pedigree requirements for medical products or implement new requirements for combination products, and whether such changes could have a material adverse effect on our business and results of operations.

Obtaining and maintaining regulatory approval has been and will continue to be increasingly difficult, time-consuming and costly. For example, in October 2009 we received Complete Response Letters from the FDA for the BLA for Prolia® in the treatment and prevention of PMO and in the treatment and prevention of bone loss due to hormone ablation therapy (HALT) in breast and prostate cancer patients. The Complete Response Letter related to the PMO indication requested several items, including further information on the design of our previously submitted post-marketing surveillance program. The FDA also requested a new clinical program to support the approval of Prolia® for the prevention of PMO, updated safety data and stated that a REMS is necessary for Prolia®. The Complete Response Letter related to the HALT indication requested additional information regarding the safety of Prolia® in patients with breast cancer receiving aromatase inhibitor therapy and patients with prostate cancer receiving Androgen Deprivation Therapy. The FDA specifically requested results from additional adequate and well-controlled clinical trials demonstrating that Prolia® has no detrimental effects on either time to disease progression or overall survival. Following the submission of further information, including clinical trial data from a number of trials evaluating denosumab in various oncology indications, in September 2011 the FDA approved Prolia® as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer and as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. In addition, there may be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to comparative products can be shown.

In addition to our innovative products, we are working to develop and commercialize biosimilar versions of six products currently manufactured, marketed and sold by other pharmaceutical companies. (See Item 1. Research and Development and Selected Product Candidates — Amgen Development of Biosimilars.) In many markets there is not yet a legislative or regulatory pathway for the approval of biosimilars. In the United States, the U.S. healthcare reform law provided for such a pathway; while the FDA is working to establish regulations to implement it, significant questions remain as to how products will be approved under the pathway. (See We expect to face increasing competition from biosimilars.) Delays or uncertainties in the development of such pathways could result in delays or difficulties in getting our products approved by regulatory authorities, subject us to unanticipated development costs or otherwise reduce the value of the investments we have made in the biosimilars area.

Some of our products are approved by U.S. and foreign regulatory authorities on a conditional basis with full approval conditioned upon fulfilling the requirements of regulators. Regulatory authorities are placing greater focus on monitoring products originally approved on an accelerated or conditional basis and on whether the sponsors of such products have met the conditions of the accelerated or conditional approvals. Vectibix®, for example, received accelerated approval in the United States and conditional approval in the EU, with full approval conditioned on conducting additional clinical trials of the use of Vectibix® as a therapy in treating mCRC. (See Item 1. Business — Marketed Products — Other Marketed Products — Vectibix® (panitumumab).) If we are unable to fulfill the requirements of regulators that were conditions of our products' accelerated or conditional approval and/or if regulators re-evaluate the data or risk-benefit profile of our product in connection with a renewal assessment, our conditional approval may not be renewed or we may not receive full approval for these products or may be required to change the products' labeled indications or even withdraw the products from the market.

Following recent FDA and FDA advisory committee discussions and actions with respect to other therapeutic oncology products previously granted accelerated approval by the FDA, questions remain about regulatory authorities' views regarding the adequacy for approval of therapeutic oncology products that have demonstrated a statistically significant improvement in progression-free survival but have not shown a statistically significant improvement in overall survival. A number of our products and product candidates have used endpoints other than overall survival, such as progression-free survival and bone-metastasis-free survival (BMFS), in clinical trials. The use of endpoints such as progression-free survival or BMFS, in the absence of other measures of clinical benefit, may not be sufficient for approval even when such results are statistically significant. For example, our pivotal phase 3 Study '147 evaluated XGEVA® for its ability to improve BMFS in men with castration-resistant prostate cancer that has not yet spread to bone. The '147 trial demonstrated that XGEVA® significantly improved median bone metastasis-free survival by 4.2 months compared to placebo and significantly prolonged median time to first bone metastases. However, overall

survival (a secondary endpoint) was similar between the XGEVA® and placebo arms. On February 8, 2012, the FDA convened the ODAC to discuss our sBLA filing for XGEVA® to delay bone metastases in prostate cancer. During its presentation to the ODAC, the FDA questioned the magnitude of the improvement in BMFS demonstrated in Study '147, and indicated that a further clinical trial might help address some of the remaining unresolved questions regarding the clinical significance of the benefit achieved by XGEVA® in this setting. The ODAC panel concluded that the magnitude of benefit demonstrated with early treatment with XGEVA® to delay bone metastases was not sufficient to conclude a positive risk-benefit ratio for XGEVA® in the absence of additional measures impacting quality of life or other disease outcomes. On April 26, 2012, the FDA issued a Complete Response Letter to us citing the same conclusion.

In addition to the clinical trials that we choose to or are required to conduct, other organizations may also conduct clinical trials that use our products. Such clinical trials may evaluate our products in areas in which we do not have and are not seeking an approved indication. However, negative results or safety signals arising in other organizations' clinical trials may nonetheless prompt regulatory agencies to take regulatory actions that affect our approved indications, including requiring the addition of relevant safety data to the approved labeling or even withdrawing approval for our products.

The occurrence of a number of high profile safety events has caused an increased public and governmental concern about potential safety issues relating to pharmaceutical and biological products and certain of our products and product candidates. (See Our ESAs continue to be under review and receive scrutiny by regulatory authorities.) As a result of this increased concern in recent years, the U.S. regulatory environment has evolved and safety signals and safety concerns resulting from preclinical data, clinical trials (including sub-analyses and meta-analyses), market use or other sources are receiving greater scrutiny. For example, a number of regulatory agencies around the world, including the FDA and the EMA, have initiated programs to directly monitor for safety issues rather than wait for patients, providers or manufacturers to report safety problems with products or medical devices. And at least one private, for-profit company has begun aggregating and analyzing FDA adverse event data on its website using its own independent methodology, which could highlight new perceived risks of our products and product candidates. We are required to communicate to regulatory agencies adverse events reported to us by patients taking our products. Regulatory agencies may periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. If regulatory agencies determine that we have not complied with the applicable reporting or other pharmacovigilance requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including monetary fines and other penalties. Actual or perceived safety problems or signals could lead to revised or restrictive labeling of our approved products or a class of products, potentially including limitations on the use of approved products in certain patients because of:

- the identification of actual or theoretical safety or efficacy concerns with respect to any of our products by regulatory agencies;
- an increased rate or number of previously-identified safety-related events;
- the discovery of significant problems or safety signals or trends with a similar product that implicates an entire class of products;
- subsequent concerns about the sufficiency of the data or studies underlying the label or changes to the underlying safety/efficacy analysis related to results from clinical trials, including sub-analyses, or meta-analysis (a meta-analysis is the review of studies using various statistical methods to combine results from previous separate but related studies) of clinical trials or clinical data performed by us or others; and
- new legislation or rules by regulatory agencies.

For example, in December 2009, based on the Trial to Reduce Cardiovascular Events with Aranesp® Therapy (TREAT) results, we updated the boxed warning in the labeling information for ESAs, to reflect an increased risk of stroke when ESAs are administered to CRF patients to target Hb levels of 13 g/dL and above. In October 2010, we submitted additional proposed labeling changes regarding the use of ESAs in CRF patients not on dialysis that would limit treatment to patients who are most likely to benefit, specifically those with significant anemia (<10 g/dL), and who are at high risk for transfusion and for whom transfusion avoidance is considered clinically important, including those in whom it is important to preserve kidney transplant eligibility. In June 2011, we announced that the FDA had approved further changes to the labels for the use of ESAs, including Aranesp® and EPOGEN®, in patients with CKD. (With the June 2011 label changes, the FDA changed the term CRF to CKD in the ESA labels. We use CRF when referring to labels prior to June 2011 for historical accuracy.) See Our ESAs continue to be under review and receive scrutiny by regulatory authorities.

In addition to revised labeling for our products, discovery of new safety information or previously unknown safety concerns and/or safety signals with our products or similar products could also lead to:

- requirement of risk management activities (including a REMS) or other FDA compliance actions related to the promotion and sale of our products;
- mandated PMCs/PMRs or pharmacovigilance programs for our approved products;
- product recalls of our approved products;
- revocation of approval for our products from the market completely, or within particular therapeutic areas;
- increased timelines or delays in being approved by the FDA or other regulatory bodies; and/or
- fewer treatments or product candidates being approved by regulatory bodies.

Product safety concerns could cause regulatory agencies to impose risk management activities upon us (including a REMS), which may require substantial costs and resources to negotiate, develop, implement and administer. The results of these risk management activities could:

- impact the ability of healthcare providers to prescribe, dispense or use our products;
- limit patient access to our products;
- reduce patient willingness to use our products;
- place administrative burdens on healthcare providers in prescribing our products; and/or
- affect our ability to compete against products that do not have a REMS or similar risk management activities.

We currently have approved REMS for our ESAs, Prolia® and Nplate®, and we use third-party service providers to assist in the administration of our REMS that include elements to assure safe use. For example, our ESA REMS requires applicable healthcare providers and institutions to enroll in the program, receive education about the product and the REMS and document and report certain information to us over time. We are responsible for tracking and documenting certain elements of healthcare provider and institution compliance with the ESA REMS and providing the FDA with periodic assessment reports to demonstrate that the goals of the REMS are being met. The FDA may modify our REMS based on the results of the periodic assessment reports. Also, if we or third-party service providers acting on our behalf fail to effectively implement and/or administer the REMS for our products, we may be required to modify such REMS, and we may be subject to FDA enforcement actions or to civil penalties.

Further, if new medical data or product quality issues suggest an unacceptable or potential safety risk or previously unidentified side-effects, we may withdraw some or all affected product-either voluntarily or by regulatory mandate-in certain therapeutic areas, or completely recall a product presentation from the market for some period or permanently. For example, in September 2009, we initiated a voluntary recall of a limited number of ENBREL SureClick® lots due to a defect in the glass syringe barrel which resulted in a small number of broken syringes following assembly of the autoinjector device. In October 2010, we initiated a voluntary recall of certain lots of ENBREL due to identification of cracks in a small number of the glass syringes which may have resulted in product leakage and syringe breakage. Further, beginning in September 2010, we initiated a voluntary recall of certain lots of EPOGEN® and J&J voluntarily recalled certain lots of PROCRIT®, manufactured by us, because a small number of vials in each lot were found to contain glass lamellae (extremely thin, barely visible glass flakes) which we believed was a result of the interaction of the product formulation with glass vials during the shelf life of the product. The recalls were executed in close cooperation with the FDA. We may experience the same or other problems in the future, resulting in broader product recalls, adverse event trends, delayed shipments, supply constraints, contract disputes and/or stock-outs of our products, which may materially and adversely affect the sales of our products, our business and results of operations. Additionally, if we or other parties (including our independent clinical trial investigators or our licensees, such as J&J, Pfizer, Glaxo and Takeda) report or fail to effectively report to regulatory agencies side effects or other safety concerns that occur from their use of our products in clinical trials or studies or from marketed use, resulting regulatory action, including monetary fines and other penalties, could materially and adversely affect the sales of our products, our business and results of operations.

Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Our operations and performance have been, and may continue to be, affected by economic conditions in the United States and throughout the world. Sales of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including government programs such as Medicare and Medicaid and private payer healthcare and insurance programs. (See Our sales depend on coverage and reimbursement from third-party payers.) As more fully explained below, financial pressures may cause government or other third-party payers to more aggressively seek cost containment through mandatory discounts on our products, policies requiring the automatic substitution of generic or biosimilars, higher hurdles for initial reimbursement approval for new products or other similar measures. (See We expect to face increasing competition from biosimilars.) Additionally, as a result of the current or a future global economic downturn, our third-party payers may delay or be unable to satisfy their reimbursement obligations. A reduction in the availability or extent of reimbursement from government and/or private payer healthcare programs or increased competition from lower cost biosimilars could have a material adverse effect on the sales of our products, our business and results of operations. In addition, as a result of the economic conditions and/or employer decisions regarding the insurance coverage mandate that goes into effect in the United States in 2014, some employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees. Job losses or other economic hardships may also result in reduced levels of coverage for some individuals, potentially resulting in lower levels of healthcare coverage for themselves or their families. These economic conditions may affect patients' ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to changes in patient behavior and spending patterns that negatively affect usage of certain of our products, including delaying treatment, rationing prescription medications, leaving prescriptions unfilled, reducing the frequency of visits to healthcare facilities, utilizing alternative therapies and/or foregoing healthcare insurance coverage. In addition to its effects on consumers, the economic downturn may have also increased cost sensitivities among medical providers in the United States, such as oncology clinics, particularly in circumstances where providers may experience challenges in the collection of patient co-pays or be forced to absorb treatment costs as a result of coverage decisions or reimbursement terms. Collectively, we believe these changes have resulted and may continue to result in reduced demand for our products, which could materially and adversely affect the sales of our products, our business and results of operations. Any resulting decrease in demand for our products could also cause us to experience excess inventory write-offs and/or excess capacity or impairment charges at certain of our manufacturing facilities.

In Europe, economic conditions across the region could potentially be impacted by countries of key concern, particularly countries in Southern Europe. Economic conditions continue to affect our operations and performance outside the United States as well, particularly in countries where government-sponsored healthcare systems are the primary payers for healthcare expenditures, including drugs and biologics. In Southern Europe, credit and economic conditions have adversely impacted the timing of collections of our trade receivables in this region. Global economic conditions may continue to impact the average length of time it takes to collect payments in Greece, Italy, Spain, Portugal or other countries, or we may never collect some or all of these receivables, which could have a material adverse impact on our operating cash flows and a material adverse effect on our financial position, liquidity or results of operations. See Our sales depend on coverage and reimbursement from third-party payers.

We also rely upon third parties for certain parts of our business, including licensees and partners, wholesale distributors of our products, contract clinical trial providers, contract manufacturers and single third-party suppliers. Because of the recent volatility in the financial markets, there may be a disruption or delay in the performance or satisfaction of commitments to us by these third parties which could have a material adverse effect on the sales of our products, our business and results of operations. Current economic conditions may adversely affect the ability of our distributors, customers and suppliers to obtain liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Further, economic conditions appear to have affected, and may continue to affect, the business practices of our wholesale distributors in a manner that contributes to lower sales of our products. Although we monitor our distributors', customers' and suppliers' financial condition and their liquidity in order to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could have a material adverse effect on the sales of our products, our business and results of operations. These risks may be elevated with respect to our interactions with third parties with substantial operations in countries where current economic conditions are the most severe, particularly where such third parties are themselves exposed to sovereign risk from business interactions directly with fiscally-challenged government payers.

We maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our Consolidated Balance Sheet. The value of our investments may be adversely affected by interest rate fluctuations, downgrades in credit ratings, illiquidity in the capital markets and other factors that may result in other than temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on the sale of investments.

Some of our products are used with drug delivery or companion diagnostic devices which have their own regulatory, manufacturing, reimbursement and other risks.

Some of our products or product candidates may be used in combination with a drug delivery device, such as an injector or other delivery system. Our product candidates or expanded indications of our products used with such drug delivery devices may not be approved or may be substantially delayed in receiving regulatory approval if such devices do not gain or maintain regulatory approval or clearance. Where approval of the product and device is sought under a single marketing drug application, the increased complexity of the review process may also delay receipt of regulatory approval. In addition, some of these drug delivery devices may be provided by single-source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or clearance by the applicable regulatory agencies. We are also dependent on those third-party companies continuing to meet the applicable regulatory and other requirements to maintain that approval or clearance once it has been received. Failure to supply the devices, delays in or failure of the Amgen or third-party studies, or failure of the third-party company to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and/or associated delays in a product candidate reaching the market or the expansion of existing product labels for new indications. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market.

Similarly, some of our products or product candidates may be used in combination with an in vitro companion diagnostic device, such as a test kit. In some cases, our product candidates or expanded indications of our products used with in vitro companion diagnostic devices may not be approved or may be substantially delayed in receiving regulatory approval if such devices do not gain or maintain regulatory approval or clearance. For example, the FDA has informed us that its approval of Vectibix® for the first- and second-line mCRC indications we are seeking will be contingent upon approval of the companion diagnostic device being developed in collaboration with QIAGEN, which identifies a patient's *KRAS* gene status. As with drug delivery devices used with our products, our ability to get and maintain the necessary regulatory approvals for our products or product candidates used with in vitro companion diagnostic devices can be substantially dependent on whether the manufacturers of such devices meet their contractual responsibilities to us and/or their obligations to regulatory authorities. Failures by these manufacturers can also result in the significant delays and added costs described above, or even result in the removal of our product from the market.

The in vitro companion diagnostic and drug delivery devices used with our products are also subject to many of the same reimbursement risks and challenges to which our products are subject. (See Our sales depend on coverage and reimbursement from third-party payers.) A reduction in the availability of, or the coverage and/or reimbursement for, in vitro companion diagnostic or drug delivery devices used with our products could have a material adverse effect on our product sales, business and results of operations.

Our ESAs continue to be under review and receive scrutiny by regulatory authorities.

Beginning in 2006, adverse safety results involving ESAs were observed and since that time our ESAs have been the subject of ongoing review and scrutiny by regulatory authorities and other agencies. In the United States, over this time frame the FDA has reviewed the benefit-risk profile of ESAs, which has resulted in changes to ESA labeling and usage in both the oncology and nephrology clinical settings. Over this same time period, CMS has also evaluated the use of ESAs and has made substantial reimbursement changes in the oncology and nephrology clinical settings. (See Our sales depend on coverage and reimbursement from third-party payers.) Together, these labeling and reimbursement changes, along with the approved REMS for ESAs, have had and may continue to have a material adverse effect on sales of our ESAs, our business and results of operations, and further labeling or reimbursement changes by these regulatory authorities could increase the severity of that effect.

We have also agreed with the FDA to conduct a number of PMCs for our ESAs. In 2004, we agreed with the FDA to a robust pharmacovigilance program to continue to study the safety surrounding the use of darbepoetin alfa in the oncology setting. Of the five studies originally included in that pharmacovigilance program, four are complete and analysis of the results from the fifth study, LHN03-6B, is currently ongoing. The results of certain of those studies contributed to safety-related product labeling changes for our ESAs and changes in reimbursement, as noted above. Other trials have subsequently been initiated to inform on the safety of ESAs. In 2009 we initiated Study '782, a phase 3 non-inferiority study evaluating overall survival when comparing NSCLC patients on Aranesp® to patients receiving placebo, as part of our Aranesp® pharmacovigilance program. In addition, JRD's EPO-ANE-3010 study, which evaluates the use of epoetin alfa in patients with breast cancer, is ongoing. Both of these studies are designated by the FDA as PMRs and must be conducted to maintain regulatory approval and marketing authorization. For the nephrology setting, we have been engaged in ongoing discussions with the FDA regarding additional PMRs to explore alternative ESA dosing strategies in CKD patients on dialysis and not on dialysis. In July 2012 we initiated study '226 to evaluate Aranesp® use in CKD patients not on dialysis. We expect to discuss further with the FDA another potential study in CKD patients on dialysis. Although we cannot predict the results or the outcomes of ongoing clinical trials, or the extent to which regulatory authorities may

require additional labeling changes as a result of these or other trials, we cannot exclude the possibility that unfavorable results from clinical trials, including PMCs, could have a material adverse effect on the reimbursement, use and sales of our ESAs and on our business and results of operations.

Regulatory authorities outside the United States have also reviewed and scrutinized the use of ESAs. In June 2008, the EMA recommended updating the product information for ESAs with a new warning for their use in cancer patients, which was approved by the EC in October 2008. Following the October 2008 revision, we experienced a reduction of Aranesp® sales in the supportive cancer care setting in the EU. In addition, following the June 2011 ESA label changes in the United States, regulatory agencies outside the United States have sought additional information from us about the use and safety of ESAs in the CKD setting. Additional labeling or reimbursement changes by these regulatory authorities could materially and adversely affect the reimbursement, use and sales of our ESAs, our business and results of operations.

We continue to receive results from meta-analyses or previously initiated clinical trials using ESAs, including PMCs. For example, in May 2009, the Cochrane Collaboration published its independent meta-analysis of patient-level data from previously conducted, randomized, controlled, clinical studies evaluating ESAs in cancer patients which we submitted to the FDA and the EMA. This Cochrane meta-analysis of patient-level data from previous studies corroborates prior analyses indicating that the use of ESAs may increase the risk of death in cancer patients. The studies in the analysis all predate the current label, which advises using the least amount of ESA necessary to avoid transfusion, but they do not exclude the potential for adverse outcomes when ESAs are prescribed according to the current label. In addition, in January 2013 we announced data from the RED-HF® trial evaluating the effect of treatment of anemia with darbepoetin alfa on morbidity and mortality in patients with symptomatic left ventricular heart failure. The trial did not meet its primary endpoint of reducing the composite endpoint of time to death from any cause or first hospital admission for worsening heart failure. While there were no new safety findings identified in the RED-HF® trial, unfavorable results from similar trials or meta-analyses of previous clinical trials could materially and adversely affect the use and sales of our ESAs, our business and results of operations.

We must conduct clinical trials in humans before we can commercialize and sell any of our product candidates or existing products for new indications.

Before we can sell any products, we must conduct clinical trials to demonstrate that our product candidates are safe and effective for use in humans. The results of those clinical trials are used as the basis to obtain approval from regulatory authorities such as the FDA and EMA. (See Our current products and products in development cannot be sold if we do not maintain or gain regulatory approval.) We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims. The length of time, number of trial sites and patients required for clinical trials vary substantially and therefore, we may spend several years and incur substantial expense in completing certain clinical trials. We may have difficulty finding a sufficient number of clinical trial sites and subjects to participate in our clinical trials, particularly if competitors are conducting similar clinical trials in certain patient populations. Delays in planned clinical trials can result in increased development costs, delays in regulatory approvals, associated delays in product candidates reaching the market and revisions to existing product labels.

In addition, in order to increase the number of patients available for enrollment for our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, India, China, South Korea, the Philippines, Singapore and some Central and South American countries either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to identify and understand the unique regulatory environments of individual countries. Further, we must ensure the timely production, distribution and delivery of the clinical supply of our product candidates to the numerous and varied clinical trial sites. If we fail to adequately manage the design, execution and regulatory aspects of our large, complex and regulatorily diverse clinical trials or manage the production or distribution of our clinical supply, corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates or could lose our ability to market existing products in certain therapeutic areas or altogether. If we are unable to market and sell our product candidates or are unable to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations could be materially and adversely affected. Additional information on our clinical trials can be found on our website at www.amgen.com. (This website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.)

We rely on independent third-party clinical investigators to recruit subjects and conduct clinical trials in accordance with the applicable study protocols and laws and regulations. We also may acquire companies that have ongoing clinical trials. These trials may not be conducted to the same standards as ours; however, once an acquisition has been completed we assume responsibility for the conduct of the trial, including any potential risks and liabilities associated with the past and prospective conduct of those trials. If regulatory authorities determine that we or others, including our licensees or the independent investigators selected by

us or by a company we have acquired, have not complied with regulations in the R&D of a product candidate, a new indication for an existing product or information to support a current indication, they may refuse to accept trial data from the site, not approve the product candidate or new indication or maintain approval of the current indication in its current form or at all, and we would not be able to market and sell it. If we were unable to market and sell our products or product candidates, our business and results of operations could be materially and adversely affected.

Further, we rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations. In addition, some of our clinical trials involve drugs manufactured and marketed by other pharmaceutical companies. These drugs may be administered in a clinical trial in combination with one of our product candidates or in a head-to-head study comparing the products' relative efficacy and safety. In the event that any of these vendors or pharmaceutical companies have unforeseen issues that negatively impact the quality of their work or creates a shortage of supply, our ability to complete our applicable clinical trials and/or evaluate clinical results may also be negatively impacted. As a result, this could adversely affect our ability to file for, gain or maintain regulatory approvals worldwide on a timely basis, if at all.

Patients may also suffer adverse medical events or side effects in the course of our, our licensees, partners or independent investigators' clinical trials which could:

- delay the clinical trial program;
- require additional or longer trials to gain approval;
- prohibit regulatory approval of our product candidates or new indications for existing products; and
- render the product candidate commercially unfeasible or limit our ability to market existing products completely or in certain therapeutic areas.

Safety signals, trends, adverse events or results from clinical trials or studies performed by us or by others (including our licensees or independent investigators) or from the marketed use of our drugs or similar products that result in revised safety-related labeling or restrictions on the use of our approved products could negatively impact healthcare provider prescribing behavior, use and sales of our products, regulatory or private health organization medical guidelines and reimbursement for our products, all of which could have a material adverse effect on our business and results of operations.

Clinical trials must be designed based on the current standard of medical care. However in certain diseases, such as cancer, the standard of care is evolving rapidly. In these diseases, the duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on an out of date standard of medical care, limiting the utility and application of such trials. We may not obtain favorable clinical trial results and may not be able to obtain regulatory approval for new product candidates, new indications for existing products or maintenance of our current labels on this basis. Further, clinical trials conducted by others, including our licensees, partners or independent investigators, may result in unfavorable clinical trials results that may call into question the safety of our products in off-label or on label uses that may result in label restrictions and/or additional trials.

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a pharmacovigilance program of our product or for approval of a new indication. For example, we initiated Study '782 as part of our Aranesp® oncology pharmacovigilance program. (See Our ESAs continue to be under review and receive scrutiny by regulatory authorities.) In connection with the June 2011 ESA label changes, we also agreed to conduct additional clinical trials examining the use of ESAs in CKD. Additional clinical trials we initiate, including those required by the FDA, could result in substantial additional expense and the outcomes could result in additional label restrictions or the loss of regulatory approval for an approved indication, each of which could have a material adverse effect on the sales of our products, our business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our products.

We expect to face increasing competition from biosimilars.

We currently face competition in Europe from biosimilars, and we expect to face increasing competition from biosimilars in the future. In 2010, lawmakers in the United States enacted healthcare reform legislation which included an abbreviated regulatory pathway for the approval of biosimilars. The EU is already approving biosimilars under such a regulatory pathway. To the extent that governments adopt more permissive approval frameworks and competitors are able to obtain broader marketing approval for biosimilars, our products will become subject to increased competition. Expiration or successful challenge of applicable patent rights could trigger such competition, and we could face more litigation regarding the validity and/or scope of our patents. Our

products may also experience greater competition from lower-cost generic or biosimilars that come to market as branded products that compete with our products lose patent protection.

In the EU, the EC has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In 2006, the EMA developed and issued regulatory guidelines related to the development and approval of biosimilars. The guidelines included clinical trial guidance for certain biosimilars, including erythropoietins and G-CSFs, recommending that applicants seeking approval of such biosimilars conduct pharmacodynamic, toxicological and clinical safety studies as well as a pharmacovigilance program. Some companies have received and other companies are seeking approval to market erythropoietin and G-CSF biosimilars in the EU, presenting additional competition for our products. (See Our marketed products face substantial competition.) For example, following the expiration of the principal European patent relating to recombinant G-CSF in August 2006, the EC issued marketing authorizations for the first G-CSF biosimilars and the products were launched in certain EU countries in 2008 and 2009. There are now several G-CSF biosimilars available in the EU marketed by different companies and these G-CSF biosimilars compete with NEUPOGEN® and Neulasta®. In December 2012, EMA guidelines on the approval process for monoclonal antibody biosimilars became effective. In an effort to spur biosimilar utilization and/or increase potential health care savings, countries in the EU may adopt biosimilar uptake measures such as requiring physician prescribing quotas or automatic substitution by pharmacists of biosimilars for the corresponding reference products. We cannot predict to what extent the entry of biosimilars or other competing products will impact future sales of our products in the EU. Our inability to compete effectively could reduce sales, which could have a material adverse effect on our business and results of operations.

In the United States, with the adoption of the healthcare reform law the FDA was authorized to approve biosimilars under a separate, abbreviated pathway. (See Our sales depend on coverage and reimbursement from third-party payers.) The law established a period of 12 years of data exclusivity for reference products in order to preserve incentives for future innovation and outlined statutory criteria for science-based biosimilar approval standards that take into account patient safety considerations. Under this framework, data exclusivity protects the data in the innovator's regulatory application by prohibiting, for a period of 12 years, others from gaining FDA approval based in part on reliance or reference to the innovator's data in their application to the FDA. The law does not change the duration of patents granted on biologic products. On February 9, 2012, the FDA released three draft guidance documents that provide insight into the FDA's current thinking on the development of biosimilars and broad parameters for the scientific assessment of biosimilar applications. The documents provide guidance in the development of biosimilar versions of currently approved biological products and indicate that the clinical trials and other steps required for approval of each biosimilar will depend on a variety of factors, including the complexity of the protein, the degree of analytical similarity with the reference product and the potential risks of the product. A growing number of companies have announced their intentions to develop biosimilar versions of existing biotechnology products, including a number of our products. Further, biosimilar manufacturers with approved products in Europe may seek to obtain U.S. approval now that the regulatory pathway for biosimilars has been enacted. In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely seek to shorten the data exclusivity period. President Obama's proposed 2013 budget included a proposal to lower the data exclusivity period to seven years, but this would require new legislation be passed by Congress. Critics may also encourage the FDA to interpret narrowly the law's provisions regarding which new products receive data exclusivity. While we are unable to predict the precise impact of the pending introduction of biosimilars on our products, or the degree to which the FDA's 2012 biosimilar guidelines will contribute to that impact, we expect in the future to face greater competition in the United States as a result of biosimilars and downward pressure on our product prices and sales, subject to our ability to enforce our patents. (See Item 7A. Management's Discussion and Analysis of Financial Condition and Results of Operations — Financial Condition, Liquidity and Capital Resources.) This additional competition could have a material adverse effect on our business and results of operations.

With respect to the biosimilars we are working to develop (see Item 1. Research and Development and Selected Product Candidates — Amgen Development of Biosimilars), a number of other companies have announced their intention to develop biosimilar versions of the same reference products that we are pursuing. Some of these companies may be ahead of us in their biosimilar development timelines, have certain technical or other advantages over us or have more experience producing or marketing generic or biosimilar products. Even if we are able to successfully get our biosimilar product candidates approved by regulatory authorities, this additional competition could limit the ability of our biosimilars to gain market acceptance with prescribers or payors or otherwise affect the sales of our biosimilars.

We may not be able to develop commercial products.

Successful product development in the biotechnology industry is highly uncertain, and very few R&D projects produce a commercial product. We intend to continue to make significant R&D investments. Product candidates or new indications for existing products (collectively, “product candidates”) that appear promising in the early phases of development may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results, for reasons that could include changes in the standard of care of medicine;
- the product candidate was not effective or more effective than currently available therapies in treating a specified condition or illness;
- the product candidate is not cost effective in light of existing therapeutics;
- the product candidate had harmful side effects in humans or animals;
- the necessary regulatory bodies, such as the FDA or EMA, did not approve our product candidate for an intended use;
- the product candidate was not economical for us to manufacture and commercialize;
- the biosimilar product candidate fails to demonstrate the requisite bioequivalence to the applicable reference product, or is otherwise determined to be unacceptable for purposes of safety or efficacy, to gain approval under the biosimilar pathway;
- other parties have or may have proprietary rights relating to our product candidate, such as patent rights, and will not let us sell it on reasonable terms, or at all;
- we and certain of our licensees, partners or independent investigators may fail to effectively conduct clinical development or clinical manufacturing activities; and
- the regulatory pathway to approval for product candidates is uncertain or not well-defined.

Several of our product candidates have failed or been discontinued at various stages in the product development process. For example, in June 2004, we announced that the phase 2 study of Glial Cell Lined-Derived Neurotrophic Factor (GDNF) for the treatment of advanced Parkinson's disease did not meet the primary study endpoint upon completion of nine months of the double-blind treatment phase of the study. The conclusion was reached even though a small phase 1 pilot investigator-initiated open-label study over a three-year period appeared to result in improvements for advanced Parkinson's disease patients. Subsequently, we discontinued clinical development of GDNF in patients with advanced Parkinson's disease.

Inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product for any of the reasons discussed could potentially have a negative impact on our net sales and earnings and could result in a significant impairment of in-process research and development (IPR&D) or other intangible assets.

Our marketed products face substantial competition.

We operate in a highly competitive environment. Our products compete with other products or treatments for diseases for which our products may be indicated. Our competitors market products or are actively engaged in R&D in areas where we have products, where we are developing product candidates or new indications for existing products. In the future, we expect that our products will compete with new drugs currently in development, drugs currently approved for other indications that may later be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. Large pharmaceutical companies and generics manufacturers of pharmaceutical products are expanding into the biotechnology field with increasing frequency, and some pharmaceutical companies and generics manufacturers have formed partnerships to pursue biosimilars. In addition, some of our competitors may have technical, competitive or other advantages over us for the development of technologies and processes. These advantages may make it difficult for us to compete with them to successfully discover, develop and market new products and for our current products to compete with new products or new product indications that these competitors may bring to market. As a result, our products may compete against products that have lower prices (including new generics or biosimilars that come to market as branded products that compete with our products lose patent protection), equivalent or superior performance, better safety profile, are easier to administer, achieve earlier entry into the market or that are otherwise competitive with our products.

Concentration of sales at certain of our wholesaler distributors and consolidation of free-standing dialysis clinic businesses may negatively impact our bargaining power and profit margins.

The substantial majority of our U.S. product sales are made to three pharmaceutical product wholesaler distributors, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation. These distributors, in turn, sell our products

to their customers, which include physicians or their clinics, dialysis centers, hospitals and pharmacies. One of our products, EPOGEN®, is sold primarily to free-standing dialysis clinics, which have experienced significant consolidation. Two organizations, DaVita and Fresenius Medical Care North America, own or manage a large number of the outpatient dialysis facilities located in the United States and account for a substantial majority of all EPOGEN® sales in the free-standing dialysis clinic setting. Due to this concentration, these entities have substantial purchasing leverage, which may put pressure on our pricing by their potential ability to extract price discounts on our products or fees for other services, correspondingly negatively impacting our bargaining position and profit margins.

Our business may be affected by litigation and government investigations.

We and certain of our subsidiaries are involved in legal proceedings. (See Note 18, Contingencies and commitments, to the Consolidated Financial Statements.) Civil and criminal litigation is inherently unpredictable, and the outcome can result in excessive verdicts, fines, penalties, exclusion from the federal healthcare programs and/or injunctive relief that affect how we operate our business. Defense of litigation claims can be expensive, time-consuming and distracting and it is possible that we could incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our business and results of operations. In addition, product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products that we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention and adversely affect our reputation and the demand for our products. Amgen and Immunex have previously been named as defendants in product liability actions for certain of our products.

We are also involved in government investigations that arise in the ordinary course of our business. As we announced on December 19, 2012, we finalized a settlement agreement with the U.S. government, 49 states and the District of Columbia to settle certain allegations regarding our sales and marketing practices arising out of ongoing civil and criminal investigations conducted by the U.S. Attorney's Offices for the Eastern District of New York and the Western District of Washington (the “Federal Investigations”). As more fully described in Note 18, Contingencies and commitments, to the Consolidated Financial Statements, this settlement resolved the Federal Investigations, the related state Medicaid claims (except for those of the State of South Carolina) and the claims of ten civil qui tam actions that had been pending against us. However, the settlement does not resolve certain of other litigation matters that will continue to be pending against us, and we may also be subject to actions by governmental entities, including those not participating in the settlement, and may in the future become subject to claims by other parties, in each case with respect to the alleged conduct which is the subject of the settlement. We may see new governmental investigations of or actions against us citing novel theories of recovery. Any of these results could have a material adverse effect on our business and results of operations.

We rely on third-party suppliers for certain of our raw materials, medical devices and components.

We rely on unaffiliated third-party suppliers for certain raw materials, medical devices and components necessary for the manufacturing of our commercial and clinical products. Certain of those raw materials, medical devices and components are the proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug application with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until the regulatory agency approved such supplier.

Among the reasons we may be unable to obtain these raw materials, medical devices and components include:

- regulatory requirements or action by regulatory agencies or others;
- adverse financial or other strategic developments at or affecting the supplier;
- unexpected demand for or shortage of raw materials, medical devices or components;
- labor disputes or shortages, including the effects of a pandemic flu outbreak, natural disaster, or otherwise;
- failure to comply with our quality standards which results in quality and product failures, product contamination and/or recall; and
- discovery of previously unknown or undetected imperfections in raw materials, medical devices or components.

These events could negatively impact our ability to satisfy demand for our products, which could materially and adversely affect our product use and sales and our business and operating results. For example, in prior years we have experienced shortages

in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility. Further quality issues which result in unexpected additional demand for certain components may lead to shortages of required raw materials or components (such as we have experienced with EPOGEN® glass vials). We may experience or continue to experience these or other shortages in the future resulting in delayed shipments, supply constraints, contract disputes and/or stock-outs of our products. Also, certain of the raw materials required in the commercial and clinical manufacturing of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues. In addition, one of our marketed products also uses bovine serum and human serum albumin. Some countries in which we market our products may restrict the use of certain biologically derived substances in the manufacture of drugs. We continue to investigate alternatives to certain biological sources and alternative manufacturing processes that do not require the use of certain biologically derived substances because such raw materials may be subject to contamination and/or recall.

A material shortage, contamination, recall and/or restriction of the use of certain biologically derived substances or other raw materials, which may be sourced from other countries and that are used in the manufacture of our products could adversely impact or disrupt the commercial manufacturing of our products or could result in a mandated withdrawal of our products from the market. This could negatively impact our ability to satisfy demand for our products, which could materially and adversely affect our product sales, business and operating results. Further, any disruptions or delays by us or by third-party suppliers or partners in converting to alternatives to certain biologically derived substances and alternative manufacturing processes or our ability to gain regulatory approval for the alternative materials and manufacturing processes could increase our associated costs or result in the recognition of an impairment in the carrying value of certain related assets, which could have a material and adverse effect on our business and results of operations.

Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. We currently are involved in the manufacture of all of our principal products and plan to manufacture many of our product candidates. In addition, we currently use third-party contract manufacturers to produce or assist in the production of ENBREL, Prolia®, Sensipar®/Mimpara®, Nplate®, XGEVA® and Vectibix® and plan to use contract manufacturers to produce or assist in the production of a number of our late-stage product candidates. Our ability to adequately and timely manufacture and supply our products is dependent on the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers, which may be impacted by:

- availability or contamination of raw materials, components and equipment used in the manufacturing process, particularly those for which we have no other source or supplier;
- capacity of our facilities and those of our contract manufacturers;
- contamination by microorganisms or viruses;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of a pandemic flu outbreak, natural disaster, or otherwise;
- degree of compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs;
- updating of manufacturing specifications;
- production success rates and yields; and
- timing and outcome of product quality testing.

If the efficient manufacture and supply of our products is interrupted, we may experience delayed shipments, supply constraints, stock-outs and/or recalls of our products. For example, over the past several years we have initiated a number of voluntary recalls of certain lots of our products. (See Our current products and products in development cannot be sold if we do not maintain or gain regulatory approval.) If we are at any time unable to provide an uninterrupted supply of our products to

patients, we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could materially and adversely affect our product sales, business and results of operations.

Our manufacturing processes and those of our third-party contract manufacturers must undergo a potentially lengthy FDA or other regulatory approval process and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build, validate and license a new manufacturing plant and it can take longer than three years to qualify and license a new contract manufacturer. For example, in order to mitigate the risk associated with the majority of our formulation and fill operations being performed in a single facility, we are completing the construction and qualification of a new formulation and filling facility at our Puerto Rico site, and we are modifying and expanding our recently acquired formulation, fill and finish manufacturing site in Ireland. Upon completion, these facilities will require licensure by the various regulatory authorities.

If regulatory authorities determine that we or our third-party contract manufacturers or certain of our third-party service providers have violated regulations or if they restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis or at all. If we or our third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers fail to supply materials, products or services to us, we may experience delayed shipments, supply constraints, stock-outs and/or recalls of our products. Additionally, we distribute a substantial volume of our commercial products through our primary distribution centers in Louisville, Kentucky for the United States and in Breda, the Netherlands for Europe and much of the rest of the world. We also conduct all the labeling and packaging of our products distributed in Europe and much of the rest of the world in Breda, the Netherlands. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics centers, our third-party logistics providers and our labeling and packaging facility in Breda. Further, we rely on commercial transportation for the distribution of our products to our customers which may be negatively impacted by natural disasters or security threats.

We perform a substantial amount of our commercial manufacturing activities at our Puerto Rico manufacturing facility and a substantial amount of our clinical manufacturing activities at our Thousand Oaks, California manufacturing facility; if significant natural disasters or production failures occur at the Puerto Rico facility, we may not be able to supply these products or, at the Thousand Oaks facility, we may not be able to continue our clinical trials.

We currently perform all of the formulation, fill and finish for Neulasta®, NEUPOGEN®, Aranesp®, EPOGEN®, Prolia® and XGEVA® and substantially all of the formulation, fill and finish operations for ENBREL at our manufacturing facility in Juncos, Puerto Rico. We also currently perform all of the bulk manufacturing for Neulasta®, NEUPOGEN® and Aranesp®, all of the purification of bulk EPOGEN® material and substantially all of the bulk manufacturing for Prolia® and XGEVA® at this facility. We perform substantially all of the bulk manufacturing and formulation, fill and finish, and packaging for product candidates to be used in clinical trials at our manufacturing facility in Thousand Oaks, California. The global supply of our products and product candidates is significantly dependent on the uninterrupted and efficient operation of these facilities. A number of factors could materially and adversely affect our operations, including:

- power failures and/or other utility failures;
- breakdown, failure or substandard performance of equipment;
- improper installation or operation of equipment;
- labor disputes or shortages, including the effects of a pandemic flu outbreak;
- inability or unwillingness of third-party suppliers to provide raw materials and components;
- natural or other disasters, including hurricanes, earthquakes or fires; and
- failures to comply with regulatory requirements, including those of the FDA.

In the past, the Puerto Rico facility has experienced manufacturing component shortages and there was evidence of adverse trends in the microbial bioburden of the production environment that reduced the production output. The same or other problems may result in our being unable to supply these products, which could materially and adversely affect our product sales, business and operating results. Although we have obtained limited insurance to protect against certain business interruption losses, there

can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all. The extent of the coverage of our insurance could limit our ability to mitigate for lost sales and such losses could materially and adversely affect our product sales, business and operating results. Our Puerto Rico facility is also subject to the same difficulties, disruptions or delays in manufacturing experienced in our other manufacturing facilities. For example, the limited number of lots of ENBREL and EPOGEN® voluntarily recalled in 2009 and 2010 were manufactured at our Puerto Rico facility. In future inspections, our failure to adequately address the FDA's expectations could lead to further inspections of the facility or regulatory actions. (See Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.)

Our intellectual property positions may be challenged, invalidated, circumvented or expire, or we may fail to prevail in present and future intellectual property litigation.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We have been in the past, and may be in the future, involved in patent litigation. A determination made by a court, agency or tribunal concerning infringement, validity, enforceability, injunctive or economic remedy, or the right to patent protection, for example, are typically subject to appellate or administrative review. Upon review, such initial determinations may be afforded little or no deference by the reviewing tribunal and may be affirmed, reversed, or made the subject of reconsideration through further proceedings. A patent dispute or litigation may not discourage a potential violator from bringing the product that is alleged to infringe to market prior to a final resolution of the dispute or litigation. For example, until the Pennsylvania District Court entered final judgment and a permanent injunction against Teva on July 15, 2011 pursuant to a joint stipulation and settlement agreement between the parties, Teva had announced that it intended to sell its filgrastim product, upon approval from the FDA, in the United States without a license from us and prior to the expiration of our G-CSF patents. The period of time from inception until resolution of a patent dispute or litigation is subject to the availability and schedule of the court, agency or tribunal before which the dispute or litigation is pending. We may be subject to competition during this period and may not be able to fully recover for the losses, damages, and harms we incur from infringement by the competitor product even if we prevail. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities, be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Further, under the Hatch-Waxman Act, our products approved by the FDA under the FDCA may be the subject of patent litigation with generic competitors before expiry of the five year period of data exclusivity provided for under the Hatch-Waxman Act and prior to the expiration of the patents listed for the product. Likewise, our innovative biologic products may be the subject of patent litigation prior to the expiration of our patents and, with respect to competitors seeking approval as a biosimilar or interchangeable version of our products, prior to the twelve year exclusivity period provided under the Biologics Price Competition and Innovation Act of 2009.

Over the next several years, certain of the existing patents on our principal products will expire. (See Item 1. Business — Marketed Products.) As our patents expire, competitors may be able to legally produce and market similar products or technologies, including biosimilars, which may have a material adverse effect on our product sales, business and results of operations. (See Item 7A. Management's Discussion and Analysis of Financial Condition and Results of Operations — Financial Condition, Liquidity and Capital Resources.) We have received, and we continue to seek, additional patent protection relating to our products, including patents on our products, specific processes for making our products, formulations and particular uses of our products. However, competitors may be able to invalidate, design around or otherwise circumvent our patents and sell competing products. For example, there are a number of competing therapies currently on the market and more in clinical development that are different from ENBREL but are used to treat the same inflammatory diseases treated by ENBREL. Although we continue to develop new products, and obtain patent protection for these new product candidates, we may not be able to replace the revenue lost upon the expiration of the patents on our current products.

From time to time, U.S. and other policymakers have proposed reforming the patent laws and regulations of their countries. In September 2011, after years of Congressional debate regarding patent reform legislation, President Obama signed into law the America Invents Act (the Act) considered by many to be the most substantial revision of U.S. patent law since 1952. The Act's

various provisions take effect over an 18-month period. The Act changes the current “first-to-invent” system to a system that awards a patent to the “first-inventor-to-file” for an application for a patentable invention. This change alters the pool of available materials that can be used to challenge patents and eliminates the ability to rely on prior research work in order to lay claim to patent rights. Disputes as to whether the first filer is in fact the true inventor will be resolved through newly implemented derivation proceedings. The Act also creates mechanisms to allow challenges to newly issued patents in the patent office in post-grant proceedings and new inter partes reexamination proceedings. Although many of the changes bring U.S. law into closer harmony with European and other national patent laws, the new bases and procedures may make it easier for competitors to challenge our patents, which could result in increased competition and have a material adverse effect on our product sales, business and results of operations. The changes may also make it harder to challenge third-party patents and place greater importance on being the first inventor to file a patent application on an invention.

Our stock price is volatile.

Our stock price, like that of our peers in the biotechnology and pharmaceutical industries, is volatile. Our revenues and operating results may fluctuate from period to period for a number of reasons. Events such as a delay in product development or even a relatively small revenue shortfall may cause financial results for a period to be below our expectations or projections. As a result, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations.

We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The capital and credit markets may experience extreme volatility and disruption which may lead to uncertainty and liquidity issues for both borrowers and investors. We may access the capital markets to supplement our existing funds and cash generated from operations in satisfying our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. In the event of adverse capital and credit market conditions, we may be unable to obtain capital market financing on similar favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Changes in credit ratings issued by nationally recognized credit rating agencies could adversely affect our cost of financing and have an adverse effect on the market price of our securities.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. However, professional societies, HTA organizations, practice management groups, insurance carriers, physicians, private health/science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to healthcare providers, administrators and payers, and patient communities. Recommendations by government agencies or those other groups/organizations may relate to such matters as usage, dosage, route of administration and use of related therapies as well as reimbursement of our products by government and private payers. Recommendations or guidelines that are followed by patients, healthcare providers and payers could result in decreased use and/or dosage of our products. Some examples of agency and organizational guidelines include:

- In August 2012, the Kidney Disease: Improving Global Outcomes group (KDIGO), a not-for-profit foundation managed by the National Kidney Foundation (NKF), published its updated global anemia guidelines in light of new study results, particularly the data from the TREAT trial, which had become available since the NKF-Kidney Disease Outcomes Quality Initiative (KDOQI™) clinical practice guidelines and clinical practice recommendations for anemia in CKD were released in 2007. The new guidelines recommend, among other things, that ESAs not be used to maintain Hb concentrations above 11.5 g/dL in adult patients with CKD. KDOQI has announced that it is preparing a U.S. commentary on the KDIGO global anemia guidelines which is expected to be released in 2013.

- In April 2012, the American Society of Clinical Oncology (ASCO) published a review in which it identified the top five opportunities to improve the quality and value of cancer care by curbing use of common tests and treatments that are not supported by clinical evidence. Among ASCO's suggestions in this review was that oncologists should avoid administering white blood cell stimulating factors (such as NEUPOGEN® and Neulasta®) to patients who have a very low risk for febrile neutropenia, a position consistent with ASCO's existing guidelines for the use of white blood cell stimulating factors.

In addition, HTA organizations, such as NICE in the UK and the Canadian Agency for Drugs and Technologies in Health, make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service impact of new, emerging and existing medicines and treatments.

Any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could materially and adversely affect our product sales, business and operating results. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price for our common stock.

The commercialization of certain of our product candidates and the marketing of certain of our products is dependent in part on our partners.

We have entered into agreements with third parties to assist in the commercialization of certain of our product candidates and the marketing of certain of our products in specified geographic areas. (See Item 1. Business — Business Relationships.) Many of these agreements involve the sharing of certain decisions and a division of responsibilities, costs and benefits. If our partners fail to effectively deliver on their marketing and commercialization commitments to us or if we and our partners fail to coordinate our efforts effectively, sales of our products may be materially and adversely affected.

Our risk mitigation measures and corporate compliance program cannot guarantee that we effectively manage all operational risks and that we are in compliance with all potentially applicable U.S. federal and state regulations and all potentially applicable foreign regulations and/or other requirements.

The development, manufacturing, distribution, pricing, sales, marketing and reimbursement of our products, together with our general operations, are subject to extensive federal and state regulation in the United States and to extensive regulation in foreign countries. (See Our current products and products in development cannot be sold if we do not maintain or gain regulatory approval and Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.) In addition, our business is complex and involves significant operational risks. While we have implemented numerous risk mitigation measures to comply with such regulations in this complex operating environment, we cannot guarantee that we will be able to effectively mitigate all operational risks. Further, we are now operating under a corporate integrity agreement with the U.S. Department of Health and Human Services, Office of Inspector General, which requires us to maintain our corporate compliance program and to undertake a set of defined corporate integrity obligations. The corporate integrity agreement requires us to make periodic attestations that we are implementing and following the provisions of the corporate integrity agreement, and provides for an independent third-party review organization to assess and report on our compliance. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws, all potentially applicable foreign regulations and/or laws and/or all requirements of the corporate integrity agreement. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements of the corporate integrity agreement, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material and adverse effect on our product sales, business and results of operations.

Cost savings initiatives may result in the carrying value of certain existing manufacturing facilities or other assets becoming impaired or other related charges being incurred.

Our business continues to face many challenges. In response to these challenges, we have worked and continue to work to improve cost efficiencies and to reduce discretionary expenditures. As part of those efforts, we undertake cost savings initiatives to evaluate our processes and procedures in order to identify opportunities for achieving greater efficiencies in how we conduct our business. In particular, we evaluate our manufacturing operations to identify opportunities to increase production yields and/or success rates as well as capacity utilization. Depending on the timing and outcomes of these cost savings initiatives, the carrying value of certain manufacturing or other assets may not be fully recoverable and could result in the recognition of impairment and/or other related charges. The recognition of such charges, if any, could have a material adverse effect on our results of operations.

The adoption of new tax legislation or exposure to additional tax liabilities could affect our profitability.

We are subject to income and other taxes in the United States and other jurisdictions in which we do business. As a result, our provision for income taxes is derived from a combination of applicable tax rates in the various places we operate. Significant judgment is required for determining our provision for income tax and our tax returns are periodically examined by various tax authorities. We believe our accrual for tax liabilities is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes

in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities, and changes in applicable tax laws, regulations or administrative interpretations thereof. For example, there are several proposals under consideration in the United States to reform tax law, including proposals that may reduce or eliminate the deferral of U.S. income tax on our unrepatriated foreign earnings. While it is uncertain how the U.S. Congress may address U.S. tax policy matters in the future, reform of U.S. taxation, including taxation of income earned outside the United States, continues to be a topic of discussion for the U.S. Congress and the Administration. A significant change to the U.S. tax system, such as a change to the taxation of income earned outside the United States, could have a material and adverse effect on our business and on the results of our operations.

There can be no assurance that we will continue to declare cash dividends or repurchase stock.

Our Board of Directors has declared quarterly dividends on our common stock since it adopted a dividend policy in 2011. In addition, in December 2012, our Board of Directors approved an increase in the total authorization for repurchases of our common stock in the amount of $2 billion. This amount was in addition to the approximately $0.5 billion then remaining under the existing stock repurchase authorization. Whether we continue and the amount and timing of such dividends and/or stock repurchases are subject to capital availability and periodic determinations by our Board of Directors that cash dividends and/or stock repurchases are in the best interest of our stockholders and are in compliance with all respective laws and agreements of the Company applicable to the declaration and payment of cash dividends and the repurchase of stock. Future dividends and stock repurchases, including their timing and amount, may be affected by, among other factors: our views on potential future capital requirements for strategic transactions, including acquisitions; debt service requirements; our credit rating; changes to applicable tax laws or corporate laws; and changes to our business model. In addition, the amount we spend and the number of shares we are able to repurchase under our stock repurchase program may further be affected by a number of other factors, including the stock price and blackout periods in which we are restricted from repurchasing shares. Our dividend payments and/or stock repurchases may change from time to time, and we cannot provide assurance that we will continue to declare dividends and/or repurchase stock in any particular amounts or at all. A reduction in or elimination of our dividend payments and/or stock repurchases could have a negative effect on our stock price.

The illegal distribution and sale by third parties of counterfeit versions of our products or of stolen or diverted products could have a negative impact on our reputation and business.

Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet the exacting standards of our Company's development, manufacturing and distribution processes. Counterfeit medicines pose a significant risk to patient health and safety because of the conditions under which they are manufactured and the lack of regulation of their contents. Counterfeit products are frequently unsafe or ineffective and can be potentially life-threatening. Our reputation and business could suffer harm as a result of counterfeit drugs sold under our brand name. In addition, products stolen from inventory, at warehouses, plants or while in transit or unlawfully diverted, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business. Public loss of confidence in the integrity of biologics and/or pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our product sales, business and results of operations.

We are increasingly dependent on information technology systems and infrastructure.

We are increasingly dependent upon information technology systems and infrastructure. The multitude and complexity of our computer systems make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to the Company, its patients, customers or other business partners, may be exposed to unauthorized persons or to the public. While we have in the past experienced cyber attacks and intrusions into our computer systems, we do not believe that such attacks have had a material adverse effect on our operations. While we have invested heavily in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us.

Our efforts to acquire other companies or products and to integrate their operations may not be successful, and may result in costs, delays or failures to realize the benefits of the transactions.

We have an ongoing process of evaluating potential merger, acquisition, partnering and in-license opportunities that we expect will contribute to our future growth and expand our geographic footprint, product offerings and/or our R&D pipeline. Such acquisitions may result in unanticipated costs, delays or other operational or financial problems related to integrating the acquired company and business with our company, which may result in the diversion of our management's attention from other business

issues and opportunities. Failures or difficulties in integrating the operations of the businesses that we acquire, including their personnel, technology, financial systems, distribution and general business operations and procedures, may affect our ability to grow and may result in us incurring asset impairment or restructuring charges.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

The following table summarizes our significant properties and their primary functions as of December 31, 2012. For additional information regarding manufacturing initiatives, see Item 1. Business — Manufacturing, Distribution and Raw Materials.

Location	Number of spaces or buildings		Other functions					
	Owned	Leased	Manufacturing	Administrative	Research and/or development	Sales and marketing	Warehouse	Distribution center
United States:								
Thousand Oaks, California	36	5	✔	✔	✔	✔	✔	✔
San Francisco, California	-	4		✔	✔			
Boulder, Colorado	2	2	✔	✔			✔	
Longmont, Colorado	6	1	✔	✔			✔	
Washington, D.C.	-	1		✔		✔		
Louisville, Kentucky	1	-					✔	✔
Cambridge, Massachusetts	1	-			✔			
Woburn, Massachusetts	-	2	✔	✔			✔	
West Greenwich, Rhode Island	6	-	✔	✔			✔	
Bothell, Washington	2	1			✔		✔	
Seattle, Washington	6	-		✔	✔			
Other U.S. cities	-	5		✔	✔	✔		
Outside United States:								
Australia	-	2		✔		✔		
Brazil	1	4	✔	✔		✔	✔	✔
Canada	-	3		✔	✔	✔		
Germany	-	5		✔	✔			
Ireland	7	2	✔	✔		✔	✔	
Japan	-	1		✔	✔			
Netherlands	8	-	✔	✔		✔	✔	✔
Puerto Rico	21	-	✔	✔			✔	
Switzerland	-	3		✔		✔		
Turkey	5	19	✔	✔		✔	✔	✔
United Kingdom	-	5	✔	✔	✔	✔		
Other countries	-	36			✔	✔	✔	

Our corporate headquarters are located in Thousand Oaks, California. In addition to the properties listed above, we have undeveloped land at certain U.S. locations, principally in Thousand Oaks, California; Longmont, Colorado; Louisville, Kentucky; Allentown, Pennsylvania; West Greenwich, Rhode Island; Seattle and Bothell, Washington; and Juncos, Puerto Rico, to accommodate future expansion as required. Excluded from the table above are leased properties that have been abandoned and certain buildings that we still own but are no longer used in our business. There are no material encumbrances on our properties.

We believe that our facilities are suitable for their intended use and, in conjunction with our third-party contracting manufacturing agreements, provide adequate capacity. We also believe that our existing facilities, our third-party contract manufacturing agreements and our anticipated additions are sufficient to meet our expected needs. See Item 1A. Risk Factors — We perform a substantial amount of our commercial manufacturing activities at our Puerto Rico manufacturing facility and a substantial amount of our clinical manufacturing activities at our Thousand Oaks, California, manufacturing facility; if significant natural disasters or production failures occur at the Puerto Rico facility, we may not be able to supply these products or, at the Thousand Oaks facility, we may not be able to continue our clinical trials, — We rely on third-party suppliers for certain of our raw materials, medical devices and components and — Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

Item 3. LEGAL PROCEEDINGS

Certain of the legal proceedings in which we are involved are discussed in Note 18, Contingencies and commitments, to our Consolidated Financial Statements in this Annual Report on Form 10-K and are hereby incorporated by reference.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Common stock

Our common stock trades on The NASDAQ Global Select Market under the symbol AMGN. As of February 19, 2013, there were approximately 8,466 holders of record of our common stock.

The following table sets forth, for the periods indicated, the range of high and low quarterly closing sales prices of the common stock as quoted on The NASDAQ Global Select Market:

Year ended December 31, 2012	High	Low
Fourth quarter	$ 90.17	$ 84.00
Third quarter	84.81	73.85
Second quarter	73.02	65.59
First quarter	69.84	63.76
Year ended December 31, 2011		
Fourth quarter	$ 64.74	$ 53.90
Third quarter	58.28	48.27
Second quarter	61.17	53.08
First quarter	57.31	50.95

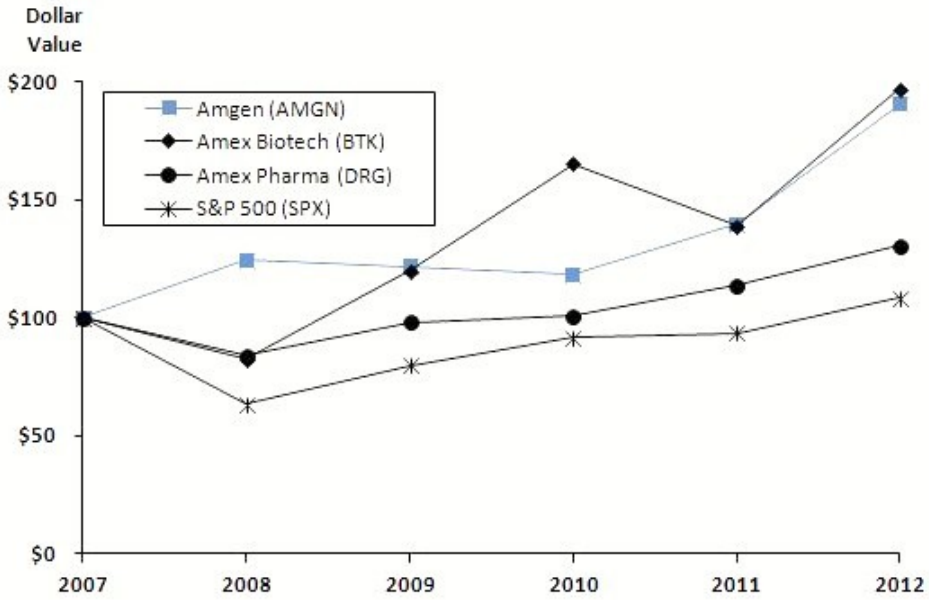
Performance graph

The following graph shows the value of an investment of $100 on December 31, 2007, in each of Amgen common stock, the Amex Biotech Index, the Amex Pharmaceutical Index and Standard & Poor's 500 Index (S&P 500). All values assume reinvestment of the pretax value of dividends and are calculated as of December 31 of each year. The historical stock price performance of the Company's common stock shown in the performance graph is not necessarily indicative of future stock price performance.

Amgen vs. Amex Biotech, Amex Pharmaceutical and S&P 500 Indices

Comparison of Five-Year Cumulative Total Return

Value of Investment of $100 on December 31, 2007



	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/31/2011	12/31/2012
Amgen (AMGN)	100.00	124.35	121.81	118.22	139.71	190.36
Amex Biotech (BTK)	100.00	82.29	119.79	164.99	138.85	196.61
Amex Pharmaceutical (DRG)	100.00	83.91	98.16	100.63	113.62	130.55
S&P 500 (SPX)	100.00	63.45	79.90	91.74	93.67	108.47

The material in this performance graph is not soliciting material, is not deemed filed with the SEC, and is not incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made on, before or after the date of this filing and irrespective of any general incorporation language in such filing.

Stock repurchase program

The Company intends to continue to return capital to stockholders through share repurchases, reflecting our confidence in the long-term value of the Company. The amount we spend, the number of shares repurchased and the timing of such repurchases will vary based on a number of factors, including the stock price, the availability of financing on acceptable terms, the amount and timing of dividend payments and blackout periods in which we are restricted from repurchasing shares; and the manner of purchases may include private block purchases, tender offers, as well as market transactions.

During the three months and year ended December 31, 2012, we had one outstanding stock repurchase program. Our repurchase activity for the three months and year ended December 31, 2012, was as follows:

	Total number of shares purchased	Average price paid per share(1)	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program(2)
October 1 - October 31	2,215,600	$ 86.39	2,215,600	$ 1,372,784,941
November 1 - November 30	7,723,400	85.72	7,723,400	710,747,356
December 1 - December 31	4,304,000	88.16	4,304,000	2,331,298,539
	14,243,000	86.56	14,243,000	
January 1 - December 31	62,334,610	$ 74.79	62,334,610	

(1) Average price paid per share includes related expenses.

(2) On October 13, 2011, our Board of Directors increased the authorization for repurchase of our common stock to an aggregate of $10 billion. On December 13, 2012, our Board of Directors increased the authorization for repurchase of our common stock by an additional $2 billion.

Dividends

We began paying quarterly cash dividends in 2011. On July 28 and October 13, 2011, the Board of Directors declared quarterly cash dividends of $0.28 per share of common stock, which were paid on September 8 and December 8, 2011, respectively. On December 15, 2011, and March 15, July 19 and October 10, 2012, the Board of Directors declared quarterly cash dividends of $0.36 per share of common stock, which were paid on March 7, June 7, September 7 and December 7, 2012, respectively. Additionally, on December 13, 2012, the Board of Directors declared a quarterly cash dividend of $0.47 per share of common stock, which will be paid on March 7, 2013.

We expect to continue to pay quarterly dividends, although the amount and timing of any future dividends are subject to approval by our Board of Directors.

Item 6. SELECTED FINANCIAL DATA

	Years ended December 31,				
Consolidated Statement of Income Data:	**2012**	**2011**	**2010**	**2009**	**2008**
	(In millions, except per share data)				
Revenues:					
Product sales	$ 16,639	$ 15,295	$ 14,660	$ 14,351	$ 14,687
Other revenues	626	287	393	291	316
Total revenues	17,265	15,582	15,053	14,642	15,003
Operating expenses:					
Cost of sales (excludes amortization of certain acquired intangible assets presented separately)	2,918	2,427	2,220	2,091	2,296
Research and development	3,380	3,167	2,894	2,864	3,030
Selling, general and administrative	4,801	4,486	3,983	3,820	3,789
Amortization of certain acquired intangible assets	294	294	294	294	294
Other[1]	295	896	117	67	380
Net income	4,345	3,683	4,627	4,605	4,052
Diluted earnings per share	5.52	4.04	4.79	4.51	3.77
Dividends paid per share	1.44	0.56	—	—	—

	As of December 31,				
Consolidated Balance Sheet Data:	**2012**	**2011**	**2010**	**2009**	**2008**
	(In millions)				
Total assets	$ 54,298	$ 48,871	$ 43,486	$ 39,629	$ 36,427
Total debt[2]	26,529	21,428	13,362	10,601	9,352
Total stockholders' equity[3]	19,060	19,029	23,944	22,667	20,885

In addition to the following notes, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and the Consolidated Financial Statements and accompanying notes and previously filed Annual Reports on Form 10-K for further information regarding our consolidated results of operations and financial position for periods reported therein and for known factors that will impact comparability of future results. Also, see Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities for information regarding cash dividends declared per share of common stock.

(1) In 2011, we recorded a $780 million legal settlement charge ($705 million, net of tax) in connection with an agreement in principle to settle allegations related to our sales and marketing practices. In 2008, we recorded loss accruals for settlements of certain commercial legal proceedings aggregating $288 million, related principally to the settlement of the Ortho Biotech Products L.P. antitrust suit.

(2) See Note 14, Financing arrangements, to the Consolidated Financial Statements for discussion of our financing arrangements. In addition, in 2009 and 2008, we issued $2.0 billion and $1.0 billion, respectively, aggregate principal amount of notes. In 2009 and 2008 we repaid $1.0 billion of fixed interest rate notes and $2.0 billion of floating-rate notes, respectively.

(3) Throughout the five years ended December 31, 2012, we had a share repurchase program authorized by the Board of Directors through which we repurchased $4.7 billion, $8.3 billion, $3.8 billion, $3.2 billion and $2.3 billion, respectively, of Amgen common stock.

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

Forward-looking statements

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business or others on our behalf, our beliefs and our management's assumptions. In addition, we, or others on our behalf, may make forward-looking statements in press releases or written statements, or in our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Such words as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume" and "continue," as well as variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in Item 1A. Risk Factors. We have based our forward-looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecast by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, earnings per share (EPS), liquidity and capital resources, trends and planned dividends and stock repurchases. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

The following management's discussion and analysis (MD&A) is intended to assist the reader in understanding Amgen's business. MD&A is provided as a supplement to, and should be read in conjunction with, our consolidated financial statements and accompanying notes. Our results of operations discussed in MD&A are presented in conformity with accounting principles generally accepted in the United States (GAAP).

We are a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. Our medicines help millions of patients in the fight against cancer, kidney disease, RA, bone disease and other serious illnesses. We operate in one business segment: human therapeutics. Therefore, our results of operations are discussed on a consolidated basis.

We earn revenues and income and generate cash primarily from sales of human therapeutic products in the areas of supportive cancer care, inflammation, nephrology and bone disease. Our principal products include Neulasta®, NEUPOGEN®, ENBREL, Aranesp®, EPOGEN®, XGEVA® and Prolia®. For additional information about our products, their approved indications and where they are marketed, see Item 1. Business — Marketed Products.

In 2012, we had several notable accomplishments, including achieving 11% revenue growth driven by strong performance across the portfolio. Product sales grew 9% in the United States and 7% in the ROW. We also continued paying quarterly dividends in 2012, and in December, we declared a dividend of $0.47 per share of common stock payable in March 2013, representing a 31% increase over the quarterly dividend paid in each of the past four quarters. Additionally, we repurchased 62 million shares of our common stock at an aggregate cost of $4.7 billion in 2012. Under our $10 billion authorized stock repurchase program announced in October 2011, we have repurchased a total of 146 million shares of our common stock for an aggregate cost of $9.7 billion at an average price of $66.37. Finally, we made significant advances in our product pipeline in 2012 including advancing AMG 145, brodalumab, romosozumab and rilotumumab to phase 3 clinical trials.

We enter 2013 with various opportunities to continue growing our business. We believe the currently approved indications for XGEVA® and Prolia® represent significant commercial opportunities. Longer-term growth may also be achieved by the successful development of our later stage pipeline, by expansion into emerging markets and Japan, and through strategic business development opportunities, such as our acquisitions of Micromet and MN in 2012. Our continued focus on increasing cost efficiencies will assist in providing the necessary resources to fund many of these future opportunities.

Our business will, however, continue to face various challenges. Certain of our products will face increasing competitive pressure as a result of competitive product launches. In the United States, ENBREL, EPOGEN® and XGEVA®, in particular, will be facing increased competition. Additionally, over the next several years, starting in 2013, certain of the existing patents on our principal products — including NEUPOGEN®, EPOGEN® and Aranesp® — will expire and, as a result, we expect to face increasing competition from biosimilars. For additional information, including with regard to the expiration of the patents for various products, see Item 1. Business — Marketed Products.

Current global economic conditions also pose challenges to our business, including continued pressure to reduce healthcare expenditures. Efforts to reduce health care costs are being made by third-party payers including governments and private payers. In the United States, various actions have been taken aimed at reducing healthcare spending. The continuing prominence of U.S. budget deficits increases the risk that taxes, fees, rebates, or other federal measures that would further reduce our revenues or increase our expenses may be enacted. As a result of the economic condition, the industry continues to experience significant pricing pressures and other cost containment measures in certain European countries also.

Our long-term success depends to a great extent on our ability to continue to discover, develop and commercialize innovative products and acquire or collaborate on therapies currently in development by other companies. The discovery and development of safe and effective new products, as well as the development of additional indications for existing products, are necessary for the continued strength of our businesses. Our product lines must be replenished over time in order to offset revenue losses when products lose their exclusivity or competing products are launched, as well as to provide for revenue and earnings growth. We devote considerable resources to R&D activities. However, successful product development in the biotechnology industry is highly uncertain. We are also confronted by increasing regulatory scrutiny of safety and efficacy before and after products have been launched.

Finally, our product sales are subject to certain influences throughout the year, including wholesaler and end-user buying patterns (e.g., wholesaler and end-user stocking, contract-driven buying and patients delaying certain purchasing or physician visits). Such factors can result in higher demand for our products and/or higher wholesaler inventory levels and, therefore, higher product sales for a given three-month period, generally followed by a decline in product sales in the subsequent three-month period. For example, sales of certain of our products in the United States for the three months ended March 31 can be slightly lower relative to the immediately preceding three-month period. While this can result in variability in quarterly product sales on a sequential basis, these effects have generally not been significant when comparing product sales in the three months ended March 31 with product sales in the corresponding period of the prior year.

See Item 1. Business — Marketed Products and Item 1A. Risk Factors for further discussion of certain of the factors that could impact our future product sales.

Selected financial information

The following is an overview of our results of operations as well as our financial condition (in millions, except percentages and per share data):

	2012	Change	2011
Product sales:			
U.S.	$ 12,815	9 %	$ 11,725
ROW	3,824	7 %	3,570
Total product sales	16,639	9 %	15,295
Other revenues	626	*	287
Total revenues	$ 17,265	11 %	$ 15,582
Operating expenses	$ 11,688	4 %	$ 11,270
Operating income	$ 5,577	29 %	$ 4,312
Net income	$ 4,345	18 %	$ 3,683
Diluted EPS	$ 5.52	37 %	$ 4.04
Diluted shares	787	(14)%	912

* Change in excess of 100%

When discussing changes in product sales below, any reference to unit growth or decline refers to changes in the purchases of our products by healthcare providers, such as physicians or their clinics, dialysis centers, hospitals and pharmacies.

The increase in U.S. product sales for 2012 reflects growth across the portfolio except ESAs, which declined 10%. Excluding ESAs, U.S. product sales increased 16% driven primarily by unit growth and, to a lesser extent, increases in average net sales prices. The increase in ROW product sales for 2012 reflects growth for all of our marketed products except Aranesp®, which declined 4%, and combined Neulasta®/NEUPOGEN®, which declined 9%.

The increase in other revenues for 2012 was driven by a modification to our Takeda collaboration, which replaced a global co-development and profit share agreement for motesanib, originally signed in 2008, with an exclusive license for Takeda to

develop, manufacture and commercialize motesanib. That modification resulted in revenue recognition of $232 million. The increase also reflects milestone payments received from AstraZeneca and Astellas Pharma Inc.

Operating expenses in 2011 included a previously disclosed charge for a legal settlement reserve of $780 million.

The increase in net income for 2012 was due primarily to higher operating income, offset partially by higher interest expense, net, and higher effective income tax rates.

The increase in diluted EPS for 2012 was driven primarily by increases in net income and by the favorable impacts of our stock repurchase program, which reduced the number of shares used to compute diluted EPS.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is offset partially by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros.

Commencing January 1, 2011, Puerto Rico imposes a temporary excise tax on the purchase of goods and services from a related manufacturer in Puerto Rico. The excise tax is imposed on the gross intercompany purchase price of the goods and services and is effective for a six-year period beginning in 2011, with the excise tax rate declining in each year (4% in 2011, 3.75% in 2012, 2.75% in 2013, 2.5% in 2014, 2.25% in 2015 and 1% in 2016). In February 2013, the Puerto Rico government proposed an amendment to the excise tax legislation which, if approved, would increase the excise tax rate to 4% effective July 1, 2013 through 2017. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in cost of sales when the related products are sold. For U.S. income tax purposes, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes in the year in which the excise tax is incurred. This excise tax has had and will continue to have a significant adverse impact on our cost of sales and a significant favorable impact on our provision for income taxes. In addition, the overall impact of the excise tax will vary from period to period as a result of the timing difference between recognizing the expense and the applicable foreign tax credit. As a result of the excise tax in 2012, cost of sales increased by $343 million, the provision for income taxes was reduced by $337 million and EPS was unfavorably impacted by $0.01. In 2011, cost of sales increased by $211 million, the provision for income taxes was reduced by $321 million and EPS was favorably impacted by $0.12.

As of December 31, 2012, our cash, cash equivalents and marketable securities totaled $24.1 billion, and total debt outstanding was $26.5 billion. Of our total cash, cash equivalents and marketable securities balance as of December 31, 2012, approximately $18.9 billion was generated from operations in foreign tax jurisdictions and is intended to be invested indefinitely outside the United States. Under current tax laws, if these funds were repatriated for use in our U.S. operations, we would be required to pay additional income taxes at the tax rates then in effect.

Results of Operations

Product sales

Worldwide product sales were as follows (dollar amounts in millions):

	2012	Change	2011	Change	2010
Neulasta®/NEUPOGEN ®	$ 5,352	3 %	$ 5,212	8 %	$ 4,844
ENBREL	4,236	14 %	3,701	5 %	3,534
Aranesp®	2,040	(11)%	2,303	(7)%	2,486
EPOGEN®	1,941	(5)%	2,040	(19)%	2,524
XGEVA®	748	*	351	*	8
Prolia®	472	*	203	*	33
Other products	1,850	25 %	1,485	21 %	1,231
Total product sales	$ 16,639	9 %	$ 15,295	4 %	$ 14,660
Total U.S.	$ 12,815	9 %	$ 11,725	4 %	$ 11,254
Total ROW	3,824	7 %	3,570	5 %	3,406
Total product sales	$ 16,639	9 %	$ 15,295	4 %	$ 14,660

* Change in excess of 100%

Future sales of our products will depend, in part, on the factors discussed in the Overview, Item 1. Business - Marketed Products, Item 1A. Risk Factors and any additional factors discussed in the individual product sections below.

Neulasta®/NEUPOGEN®

Total Neulasta® and total NEUPOGEN® sales by geographic region were as follows (dollar amounts in millions):

	2012	Change	2011	Change	2010
Neulasta® — U.S.	$ 3,207	7 %	$ 3,006	13 %	$ 2,654
Neulasta® — ROW	885	(6)%	946	5 %	904
Total Neulasta®	4,092	4 %	3,952	11 %	3,558
NEUPOGEN® — U.S.	1,007	5 %	959	3 %	932
NEUPOGEN® — ROW	253	(16)%	301	(15)%	354
Total NEUPOGEN®	1,260	— %	1,260	(2)%	1,286
Total Neulasta®/NEUPOGEN®	$ 5,352	3 %	$ 5,212	8 %	$ 4,844

The increase in U.S. Neulasta® sales for 2012 was driven by an increase in the average net sales price. The decrease in ROW Neulasta® sales for 2012 was due primarily to a decrease in unit demand from loss of share to biosimilars in Europe and a decrease in the average net sales price.

The increase in U.S. NEUPOGEN® sales for 2012 was driven by an increase in the average net sales price. The decrease in ROW NEUPOGEN® sales for 2012 was driven by a decrease in unit demand from loss of share to biosimilars in Europe.

The increase in U.S. Neulasta® sales for 2011 was driven by increases in both unit demand and the average net sales price. The increase in ROW Neulasta® sales for 2011 was driven primarily by an increase in unit demand.

The increase in U.S. NEUPOGEN® sales for 2011 was driven by an increase in the average net sales price, offset partially by a decrease in unit demand. The decrease in ROW NEUPOGEN® sales for 2011 was driven by a decrease in unit demand, in part, from loss of share to biosimilars in Europe, and a decrease in the average net sales price.

Our outstanding material U.S. patents for Filgrastim (NEUPOGEN®) expire in December 2013. We expect to face competition in the United States beginning in the fourth quarter of 2013, which may have a material adverse impact over time on future sales of NEUPOGEN® and, in turn, Neulasta®. See Financial Condition, Liquidity and Capital Resources for further discussion of the potential impact of patent expiration. Our outstanding material U.S. patent for pegfilgrastim (Neulasta®) expires in 2015.

Future Neulasta®/NEUPOGEN® sales will also depend, in part, on the development of new protocols, tests and/or treatments for cancer and/or new chemotherapy treatments or alternatives to chemotherapy that may have reduced and may continue to reduce the use of chemotherapy in some patients.

ENBREL

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	2012	Change	2011	Change	2010
ENBREL — U.S.	$ 3,967	15%	$ 3,458	5%	$ 3,304
ENBREL — Canada	269	11%	243	6%	230
Total ENBREL	$ 4,236	14%	$ 3,701	5%	$ 3,534

The increase in ENBREL sales for 2012 was driven primarily by an increase in the average net sales price and, to a lesser extent, an increase in unit demand.

The increase in ENBREL sales for 2011 was driven primarily by an increase in the average net sales price.

ENBREL also faces increased competition. See Item 1. Business — Marketed Products.

Aranesp®

Total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	2012	Change	2011	Change	2010
Aranesp® — U.S.	$ 782	(21)%	$ 986	(11)%	$ 1,103
Aranesp® — ROW	1,258	(4)%	1,317	(5)%	1,383
Total Aranesp®	$ 2,040	(11)%	$ 2,303	(7)%	$ 2,486

The decrease in U.S. Aranesp® sales for 2012 was driven by a decline in unit demand. The unit decline reflects changes in practice patterns resulting from changes to the label and to the reimbursement environment that occurred during 2011 (2011 changes). The decrease in ROW Aranesp® sales for 2012 was due primarily to a decrease in the average net sales price.

Sequentially, global Aranesp® unit demand was down 5% in the quarter ended December 31, 2012, compared with the quarter ended September 30, 2012.

The decrease in U.S. Aranesp® sales for 2011 was driven primarily by a decline in unit demand due to the impact of the 2011 changes, offset partially by an increase in the average net sales price. The decrease in ROW Aranesp® sales for 2011 was due to a decrease in the average net sales price and a unit decline, reflecting segment contraction.

EPOGEN®

Total EPOGEN® sales were as follows (dollar amounts in millions):

	2012	Change	2011	Change	2010
EPOGEN® — U.S.	$ 1,941	(5)%	$ 2,040	(19)%	$ 2,524

The decrease in EPOGEN® sales for 2012 was driven by a 23% decrease in unit demand, driven by reductions in dose utilization due to changes to the label and to the reimbursement environment that occurred in 2011. This decrease was offset partially by reductions in customer discounts, as part of new provider contracts that became effective January 1, 2012, and by a year-over-year favorable change in accounting estimates of $96 million.

The decrease in EPOGEN® sales for 2011 was due primarily to a decrease in unit demand due to the impact of the 2011 changes, offset partially by an increase in the average net sales price and patient population growth.

Future EPOGEN® sales will also depend, in part, on such factors as:

- increased competition in the U.S. dialysis setting;
- changes in dose utilization as healthcare providers continue to refine their treatment practices in accordance with approved labeling;
- new or amended contracts with dialysis centers; and
- adoption of alternative therapies or development of new modalities to treat anemia associated with CKD.

XGEVA® and Prolia®

Total XGEVA® and total Prolia® sales by geographic region were as follows (dollar amounts in millions):

	2012	Change	2011	Change	2010
XGEVA® — U.S.	$ 644	88%	$ 343	*	$ 8
XGEVA® — ROW	104	*	8	N/A	—
Total XGEVA®	748	*	351	*	8
Prolia® — U.S.	292	*	130	*	26
Prolia® — ROW	180	*	73	*	7
Total Prolia®	472	*	203	*	33
Total XGEVA®/Prolia®	$ 1,220	*	$ 554	*	$ 41

* Change in excess of 100%

The increases in global XGEVA® and Prolia® sales for 2012 and 2011 were driven primarily by unit growth.

Sequentially, global XGEVA® and Prolia® sales increased 7% and 40%, respectively, in the quarter ended December 31, 2012, compared with the quarter ended September 30, 2012.

XGEVA® also faces increased competition. See Item 1. Business — Marketed Products.

Other products

Other product sales by geographic region were as follows (dollar amounts in millions):

	2012	Change	2011	Change	2010
Sensipar®—U.S.	$ 639	23%	$ 518	13%	$ 459
Sensipar®/Mimpara®—ROW	311	7%	290	14%	255
Vectibix®—U.S.	122	—%	122	6%	115
Vectibix®—ROW	237	19%	200	16%	173
Nplate®—U.S.	214	31%	163	26%	129
Nplate®—ROW	154	15%	134	34%	100
Other—ROW	173	*	58	N/A	—
Total other product sales	$ 1,850	25%	$ 1,485	21%	$ 1,231
Total U.S.— other products	$ 975	21%	$ 803	14%	$ 703
Total ROW— other products	875	28%	682	29%	528
Total other product sales	$ 1,850	25%	$ 1,485	21%	$ 1,231

* Change in excess of 100%

Operating expenses

Operating expenses were as follows (dollar amounts in millions):

	2012	Change	2011	Change	2010
Operating expenses:					
Cost of sales (excludes amortization of certain acquired intangible assets presented separately)	$ 2,918	20 %	$ 2,427	9%	$ 2,220
% of product sales	17.5%		15.9%		15.1%
Research and development	$ 3,380	7 %	$ 3,167	9%	$ 2,894
% of product sales	20.3%		20.7%		19.7%
Selling, general and administrative	$ 4,801	7 %	$ 4,486	13%	$ 3,983
% of product sales	28.9%		29.3%		27.2%
Amortization of certain acquired intangible assets	$ 294	— %	$ 294	—%	$ 294
Other	$ 295	(67)%	$ 896	*	$ 117

* Change in excess of 100%

Cost of sales

Cost of sales, which excludes the amortization of certain acquired intangible assets, increased to 17.5% of product sales for 2012, driven primarily by product mix and the Puerto Rico excise tax. Excluding the impacts of the Puerto Rico excise tax, cost of sales would have been 15.5% and 14.5% of product sales for 2012 and 2011, respectively.

Cost of sales increased to 15.9% of product sales for 2011. Excluding the impact of the Puerto Rico excise tax, cost of sales would have been 14.5% of product sales compared with 15.1% for 2010. The decrease was driven by improved productivity, offset partially by certain expenses related to actions to improve cost efficiencies.

Research and development

R&D costs are expensed as incurred and include primarily salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems' costs and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs and cost recoveries associated with K-A and third-party R&D arrangements, including upfront fees and milestones paid to third parties in connection with technologies which had not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs is recognized when the obligations are incurred or as we become entitled to the cost recovery.

The Company groups all of its R&D activities and related expenditures into three categories: (1) Discovery Research and Translational Sciences, (2) later stage clinical programs and (3) marketed products. These categories include the Company's R&D activities as set forth in the following table:

Category	Description
Discovery Research and Translational Sciences	R&D expenses incurred in activities substantially in support of early research through the completion of phase 1 clinical trials. These activities encompass our discovery research and translational sciences functions, including drug discovery, toxicology, pharmacokinetics and drug metabolism, and process development.
Later stage clinical programs	R&D expenses incurred in or related to phase 2 and phase 3 clinical programs intended to result in registration of a new product or a new indication for an existing product in the United States or the EU.
Marketed products	R&D expenses incurred in support of the Company's marketed products that are authorized to be sold in the United States or the EU. Includes clinical trials designed to gather information on product safety (certain of which may be required by regulatory authorities) and their product characteristics after regulatory approval has been obtained, as well as the costs of obtaining regulatory approval of a product in a new market after approval in either the United States or the EU has been obtained.

R&D expense by category was as follows (in millions):

	2012	2011	2010
Discovery Research and Translational Sciences	$ 1,137	$ 1,125	$ 1,154
Later stage clinical programs	1,285	983	832
Marketed products	958	1,059	908
Total R&D expense	$ 3,380	$ 3,167	$ 2,894

The increase in R&D expense for 2012 was driven primarily by an increase of $302 million in our later stage clinical programs, including AMG 145 and romosozumab; and an increase of $12 million in Discovery Research and Translational Sciences activities, offset partially by reduced expenses associated with marketed product support of $101 million.

The increase in R&D expense for 2011 was driven primarily by an increase of $151 million in our marketed product support driven largely by our continued support for Prolia® and XGEVA® which, subsequent to their approvals during 2010, were categorized as marketed products rather than later stage clinical programs; and an increase of $151 million in our later stage clinical program support, including AMG 386, ganitumab (AMG 479), talimogene laherparepvec and AMG 145, offset partially by decreased support for Prolia® and XGEVA® as a result of their aforementioned approvals. These increases were offset partially by a decrease of $29 million in our Discovery Research and Translational Sciences activities, due primarily to reduced amortization expense related to R&D technology intangible assets acquired in business combinations in prior years.

Selling, general and administrative

Selling, general and administrative (SG&A) expenses are comprised primarily of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses; and other general and administrative costs. Advertising costs are expensed as incurred. SG&A expenses also include costs and cost recoveries associated with marketing and promotion efforts under certain collaboration arrangements. Net payment or reimbursement of SG&A costs is recognized when the obligations are incurred or when we become entitled to the cost recovery. Beginning January 1, 2011, SG&A expenses also include the annual U.S. healthcare reform federal excise fee.

The increase in SG&A expense for 2012 was driven primarily by higher ENBREL profit share expenses of $207 million as well as international expansion of $87 million, offset partially by lower U.S. healthcare reform federal excise fee expense of $106 million in 2012 compared with 2011, which includes a $61 million favorable adjustment related to the 2011 fee.

The increase in SG&A expense for 2011 was driven primarily by the U.S. healthcare reform estimated federal excise fee of $151 million; higher ENBREL profit share expense of $104 million; increased expenses related to the launches of Prolia® and XGEVA® and expansion of our international operations of $89 million; and the unfavorable impact of foreign exchange of $67 million.

For the years ended December 31, 2012, 2011 and 2010, the expenses associated with the ENBREL profit share were $1,495 million, $1,288 million and $1,184 million, respectively.

Other

Other operating expenses for 2012 included certain charges related to our cost savings initiatives of $175 million, which includes severance and expenses associated with abandoning leased facilities, legal proceedings charges of $64 million and other operating expenses of $56 million, which includes adjustments to our estimated contingent consideration liability related to a prior-year business combination.

Other operating expenses for 2011 included primarily a legal settlement charge of $780 million and certain charges related to cost savings initiatives, primarily severance, of $109 million.

In 2010, we recorded a $118 million asset impairment charge for our manufacturing operations located in Fremont, California, associated with our efforts to optimize our network of manufacturing facilities and improve cost efficiencies.

See Note 18, Contingencies and commitments, to the Consolidated Financial Statements for further discussion of our 2011 legal settlement.

Non-operating expenses/income and provision for income taxes

Non-operating expenses/income and provisions for income taxes were as follows (dollar amounts in millions):

	2012	2011	2010
Interest expense, net	$ 1,053	$ 610	$ 604
Interest and other income, net	$ 485	$ 448	$ 376
Provisions for income taxes	$ 664	$ 467	$ 690
Effective tax rate	13.3%	11.3%	13.0%

Interest expense, net

Included in interest expense, net, for the years ended December 31, 2012, 2011 and 2010, is the impact of non-cash interest expense of $140 million, $143 million and $266 million, respectively, on our convertible debt. The increase of interest expense in 2012 was due primarily to a higher average debt balance.

Interest and other income, net

The increase in interest and other income, net, for 2012 was due primarily to higher interest income due to a higher average balance of cash, cash equivalents and marketable securities offset partially by lower yields and lower net gains realized on investments.

The increase in interest and other income, net, for 2011 was due primarily to higher net realized gains on sales of investments.

Income taxes

The increase in our effective tax rate for 2012 was due primarily to the unfavorable tax impact of changes in the jurisdictional mix of income and expenses and the exclusion of the federal R&D tax credit in 2012, offset partially by the favorable resolution of certain state tax matters related to prior years. Because the ATRA of 2012 was not enacted until 2013, certain provisions of the Act which will retroactively benefit the Company's 2012 federal taxes, including the reinstatement of the R&D tax credit for 2012, cannot be recognized in the Company's 2012 financial results and instead will be reflected in the company's 2013 financial results for the first quarter. The tax benefit of the retroactive reinstatement of the 2012 R&D tax credit that will be recognized in the first quarter of 2013 is approximately $65 million. Subsequent to December 31, 2012, we also settled the examination of our U.S. tax returns with the Internal Revenue Service relating to years ended December 31, 2007, 2008, and 2009. We will recognize the tax

impact of this settlement in the first quarter of 2013. We expect the settlement to result in a tax benefit of approximately $185 million.

The decrease in our effective tax rate for 2011 was due primarily to the foreign tax credits associated with the Puerto Rico excise tax described below offset partially by the effect of the non-deductible U.S. healthcare reform federal excise fee in 2011, the non-deductible portion of the legal settlement reached in principle in 2011 and the favorable resolution in 2010 of certain prior years' non-routine transfer pricing matters with tax authorities.

Commencing January 1, 2011, Puerto Rico imposes a temporary excise tax on the purchase of goods and services from a related manufacturer in Puerto Rico. The excise tax is imposed on the gross intercompany purchase price of the goods and services and is effective for a six-year period beginning in 2011, with the excise tax rate declining in each year (4% in 2011, 3.75% in 2012, 2.75% in 2013, 2.5% in 2014, 2.25% in 2015 and 1% in 2016). In February 2013, the Puerto Rico government proposed an amendment to the excise tax legislation which, if approved, would increase the excise tax rate to 4% effective July 1, 2013 through 2017. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in cost of sales when the related products are sold. For U.S. income tax purposes, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes in the year in which the excise tax is incurred. The effective tax rates for 2012 and 2011 would have been approximately 18.7% and 18.0%, respectively, without the impact of the tax credits associated with the Puerto Rico excise tax.

As permitted under U.S. GAAP, we do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be invested indefinitely outside the United States.

See Summary of Critical Accounting Policies — Income taxes and Note 4, Income taxes, to the Consolidated Financial Statements for further discussion.

Financial Condition, Liquidity and Capital Resources

Selected financial data was as follows as of December 31, 2012 and 2011 (in millions):

	2012	2011
Cash, cash equivalents and marketable securities	$ 24,061	$ 20,641
Total assets	54,298	48,871
Current portion of long-term debt	2,495	84
Long-term debt	24,034	21,344
Stockholders’ equity	19,060	19,029

The Company intends to continue to return capital to stockholders through share repurchases and the payment of cash dividends, reflecting our confidence in the future cash flows of our business. The amount we spend, the number of shares repurchased and the timing of such repurchases will vary based on a number of factors, including the stock price, the availability of financing on acceptable terms, the amount and timing of dividend payments and blackout periods in which we are restricted from repurchasing shares; and the manner of purchases may include private block purchases, tender offers, and market transactions. Whether and when we declare dividends or repurchase stock, the size of any dividend and the amount of stock we repurchase could be affected by a number of additional factors. (See Item 1A. Risk Factors — There can be no assurance that we will continue to declare cash dividends or repurchase stock). During 2011, we repurchased a total of 144 million shares of our common stock at an aggregate cost of $8.3 billion. In October 2011, we announced our intent to accelerate our repurchase program and that our Board of Directors had authorized an increase in our stock repurchase program to $10 billion. Subsequent to this authorization through December 31, 2011, we repurchased 83 million shares of our common stock at an aggregate cost of $5.0 billion. During 2012, we repurchased 62 million shares of our common stock at an aggregate cost of $4.7 billion. This brings the total of shares repurchased under this approved $10 billion authorization to 146 million at a total cost of $9.7 billion at an average cost of $66.37 per share. In December 2012, the Board of Directors approved an increase in the stock repurchase authorization by $2.0 billion, and as of December 31, 2012, $2.3 billion remained available under this stock repurchase program, which is expected to cover our share repurchase activity into 2014.

In February 2013, our 0.375% 2013 Convertible Notes matured/converted, and accordingly, the $2.5 billion principal amount was settled in cash. We also elected to pay the note holders who converted their notes $99 million of cash for the excess conversion value, as allowed by the original terms of the notes, which was offset by the receipt of the same amount of cash from the counterparty to the related convertible note hedge. See Note 14, Financing arrangements, to the Consolidated Financial Statements for a discussion of these convertible notes.

In April 2011, the Board of Directors approved a dividend policy related to our common stock and subsequently declared quarterly cash dividends of $0.28 per share of common stock in July and October 2011, resulting in dividend payments aggregating $500 million in 2011. In December 2011, the Board of Directors declared a 29% increase in our quarterly cash dividend to $0.36 per share of common stock, resulting in dividend payments aggregating $1.1 billion in 2012. In December 2012, the Board of Directors declared a 31% increase in our quarterly cash dividend to $0.47 per share of common stock, payable in March 2013.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities, in each case for the foreseeable future. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or our syndicated credit facility and access to other domestic and foreign debt markets and equity markets. With respect to our U.S. operations, we believe that existing funds intended for use in the United States; cash generated from our U.S. operations, including intercompany payments and receipts; and existing sources of and access to financing (collectively referred to as “U.S. funds”) are adequate to continue to meet our U.S. obligations (including our plans to repurchase stock and pay dividends with U.S. funds) for the foreseeable future. See Item 1A. Risk Factors — Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

A significant portion of our operating cash flows is dependent on the timing of payments from our customers located in the United States and, to a lesser extent, our customers outside the United States, which include government-owned or -supported healthcare providers (government healthcare providers). Payments from these government healthcare providers are dependent in part on the economic stability and creditworthiness of their applicable country. Historically, some payments from a number of European government healthcare providers have extended beyond the contractual terms of sale, and regional economic uncertainty continues. In particular, credit and economic conditions in Southern Europe, particularly in Spain, Italy, Greece and Portugal, continue to adversely impact the timing of collections of our trade receivables in this region. As of December 31, 2012, accounts receivable in these four countries totaled $400 million, of which $281 million was past due, with the past due receivables primarily in Italy, Spain and Portugal. Although economic conditions in this region may continue to affect the average length of time it takes to collect payments, to date we have not incurred any significant losses related to these receivables; and the timing of payments in these countries has not had nor is it currently expected to have a material adverse impact on our overall operating cash flows. However, if government funding for healthcare were to become unavailable in these countries or if significant adverse adjustments to past payment practices were to occur, we might not be able to collect the entire balance of these receivables. We will continue working closely with these customers, monitoring the economic situation and taking appropriate actions as necessary.

Over the next several years, certain of the existing patents on our principal products will expire. As a result, we expect to face increasing competition thereafter, including from biosimilars, which may have a material adverse impact on our product sales, results of operations and liquidity. In the EU, there is already an established regulatory pathway for biosimilars and we are facing increasing competition from biosimilars. The 2010 U.S. healthcare reform legislation authorized the FDA to approve biosimilars under a new, abbreviated pathway. (See Item 1. Business — Marketed Products.) In the United States after patent expiration, we expect to face greater competition than today, including from manufacturers with biosimilars approved in Europe that may seek to obtain U.S. approval. We have many opportunities to grow our business, including the continued commercialization of XGEVA® and Prolia® and expansion into emerging markets and Japan, which we believe may offset the adverse financial impact of our principal products' patent expiries.

Cash, cash equivalents and marketable securities

Of our total cash, cash equivalents and marketable securities balances as of December 31, 2012, approximately $18.9 billion was generated from operations in foreign tax jurisdictions and is intended to be invested indefinitely outside the United States. Under current tax laws, if these funds were repatriated for use in our U.S. operations, we would be required to pay additional income taxes at the tax rates then in effect.

The primary objective of our investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits debt security investments to certain types of debt and money market instruments issued by institutions with primarily investment grade credit ratings and places restrictions on maturities and concentration by asset class and issuer.

Financing arrangements

The current and noncurrent portions of our long-term borrowings at December 31, 2012, were $2.5 billion and $24.0 billion, respectively. The current and noncurrent portions of our long-term borrowings at December 31, 2011, were $84 million and $21.3 billion, respectively.

We issued debt securities in various offerings during the three years ended December 31, 2012, including $5.0 billion, $10.5 billion and $2.5 billion aggregate principal amounts of notes in 2012, 2011 and 2010, respectively.

In 2012, we repaid $123 million of debt, including the redemption of all of our outstanding zero-coupon convertible notes due in 2032 and debt assumed in the acquisition of MN and deCODE Genetics. In February 2011, our 0.125% 2011 Convertible Notes became due, and we repaid the $2.5 billion aggregate principal amount. No debt was due or repaid in 2010.

To achieve a desired mix of fixed and floating interest rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating London Interbank Offered Rates (LIBOR)-based coupon over the life of the respective note. These interest rate swap contracts qualified and were designated as fair value hedges. As of December 31, 2011, we had interest rate swap contracts on debt with an aggregate face value of $3.6 billion, which, due to historically low interest rates, were terminated in May 2012. See Note 14, Financing arrangements, and Note 17, Derivative instruments, to the Consolidated Financial Statements for further discussion of our interest rate swap contracts.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts, which effectively convert the interest payments and principal repayment of the respective notes from euros/pounds sterling to U.S. dollars. These cross-currency swap contracts qualify and are designated as cash flow hedges. As of December 31, 2012 and 2011, we had cross-currency swap contracts with aggregate notional amounts of $2.7 billion and $748 million, respectively. See Note 17, Derivative instruments, to the Consolidated Financial Statements for further discussion of our cross-currency swap contracts.

As of December 31, 2012, we have a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working capital needs. At December 31, 2012 and 2011, we had no amounts outstanding under our commercial paper program.

In December 2011, we entered into a $2.5 billion syndicated, unsecured, revolving credit agreement which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $500 million with the agreement of the banks. Each bank which is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.1% based on our current credit rating. Generally, we would be charged interest at LIBOR plus 0.9% for any amounts borrowed under this facility. As of December 31, 2012 and 2011, no amounts were outstanding under this facility.

In March 2011, we filed a shelf registration statement with the SEC to replace an existing shelf registration statement that was scheduled to expire in April 2011. This shelf registration statement allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depository shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depository shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in March 2014.

In 1997, we established a $400 million medium-term note program under which medium-term debt securities may be offered from time to time with terms to be determined at the time of issuance. As of December 31, 2012 and 2011, no securities were outstanding under this medium-term note program.

Certain of our financing arrangements contain non-financial covenants. In addition, our revolving credit agreement includes a financial covenant with respect to the level of our borrowings in relation to our equity, as defined. We were in compliance with all applicable covenants under these arrangements as of December 31, 2012.

See Note 14, Financing arrangements, to the Consolidated Financial Statements for further discussion of our financing arrangements.

Cash flows

Our cash flow activity was as follows (in millions):

	2012	2011	2010
Net cash provided by operating activities	$ 5,882	$ 5,119	$ 5,787
Net cash used in investing activities	(9,990)	(786)	(4,152)
Net cash provided by (used in) financing activities	419	(674)	(1,232)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities increased during 2012 due primarily to the timing and amount of receipts from customers, an increase in net income, timing of payments to vendors and taxing authorities, cash received in connection with the termination of our interest rate swap agreements of $397 million and the impact of decreased inventory-related expenditures. These increases were offset partially by a payment associated with the previously disclosed litigation settlement. Cash provided by operating activities during 2011 decreased due primarily to increased interest payments, working capital increases related to the launch of Prolia® and XGEVA® and the prepayment of certain royalties.

Investing

Capital expenditures, which were associated primarily with manufacturing capacity expansions in Ireland and Puerto Rico, as well as other site developments, totaled $689 million, $567 million and $580 million in 2012, 2011 and 2010, respectively. We currently estimate 2013 spending on capital projects and equipment to be approximately $700 million.

Cash used in investing activities during the years ended December 31, 2012 and 2011, also included the cost of acquiring certain businesses, net of cash acquired, which totaled $2.4 billion and $701 million, respectively.

Net purchases of marketable securities were $6.9 billion for 2012, compared to net proceeds of $437 million for 2011 and net purchases of $3.5 billion for 2010.

Financing

Cash provided by financing activities during 2012 was due to net proceeds from the issuance of long-term debt of $4.9 billion and net proceeds from the issuance of common stock in connection with the Company's equity award programs of $1.3 billion, offset partially by repurchases of our common stock of $4.6 billion and the payment of dividends of $1.1 billion. Cash used in financing activities during 2011 was due to the repurchases of our common stock of $8.3 billion, including $5 billion purchased in a modified Dutch auction tender offer in December 2011; repayment of long-term debt of $2.5 billion; and payment of dividends of $500 million, offset partially by net proceeds from the issuance of long-term debt of $10.4 billion, including $7.5 billion issued in November and December 2011, in part, to finance the repurchase of our common stock in the modified Dutch auction tender offer. Cash used in financing activities during 2010 was due to the repurchases of our common stock of $3.8 billion, offset partially by the net proceeds from issuance of long-term debt of $2.5 billion.

See Note 14, Financing arrangements, and Note 15, Stockholders' equity, to the Consolidated Financial Statements for further discussion.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are material or reasonably likely to become material to our consolidated financial position or consolidated results of operations.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payment. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information. Timing of payments and actual amounts paid may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations.

The following table represents our contractual obligations as of December 31, 2012, aggregated by type (in millions):

	Payments due by period				
Contractual obligations	Total	Year 1	Years 2 and 3	Years 4 and 5	Years 6 and beyond
Long-term debt obligations [1] [2]	$ 44,885	$ 3,601	$ 4,114	$ 6,048	$ 31,122
Operating lease obligations	741	121	187	146	287
Purchase obligations [3]	2,921	832	681	393	1,015
Unrecognized tax benefits (UTBs) [4]	—	—	—	—	—
Total contractual obligations	$ 48,547	$ 4,554	$ 4,982	$ 6,587	$ 32,424

(1) Long-term debt obligations include contractual interest payments and principal repayment of our debt obligations. In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our pound sterling and euro denominated long-term debt issued in 2012 and 2011, we entered into cross-currency swap contracts that effectively convert interest payments and principal repayment on this debt from pounds sterling/euros to U.S. dollars. For purposes of this table, we used the contracted exchange rates in the cross-currency swap contracts to compute the net amounts of future interest payments and principal repayments on this debt. See Note 17, Derivative instruments, to the Consolidated Financial Statements for further discussion of our cross-currency swap contracts.

(2) Interest payments and the repayment of principal on our 4.375% 2018 euro Notes were translated into U.S. dollars at the foreign currency exchange rate in effect at December 31, 2012. See Note 14, Financing arrangements, to the Consolidated Financial Statements for further discussion of our long-term debt obligations.

(3) Purchase obligations relate primarily to (i) our long-term supply agreements with third-party manufacturers, which are based on firm commitments for the purchase of production capacity; (ii) R&D commitments (including those related to clinical trials) for new and existing products; (iii) capital expenditures; and (iv) open purchase orders for the acquisition of goods and services in the ordinary course of business. Our obligation to pay certain of these amounts may be reduced based on certain future events.

(4) Liabilities for UTBs (net of foreign tax credits and federal tax benefit of state taxes) and related accrued interest and penalties totaling approximately $1.1 billion at December 31, 2012, are not included in the table above because, due to their nature, there is a high degree of uncertainty regarding the timing of future cash outflows and other events that extinguish these liabilities.

In addition to amounts in the table above, we are contractually obligated to pay additional amounts, which in the aggregate are significant, upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties, including contingent consideration incurred with the acquisition of BioVex Group, Inc. (BioVex). These payments are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring. These contingent payments have not been included in the table above, and, except with respect to the fair value of the BioVex contingent consideration, are not recorded on our Consolidated Balance Sheets. As of December 31, 2012, the maximum amount that may be payable in the future for agreements we have entered into with third parties is approximately $2.5 billion, including $575 million in connection with the acquisition of BioVex. See Note 2, Business combinations, to the Consolidated Financial Statements.

Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

Product sales and sales deductions

Revenues from sales of our products are recognized when the products are shipped and title and risk of loss have passed. Product sales are recorded net of accruals for estimated rebates, wholesaler chargebacks, cash discounts and other deductions (collectively, “sales deductions”) and returns, which are established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate. Accruals are also adjusted to reflect actual results. Amounts recorded in Accrued liabilities in the Consolidated Balance Sheets for sales deductions were as follows (in millions):

	Rebates	Chargebacks	Other deductions	Total
Balance as of January 1, 2010	$ 707	$ 128	$ 135	$ 970
Amounts charged against product sales	1,861	2,593	580	5,034
Payments	(1,724)	(2,548)	(588)	(4,860)
Balance as of December 31, 2010	844	173	127	1,144
Amounts charged against product sales	1,795	2,626	670	5,091
Payments	(1,592)	(2,600)	(717)	(4,909)
Balance as of December 31, 2011	1,047	199	80	1,326
Amounts charged against product sales	1,480	2,709	659	4,848
Payments	(1,680)	(2,741)	(624)	(5,045)
Balance as of December 31, 2012	$ 847	$ 167	$ 115	$ 1,129

For the years ended December 31, 2012, 2011 and 2010, total sales deductions were 23%, 25% and 25% of gross product sales, respectively. Included in these amounts are immaterial adjustments related to prior-year sales due to changes in estimates. Such amounts represent 3% or less of the aggregate sales deductions charged against product sales in each of the three years ended December 31, 2012.

In the United States, we utilize wholesalers as the principal means of distributing our products to healthcare providers, such as physicians or their clinics, dialysis centers, hospitals and pharmacies. Products we sell in the EU are distributed principally to hospitals and/or wholesalers depending on the distribution practice in each country where the product is sold. We monitor the inventory levels of our products at our wholesalers by using data from our wholesalers and other third parties, and we believe wholesaler inventories have been maintained at appropriate levels (generally two to three weeks) given end-user demand. Accordingly, historical fluctuations in wholesaler inventory levels have not significantly impacted our method of estimating sales deductions and returns.

Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product-specific and, therefore, for any given year, can be impacted by the mix of products sold.

Rebates include primarily amounts paid to payers and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements which vary by product, by payer and individual payer plans. We estimate the amount of rebate that will be paid based on the product sold, contractual terms, historical experience and wholesaler inventory levels and accrue these rebates in the period the related sale is recorded. Additionally, for Medicaid rebates, we consider the estimated patient population and the amount of unbilled managed Medicaid claims. We adjust the rebate accruals as more information becomes available and to reflect actual experience. Estimating such rebates is complicated, in part, due to the time delay between the date of sale and the actual settlement of the liability, which for certain rebates can take up to one year and more than one year for certain government programs. Rebate accruals totaled $1.5 billion, $1.8 billion and $1.9 billion for the years ended December 31, 2012, 2011 and 2010, respectively. We believe the methodology we use to accrue for rebates is reasonable and appropriate given current facts and circumstances. However, actual results may differ. Changes in annual estimates related to prior annual periods were less than 10% of the estimated rebate amounts charged against product sales for the year ended December 31, 2012, and less than 5% for the years ended December 31, 2011 and 2010. A 10% change in our rebate estimate attributable to rebates recognized in 2012 would have had an impact of approximately $150 million, or approximately 1% of our 2012 product sales and a corresponding impact on our financial condition and liquidity.

Wholesaler chargebacks relate to our contractual agreements to sell products to healthcare providers in the United States at fixed prices that are lower than the prices we charge wholesalers. When healthcare providers purchase our products through wholesalers at these reduced prices, wholesalers charge us for the difference between their purchase price and the contractual price between Amgen and the healthcare providers. The provision for chargebacks is based on the expected sales by our wholesaler customers to healthcare providers. Those chargebacks from wholesalers totaled $2.7 billion, $2.6 billion and $2.6 billion for the years ended December 31, 2012, 2011 and 2010, respectively. Accruals for wholesaler chargebacks are less difficult to estimate than rebates and closely approximate actual results since chargeback amounts are fixed at the date of purchase by the healthcare providers, and we generally settle the liability for these deductions within a few weeks.

Product returns

Returns are estimated through comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. Historically, sales return provisions have amounted to less than 1.5% of gross product sales. Changes in estimates for prior year sales return provisions have historically been insignificant.

Income taxes

The Company provides for income taxes based on pretax income, applicable tax rates and tax planning opportunities available in the various jurisdictions in which it operates.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the financial statements on a particular tax position are measured based on the largest benefit that is more likely than not to be realized. The amount of UTBs is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We believe our estimates for uncertain tax positions are appropriate and sufficient for any assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense.

Certain items are included in the Company's tax return at different times than they are reflected in the financial statements and cause temporary differences between the tax basis of assets and liabilities and their reported amount. Such temporary differences create deferred tax assets and liabilities. Deferred tax assets are generally items that can be used as a tax deduction or credit in the tax return in future years but for which the Company has already recorded the tax benefit in the financial statements. The Company establishes valuation allowances against its deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities are either: (i) tax expenses recognized in the financial statements for which payment has been deferred; (ii) expenses for which the Company has already taken a deduction on the tax return, but has not yet recognized the expense in the financial statements; or (iii) liabilities for the difference between the book basis and tax basis of the intangible assets acquired in many business combinations, as future expenses associated with these assets most often will not be tax deductible.

The Company is a vertically integrated enterprise with operations in the U.S. and various foreign jurisdictions. The Company is subject to income tax in the foreign jurisdictions where it conducts activities based on the tax laws and principles of such jurisdictions and the functions, risks and activities performed therein. The Company’s pretax income is therefore attributed to domestic or foreign sources based on the operations performed in each location and the tax laws and principles of the respective taxing jurisdictions. For example, the Company conducts significant operations outside the United States in Puerto Rico pertaining to manufacturing, distribution and other related functions to meet its worldwide product demand. Income from the Company’s operations in Puerto Rico is subject to a tax incentive grant that expires in 2020.

Our effective tax rate reflects the impact of undistributed foreign earnings for which no U.S. income taxes or foreign withholding taxes have been provided because such earnings are intended to be invested indefinitely outside the United States. Substantially all of this benefit is attributable to the Company’s foreign income associated with the Company’s operations conducted in Puerto Rico.

If future events, including material changes in cash, working capital and long-term investment requirements necessitate that certain assets associated with these earnings be repatriated to the United States, under current tax laws an additional tax provision and related liability would be required at the applicable income tax rates which could have a material adverse effect on both our future effective tax rate and our financial results.

Our operations are subject to the tax laws, regulations and administrative practices of the United States, U.S. state jurisdictions and other countries in which we do business. Significant changes in these rules could have a material adverse effect on the Company's results of operations. See Item 1A. Risk Factors — The adoption of new tax legislation or exposure to additional tax liabilities could affect our profitability.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings and other matters such as intellectual property disputes, contractual disputes, governmental investigations and class action suits which are complex in nature and have outcomes that are difficult to predict. Certain of these proceedings are discussed in Note 18, Contingencies and commitments, to the Consolidated Financial Statements. We record accruals for loss contingencies to the extent that we conclude that it is probable

that a liability has been incurred and the amount of the related loss can be reasonably estimated. We consider all relevant factors when making assessments regarding these contingencies.

While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Valuation of assets and liabilities in connection with business combinations

We have acquired and continue to acquire intangible assets in connection with business combinations. These intangible assets consist primarily of technology associated with currently marketed human therapeutic products and IPR&D product candidates. Discounted cash flow models are typically used to determine the fair values of these intangible assets for purposes of allocating consideration paid to the net assets acquired in a business combination. These models require the use of significant estimates and assumptions, including, but not limited to:

- determining the timing and expected costs to complete in-process projects taking into account the stage of completion at the acquisition date;
- projecting the probability and timing of obtaining marketing approval from the FDA and other regulatory agencies for product candidates;
- estimating the timing of and future net cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates to calculate the present values of the cash flows.

Significant estimates and assumptions are also required to determine the acquisition date fair values of any contingent consideration obligations incurred in connection with business combinations. In addition, we must revalue these obligations each subsequent reporting period until the related contingencies are resolved and record changes in their fair values in earnings. The acquisition date fair values of the various contingent consideration obligations incurred in the acquisition of BioVex (see Note 2, Business combinations, to the Consolidated Financial Statements) were determined using a combination of valuation techniques. Significant estimates and assumptions required for these valuations included, but were not limited to, the probability of achieving regulatory milestones, product sales projections under various scenarios and discount rates used to calculate the present value of the required payments. These estimates and assumptions are required to be updated in order to revalue these contingent consideration obligations each reporting period. Accordingly, subsequent changes in underlying facts and circumstances could result in changes in these estimates and assumptions, which could have a material impact on the estimated future fair values of these obligations.

We believe the fair values used to record intangible assets acquired and contingent consideration obligations incurred in connection with business combinations are based upon reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Impairment of long-lived assets

We review the carrying value of our property, plant and equipment and our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows to be generated by the long-lived asset is compared to the carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value.

Indefinite-lived intangible assets, composed primarily of IPR&D projects acquired in a business combination which have not reached technological feasibility, are reviewed annually for impairment and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. We determine impairment by comparing the fair value of the asset to its carrying value. If the asset's carrying value exceeds its fair value, an impairment charge is recorded for the difference and its carrying value is reduced accordingly.

Estimating future cash flows of an IPR&D product candidate for purposes of an impairment analysis requires us to make significant estimates and assumptions regarding the amount and timing of costs to complete the project and the amount, timing and probability of achieving revenues from the completed product similar to how the acquisition date fair value of the project was determined, as described above. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market these products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its estimated fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods which could have a material adverse effect on our results of operations.

We believe our estimations of future cash flows used for assessing impairment of long-lived assets are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks that may result from changes in interest rates, foreign currency exchange rates and prices of equity instruments as well as changes in general economic conditions in the countries where we conduct business. To reduce certain of these risks, we enter into various types of foreign currency and interest rate derivative hedging transactions as part of our risk management program. We do not use derivatives for speculative trading purposes.

In the capital and credit markets, strong demand for fixed-income instruments led to continued low interest rates on corporate debt issuances during 2012. Short-term interest rates on U.S. Treasury instruments remained near historical lows due to a combination of the Federal Reserve's monetary policies and the challenging macroeconomic environment. As a result, in the discussion that follows, we have assumed a hypothetical change in interest rates of 100 basis points from those at December 31, 2012 and 2011. Continued uncertainty surrounding European sovereign debt resulted in ongoing volatility in the foreign exchange markets, and we have consequently assumed a hypothetical 20% change in foreign currency exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2012 and 2011.

Interest rate sensitive financial instruments

Our portfolio of available-for-sale interest-bearing securities at December 31, 2012 and 2011, was comprised of: U.S. Treasury securities and other government-related debt securities; corporate debt securities; residential mortgage-backed and other mortgage- and asset-backed securities; money market mutual funds; and additionally at December 31, 2012, other short-term interest-bearing securities, composed principally of commercial paper. The fair values of our investment portfolio of interest-bearing securities were $23.7 billion and $20.0 billion at December 31, 2012 and 2011, respectively. Duration is a sensitivity measure that can be used to approximate the change in the value of a security that will result from a 100 basis point change in interest rates. Applying a duration model, a hypothetical 100 basis point increase in interest rates at December 31, 2012 and 2011, would not have resulted in a material effect on the fair values of these securities on these dates. In addition, a hypothetical 100 basis point decrease in interest rates at December 31, 2012 and 2011, would not result in a material effect on the related income or cash flows in the respective ensuing year.

As of December 31, 2012, we had outstanding debt with a carrying value of $26.5 billion and a fair value of $29.9 billion. As of December 31, 2011, we had outstanding debt with a carrying value of $21.4 billion and a fair value of $23.0 billion. Our outstanding debt at December 31, 2012 and 2011, was comprised entirely of debt with fixed interest rates. Changes in interest rates do not affect interest expense or cash flows on fixed-rate debt. Changes in interest rates would, however, affect the fair values of fixed-rate debt. A hypothetical 100 basis point decrease in interest rates relative to interest rates at December 31, 2012, would have resulted in an increase of approximately $2.6 billion in the aggregate fair value of our outstanding debt on this date. A hypothetical 100 basis point decrease in interest rates relative to the interest rates at December 31, 2011, would have resulted in an increase of approximately $2.1 billion in the aggregate fair value of our outstanding debt on this date. The analysis for the debt does not consider the impact that hypothetical changes in interest rates would have on the related interest rate swap contracts, while outstanding, and cross-currency swap contracts.

To achieve a desired mix of fixed and floating interest rate debt, we entered into interest rate swap contracts, which qualified and were designated for accounting purposes as fair value hedges, for certain of our fixed-rate debt. These derivative contracts effectively converted a fixed-rate interest coupon to a floating-rate LIBOR-based coupon over the life of the respective note. Due to historically low interest rates, we terminated all of these swap contracts in May 2012. Interest rate swap contracts with notional amounts totaling $3.6 billion were outstanding at December 31, 2011. A hypothetical 100 basis point increase in interest rates relative to interest rates at December 31, 2011, would have resulted in a reduction in fair value of approximately $200 million on our interest rate swap contracts on this date and would not result in a material effect on the related income or cash flows in the respective ensuing year. The analysis for the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair values of debt that these interest rate sensitive instruments were designed to offset.

As of December 31, 2012 and 2011, we had outstanding cross-currency swap contracts with aggregate notional amounts of $2.7 billion and $748 million, respectively, that hedge certain of our foreign denominated debt and related interest payments. These contracts effectively convert interest payments and principal repayment of this debt to U.S. dollars from euros/pounds sterling and are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates at December 31, 2012, would have resulted in approximately a $400 million reduction in the fair value of our cross-currency swap contracts on this date but would have no effect on cash flows or income in the ensuing year. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates at December 31, 2011, would have resulted in approximately a $130 million reduction in the fair value of our cross-currency swap contracts on this date but would have no effect on cash flows or income in the ensuing year.

Foreign currency sensitive financial instruments

Our international operations are affected by fluctuations in the value of the U.S. dollar as compared to foreign currencies, predominantly the euro. Increases and decreases in our international product sales from movements in foreign currency exchange rates are offset partially by the corresponding increases or decreases in our international operating expenses. Increases and decreases in our foreign currency denominated assets from movements in foreign currency exchange rates are offset partially by the corresponding increases or decreases in our foreign currency denominated liabilities. To further reduce our net exposure to foreign currency exchange rate fluctuations on our results of operations, we enter into foreign currency forward, option and cross-currency swap contracts.

As of December 31, 2012, we had outstanding euro and pound sterling denominated debt with a carrying value and fair value of $3.5 billion and $3.8 billion, respectively. As of December 31, 2011, we had outstanding euro and pound sterling denominated debt with both a carrying value and fair value of $1.5 billion. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2012, would have resulted in an increase in fair value of this debt of approximately $760 million on this date and a reduction in income in the ensuing year of approximately $700 million, but would have no material effect on the related cash flows in the ensuing year. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2011, would have resulted in an increase in fair value of this debt of approximately $290 million on this date with a corresponding reduction in income in the ensuing year, but would have no material effect on the related cash flows in the ensuing year. The analysis for this debt does not consider the offsetting impact that hypothetical changes in foreign currency exchange rates would have on the related cross-currency swap contracts which are in place for the majority of the foreign currency denominated debt.

With regard to our $2.7 billion notional amount of cross-currency swap contracts that are designated as cash flow hedges of certain of our debt denominated in euros and pound sterling as of December 31, 2012, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on this date, would have resulted in a reduction in the fair value of these contracts of approximately $710 million on this date, but would have no material effect on the related cash flows in the ensuing year. The impact on income in the ensuing year from these contracts of this hypothetical adverse movement in foreign currency exchange rates would be fully offset by the corresponding hypothetical change in the carrying amount of the related hedged debt. With regard to our $748 million notional amount of cross-currency swap contracts that are designated as cash flow hedges of certain of our debt denominated in pounds sterling as of December 31, 2011, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on this date, would have resulted in a reduction in the fair value of these contracts of approximately $210 million on this date, but would have no material effect on the related cash flows in the ensuing year. The impact on income in the ensuing year from these contracts of this hypothetical adverse movement in foreign currency exchange rates would be fully offset by the corresponding hypothetical change in the carrying amount of the related hedged debt.

We enter into foreign currency forward and options contracts that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2012, we had open foreign currency forward and options contracts, primarily euro-based, with notional amounts of $3.7 billion and $200 million, respectively. As of December 31, 2011, we had open foreign currency forward and options contracts, primarily euro-based, with notional amounts of $3.5 billion and $292 million, respectively. As of December 31, 2012 and 2011, the net unrealized gains on these contracts were not material. With regard to foreign currency forward and option contracts that were open at December 31, 2012, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2012, would have resulted in a reduction in fair value of these contracts of approximately $730 million on this date and, in the ensuing year, a reduction in income and cash flows of approximately $350 million. With regard to contracts that were open at December 31, 2011, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2011, would have resulted in a reduction in fair value of these contracts of approximately $700 million on this date and, in the ensuing year, a reduction in income and cash flows of approximately $330 million. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign currency sensitive instruments were designed to offset.

As of December 31, 2012 and 2011, we had open foreign currency forward contracts with notional amounts totaling $629 million and $389 million, respectively, that hedged fluctuations of certain assets and liabilities denominated in foreign currencies but were not designated as hedges for accounting purposes. These contracts had no material net unrealized gains or losses at December 31, 2012 and 2011. With regard to these foreign currency forward contracts that were open at December 31, 2012 and 2011, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would not have resulted in a material reduction in the fair value of these contracts on this date and would not result in a material effect on the related income or cash flows in the respective ensuing year. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on assets and liabilities that these foreign currency sensitive instruments were designed to offset.

Market price sensitive financial instruments

As of December 31, 2012 and 2011, we were also exposed to price risk on equity securities included in our portfolio of investments, which were acquired primarily for the promotion of business and strategic objectives. These investments are generally in small capitalization stocks in the biotechnology industry sector. Price risk relative to our equity investment portfolio as of December 31, 2012 and 2011, was not material.

Counterparty credit risks

Our financial instruments, including derivatives, are subject to counterparty credit risk which we consider as part of the overall fair value measurement. Our financial risk management policy limits derivative transactions by requiring transactions to be with institutions with investment grade credit ratings and requires placing exposure limits on the amount with any individual counterparty. In addition, we have an investment policy that limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restriction on maturities and concentrations by asset class and issuer.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is incorporated herein by reference to the financial statements and schedule listed in Item 15(a)1 and (a)2 of Part IV and included in this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

Item 9A. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance Amgen's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2012.

Management determined that, as of December 31, 2012, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is 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 in the United States. However, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and reporting.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2012. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

The effectiveness of the Company's internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing below, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2012.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Amgen Inc.

We have audited Amgen Inc.'s (the "Company") internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Amgen Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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.

In our opinion, Amgen Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Consolidated Balance Sheets as of December 31, 2012 and 2011, and the related Consolidated Statements of Income, Comprehensive Income, Stockholders' Equity and Cash Flows for each of the three years in the period ended December 31, 2012 of Amgen Inc. and our report dated February 27, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California
February 27, 2013

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE OF THE REGISTRANT

Information about our Directors is incorporated by reference from the section entitled ITEM 1 — ELECTION OF DIRECTORS in our Proxy Statement for the 2013 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2012 (the Proxy Statement). Information about compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated by reference from the section entitled OTHER MATTERS — Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement. Information about the procedures by which stockholders may recommend nominees for the Board of Directors is incorporated by reference from Appendix A — AMGEN INC. BOARD OF DIRECTORS GUIDELINES FOR DIRECTOR QUALIFICATIONS AND EVALUATIONS in our Proxy Statement. Information about our Audit Committee, members of the committee and our Audit Committee financial experts is incorporated by reference from the section entitled CORPORATE GOVERNANCE — Board Committees and Charters — Audit Committee in our Proxy Statement. Information about our executive officers is contained in the discussion entitled Item 1. Business — Executive Officers of the Registrant.

Code of Ethics

We maintain a code of ethics applicable to our principal executive officer, principal financial officer, principal accounting officer or controller, and other persons performing similar functions. To view this code of ethics free of charge, please visit our website at www.amgen.com (This website address is not intended to function as a hyperlink, and the information contained in our website is not intended to be a part of this filing). We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics, if any, by posting such information on our website as set forth above.

Item 11. EXECUTIVE COMPENSATION

Information about director and executive compensation is incorporated by reference from the section entitled EXECUTIVE COMPENSATION in our Proxy Statement. Information about compensation committee matters is incorporated by reference from the sections entitled CORPORATE GOVERNANCE — Board Committees and Charters — Compensation and Management Development Committee and CORPORATE GOVERNANCE — Compensation Committee Report in our Proxy Statement.

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

Securities Authorized for Issuance Under Existing Equity Compensation Plans

Information about securities authorized for issuance under existing equity compensation plans is incorporated by reference from the section entitled SECURITIES AUTHORIZED FOR ISSUANCE UNDER EXISTING EQUITY COMPENSATION PLANS in our Proxy Statement.

Security Ownership of Directors and Executive Officers and Certain Beneficial Owners

Information about security ownership of certain beneficial owners and management is incorporated by reference from the sections entitled SECURITY OWNERSHIP OF DIRECTORS AND EXECUTIVE OFFICERS and SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS in our Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information about certain relationships and related transactions and directors independence is incorporated by reference from the sections entitled CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS and CORPORATE GOVERNANCE — Board Independence in our Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information about the fees for professional services rendered by our independent registered public accountants is incorporated by reference from the section entitled AUDIT MATTERS — Independent Registered Public Accountants in our Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)1. Index to Financial Statements

The following Consolidated Financial Statements are included herein:

(a)2. Index to Financial Statement Schedules

The following Schedule is filed as part of this Annual Report on Form 10-K:

All other schedules are omitted because they are not applicable, not required or because the required information is included in the consolidated financial statements or notes thereto.

(a)3. Exhibits

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated December 7, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
3.2	Certificate of Amendment to the Restated Certificate of Incorporation of Amgen Inc. (As Amended May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.3	Certificate of Correction of Restated Certificate of Incorporation of Amgen Inc. (As Corrected May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.4	Certificate of Elimination of the Certificate of Designations of the Series A Junior Participating Preferred Stock (As Eliminated December 9, 2008). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
3.5*	Certificate of Change of Location of Registered Office and of Registered Agent of Amgen Inc. (As Changed January 2, 2009).

Exhibit No.	Description
3.6	Certificate of Amendment of Restated Certificate of Incorporation of Amgen Inc. (As Amended May 11, 2009). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 on August 10, 2009 and incorporated herein by reference.)
3.7	Certificate of Correction of Restated Certificate of Incorporation of Amgen Inc. (As Corrected May 11, 2009). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 on August 10, 2009 and incorporated herein by reference.)
3.8	Certificate of Correction of Restated Certificate of Incorporation of Amgen Inc. (As Corrected May 13, 2010). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2010 on August 9, 2010 and incorporated herein by reference.)
3.9	Certificate of Amendment of Restated Certificate of Incorporation of Amgen Inc. (As Amended May 23, 2012) (Filed as Appendix B to the Definitive Proxy Statement on Schedule 14A on April 12, 2012 and incorporated herein by reference.)
3.10	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated October 6, 2009). (Filed as an exhibit to Form 8-K filed on October 7, 2009 and incorporated herein by reference.)
3.11	First Amendment to the Amended and Restated Bylaws of Amgen Inc. (Filed as an exhibit to Form 8-K filed on May 24, 2012 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 13, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.6	Officer's Certificate, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of February 26, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.7	Indenture, dated as of August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.8	Form of 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.9	Officers' Certificate, dated November 18, 2004, including forms of the 4.00% Senior Notes due 2009 and 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.10	Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006 (including form of 0.375% Convertible Senior Note due 2013). (Filed as exhibit to Form 10-Q for the quarter ended June 30, 2006 on August 9, 2006 and incorporated herein by reference.)
4.11	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.12	Officers' Certificate of Amgen Inc., dated as of May 30, 2007, including forms of the Company's Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)

Exhibit No.	Description
4.13	Officers' Certificate of Amgen Inc., dated as of May 23, 2008, including forms of the Company's 6.15% Senior Notes due 2018 and 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2009 and incorporated herein by reference.)
4.14	Officers' Certificate of Amgen Inc., dated as of January 16, 2009, including forms of the Company's 5.70% Senior Notes due 2019 and 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)
4.15	Officers' Certificate of Amgen Inc., dated as of March 12, 2010, including forms of the Company's 4.50% Senior Notes due 2020 and 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 15, 2010 and incorporated herein by reference.)
4.16	Officers' Certificate of Amgen Inc., dated as of September 16, 2010, including forms of the Company's 3.45% Senior Notes due 2020 and 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)
4.17	Officers' Certificate of Amgen Inc., dated as of June 30, 2011, including forms of the Company's 2.30% Senior Notes due 2016, 4.10% Senior Notes due 2021 and 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)
4.18	Officers' Certificate of Amgen Inc., dated as of November 10, 2011, including forms of the Company's 1.875% Senior Notes due 2014, 2.50% Senior Notes due 2016, 3.875% Senior Notes due 2021 and 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)
4.19	Officers' Certificate of Amgen Inc., dated as of December 5, 2011, including forms of the Company's 4.375% Senior Notes due 2018 and 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)
4.20	Officers' Certificate of Amgen Inc., dated as of May 15, 2012, including forms of the Company's 2.125% Senior Notes due 2017, 3.625% Senior Notes due 2022 and 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)
4.21	Officers' Certificate of Amgen Inc., dated as of September 13, 2012, including forms of the Company's 2.125% Senior Notes due 2019 and 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)
10.1+	Amgen Inc. 2009 Equity Incentive Plan. (Filed as Appendix A to the Definitive Proxy Statement on Schedule 14A on March 26, 2009 and incorporated herein by reference.)
10.2+	Form of Stock Option Agreement for the Amgen Inc. 2009 Equity Incentive Plan. (As Amended on October 10, 2012.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2012 on November 6, 2012 and incorporated herein by reference.)
10.3+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Equity Incentive Plan. (As Amended on October 10, 2012.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2012 on November 6, 2012 and incorporated herein by reference.)
10.4+*	Amgen Inc. 2009 Performance Award Program. (As Amended on December 13, 2012.)
10.5+	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on March 14, 2012.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2012 on May 8, 2012 and incorporated herein by reference.)
10.6+*	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended and Restated on December 13, 2012.)
10.7+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.8+*	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended and Restated on December 13, 2012.)

Exhibit No.	Description
10.9+	Amgen Supplemental Retirement Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.10+	First Amendment to the Amgen Supplemental Retirement Plan, effective April 11, 2011. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2011 on August 8, 2011 and incorporated herein by reference.)
10.11+	Second Amendment to the Amgen Supplemental Retirement Plan, effective October 12, 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 on February 29, 2012 and incorporated herein by reference.)
10.12+	Third Amendment to the Amgen Supplemental Retirement Plan, effective January 1, 2012. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 on February 29, 2012 and incorporated herein by reference.)
10.13+	Fourth Amendment to the Amgen Supplemental Retirement Plan, effective June 18, 2012. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2012 on August 8, 2012 and incorporated herein by reference.)
10.14+	Fifth Amendment to the Amgen Supplemental Retirement Plan, effective August 27, 2012. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2012 on November 6, 2012 and incorporated herein by reference.)
10.15+	Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.)
10.16+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.17+*	First Amendment to the Amgen Inc. Executive Incentive Plan, effective December 13, 2012.
10.18+	Amgen Inc. Executive Nonqualified Retirement Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.19+	First Amendment to the Amgen Inc. Executive Nonqualified Retirement Plan, effective July 21, 2010. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2010 on August 9, 2010 and incorporated herein by reference.)
10.20+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.21+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective April 11, 2011. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2011 on August 8, 2011 and incorporated herein by reference.)
10.22+	Second Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 12, 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 on February 29, 2012 and incorporated herein by reference.)
10.23+	Third Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective June 18, 2012. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2012 on August 8, 2012 and incorporated herein by reference.)
10.24+	Fourth Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective August 27, 2012. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2012 on November 6, 2012 and incorporated herein by reference.)

Exhibit No.	Description
10.25+	Agreement between Amgen Inc. and Mr. Jonathan M. Peacock, dated July 5, 2010. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2010 on November 8, 2010 and incorporated herein by reference.)
10.26+	Agreement between Amgen Inc. and Mr. Anthony C. Hooper, dated October 12, 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 on February 29, 2012 and incorporated herein by reference.)
10.27+	Consulting Services Agreement, effective February 13, 2012, between Amgen Inc., Perlmutter Consulting, Inc. and Dr. Roger M. Perlmutter. (Filed as an exhibit to Form 8-K on March 1, 2012 and incorporated herein by reference.)
10.28+	Grant Agreement, dated December 3, 2012, between Amgen Inc., and Reed College. (Filed as an exhibit to Form 8-K on December 7, 2012 and incorporated herein by reference.)
10.29+	Restricted Stock Unit Agreement, dated April 27, 2012, between Amgen Inc. and Kevin W. Sharer. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2012 on August 8, 2012 and incorporated herein by reference.)
10.30+	Performance Unit Agreement, dated April 27, 2012, between Amgen Inc. and Kevin W. Sharer. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2012 on August 8, 2012 and incorporated herein by reference.)
10.31	Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated, September 30, 1985 between Amgen and Ortho Pharmaceutical Corporation. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
10.32	Shareholders' Agreement, dated May 11, 1984, among Amgen, Kirin Brewery Company, Limited and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.33	Amendment No. 1 dated March 19, 1985, Amendment No. 2 dated July 29, 1985 (effective July 1, 1985), and Amendment No. 3, dated December 19, 1985, to the Shareholders' Agreement dated May 11, 1984. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
10.34	Amendment No. 4 dated October 16, 1986 (effective July 1, 1986), Amendment No. 5 dated December 6, 1986 (effective July 1, 1986), Amendment No. 6 dated June 1, 1987, Amendment No. 7 dated July 17, 1987 (effective April 1, 1987), Amendment No. 8 dated May 28, 1993 (effective November 13, 1990), Amendment No. 9 dated December 9, 1994 (effective June 14, 1994), Amendment No. 10 effective March 1, 1996, and Amendment No. 11 effective March 20, 2000 to the Shareholders' Agreement, dated May 11, 1984. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.35	Amendment No. 12 to the Shareholders' Agreement, dated January 31, 2001. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2005 on August 8, 2005 and incorporated herein by reference.)
10.36	Amendment No. 13 to the Shareholders' Agreement, dated June 28, 2007 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.37	Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated September 30, 1985, between Kirin-Amgen, Inc. and Ortho Pharmaceutical Corporation. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
10.38	Research, Development Technology Disclosure and License Agreement: PPO, dated January 20, 1986, by and between Kirin Brewery Co., Ltd. and Amgen Inc. (Filed as an exhibit to Amendment No. 1 to Form S-1 Registration Statement on March 11, 1986 and incorporated herein by reference.)
10.39	Assignment and License Agreement, dated October 16, 1986 (effective July 1, 1986), between Amgen and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)

Exhibit No.	Description
10.40	G-CSF United States License Agreement, dated June 1, 1987 (effective July 1, 1986), Amendment No. 1, dated October 20, 1988, and Amendment No. 2, dated October 17, 1991 (effective November 13, 1990), between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.41	G-CSF European License Agreement, dated December 30, 1986, between Kirin-Amgen and Amgen, Amendment No. 1 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated June 1, 1987, Amendment No. 2 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated March 15, 1998, Amendment No. 3 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated October 20, 1988, and Amendment No. 4 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated December 29, 1989, between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.42	Agreement Regarding Governance and Commercial Matters, dated December 16, 2001, by and among American Home Products Corporation, American Cyanamid Company and Amgen Inc. (with certain confidential information deleted therefrom). (Filed as an exhibit to Amendment No. 1 to Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
10.43	Amended and Restated Promotion Agreement, dated as of December 16, 2001, by and among Immunex Corporation, American Home Products Corporation and Amgen Inc. (with certain confidential information deleted therefrom). (Filed as an exhibit to Amendment No. 1 to Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
10.44	Description of Amendment No. 1 to Amended and Restated Promotion Agreement, effective as of July 8, 2003, among Wyeth, Amgen Inc. and Immunex Corporation (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2003 on March 11, 2004 and incorporated herein by reference.)
10.45	Description of Amendment No. 2 to Amended and Restated Promotion Agreement, effective as of April 20, 2004, by and among Wyeth, Amgen Inc. and Immunex Corporation. (Filed as an exhibit to Amendment No. 1 to Form S-4 Registration Statement on June 29, 2004 and incorporated herein by reference.)
10.46	Amendment No. 3 to Amended and Restated Promotion Agreement, effective as of January 1, 2005, by and among Wyeth, Amgen Inc. and Immunex Corporation (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2005 on May 4, 2005 and incorporated herein by reference.)
10.47	Confirmation of OTC Convertible Note Hedge related to 2013 Notes, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International related to 0.375% Convertible Senior Notes Due 2013. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.48	Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International for warrants expiring in 2013. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.49	Credit Agreement, dated as of December 2, 2011, among Amgen Inc., with Citibank, N.A., as administrative agent, JPMorgan Chase Bank, N.A., as syndication agent, Citigroup Global Markets Inc. and J.P. Morgan Securities LLC as joint lead arrangers and joint book runners, and the other banks party thereto. (Filed as an exhibit to Form 8-K filed on December 2, 2011 and incorporated herein by reference.)
10.50	Multi-product License Agreement with Respect to Japan between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.51*	Amendment No. 1 dated as of June 25, 2010 to the License Agreement dated February 1, 2008 between Amgen Inc. and Takeda Pharmaceutical Company Limited.
10.52*	Amendment No. 2 dated as of June 29, 2012 to the License Agreement dated February 1, 2008 between Amgen Inc. and Takeda Pharmaceutical Company Limited.

Exhibit No.	Description
10.53	Supply Agreement between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.54*	Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (with certain confidential information deleted therefrom) and Amendment No. 1, effective as of June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (with certain confidential information deleted therefrom).
10.55	Integrated Facilities Management Services Agreement, dated February 4, 2009, between Amgen Inc. and Jones Lang LaSalle Americas, Inc. (with certain confidential information deleted therefrom) (Previously filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009.), as amended by Amendment Number 1 dated March 31, 2010 (with certain confidential information deleted therefrom), Amendment Number 2 dated May 12, 2011 (as corrected by the Letter Agreement) (with certain confidential information deleted therefrom), and Letter Agreement dated July 19, 2011. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2011 on August 8, 2011 and incorporated herein by reference.)
10.56	Amendment Number 3, dated July 1, 2011, to the Integrated Facilities Management Services Agreement, dated February 4, 2009, between Amgen Inc. and Jones Lang LaSalle Americas, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2011 on November 4, 2011 and incorporated herein by reference.)
10.57	Collaboration Agreement dated July 27, 2009 between Amgen Inc. and Glaxo Group Limited, a wholly owned subsidiary of GlaxoSmithKline plc (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2009 on November 6, 2009 and incorporated herein by reference.)
10.58*	Amendment Number 1, dated as of January 24, 2012, to Collaboration Agreement dated July 27, 2009 between Amgen Inc. and Glaxo Group Limited, a wholly owned subsidiary of GlaxoSmithKline plc.
10.59	Expansion Agreement dated July 27, 2009 between Amgen Inc. and Glaxo Group Limited, a wholly owned subsidiary of GlaxoSmithKline plc (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2009 on November 6, 2009 and incorporated herein by reference.)
10.60	Amendment Number 1, dated September 20, 2010, to Expansion Agreement dated July 27, 2009 between Amgen Inc. and Glaxo Group Limited, a wholly owned subsidiary of GlaxoSmithKline plc (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2010 on November 8, 2010 and incorporated herein by reference.)
10.61*	Amendment Number 2, dated as of January 24, 2012, to Expansion Agreement dated July 27, 2009 between Amgen Inc. and Glaxo Group Limited, a wholly owned subsidiary of GlaxoSmithKline plc.
10.62	Sourcing and Supply Agreement, dated November 15, 2011, by and between Amgen USA Inc, a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 on February 29, 2012 and incorporated herein by reference.)
10.63*	Amendment Number 1 to Sourcing and Supply Agreement, effective as of January 1, 2013, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Healthcare Partners Inc. f/k/a DaVita Inc. (with certain confidential information deleted therefrom).
10.64	Collaboration Agreement dated March 30, 2012 by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, a wholly owned subsidiary of AstraZeneca Pharmaceuticals LP (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2012 on May 8, 2012 and incorporated herein by reference.)
21*	Subsidiaries of the Company.
23	Consent of the Independent Registered Public Accounting Firm. The consent is set forth on pages 90 and 91 of this Annual Report on Form 10-K.
24	Power of Attorney. The Power of Attorney is set forth on page 92 of this Annual Report on Form 10-K.

Exhibit No.	Description
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

(* = filed herewith)

(** = furnished herewith and not “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended)

(+ = management contract or compensatory plan, contract or arrangement)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMGEN INC.
(Registrant)

Date: 02/27/2013

By: /S/ JONATHAN M. PEACOCK

Jonathan M. Peacock
Executive Vice President
and Chief Financial Officer

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-8 No. 333-159377) pertaining to the Amgen Inc. 2009 Equity Incentive Plan;
- Registration Statement (Form S-8 No. 33-39183) pertaining to the Amended and Restated Employee Stock Purchase Plan;
- Registration Statements (Form S-8 No. 33-39104, as amended by Form S-8 No. 333-144581) pertaining to the Amended and Restated Amgen Retirement and Savings Plan (formerly known as the Amgen Retirement and Savings Plan);
- Registration Statements (Form S-8 Nos. 33-42072 and 333-144579) pertaining to the Amgen Inc. Amended and Restated 1991 Equity Incentive Plan;
- Registration Statements (Form S-8 Nos. 33-47605 and 333-144580) pertaining to the Retirement and Savings Plan for Amgen Manufacturing, Limited (formerly known as the Retirement and Savings Plan for Amgen Manufacturing, Inc.);
- Registration Statements (Form S-8 Nos. 333-44727, 333-62735, 333-56672 and 333-83824) pertaining to the Amgen Inc. Amended and Restated 1997 Special Non-Officer Equity Incentive Plan (formerly known as the Amgen Inc. 1997 Special Non-Officer Equity Incentive Plan);
- Registration Statement (Form S-3 No. 333-19931) pertaining to debt securities of Amgen Inc.;
- Registration Statement (Form S-3 No. 333-40405) pertaining to debt securities of Amgen Inc.;
- Registration Statement (Form S-3 No. 333-53929) pertaining to the Amgen Inc. 1997 Special Non-Officer Equity Incentive Plan, the Amgen Inc. Amended and Restated 1991 Equity Incentive Plan, the Amended and Restated 1988 Stock Option Plan of Amgen Inc. and the Amended and Restated 1987 Directors' Stock Option Plan;
- Registration Statements (Form S-8 Nos. 333-81284 and 333-177868) pertaining to the Amgen Nonqualified Deferred Compensation Plan;
- Registration Statements (Form S-3 No. 333-56664 and Amendment No. 1 thereto) pertaining to the Amgen Inc. 1997 Special Non-Officer Equity Incentive Plan, the Amgen Inc. Amended and Restated 1991 Equity Incentive Plan;
- Registration Statement (Form S-3 No. 333-88834) pertaining to Amgen Inc.'s Liquid Yield Option™ Notes due 2032;
- Registration Statements (Form S-3 No. 333-92450 and Amendment No. 1 thereto) pertaining to Amgen Inc.'s Common Stock;
- Registration Statements (Form S-8 No. 333-92424 and Amendment No. 1 thereto) pertaining to the Amgen Inc. Amended and Restated 1993 Equity Incentive Plan (formerly known as the Immunex Corporation 1993 Stock Option Plan), the Amgen Inc. Amended and Restated 1999 Equity Incentive Plan (formerly known as the Immunex Corporation 1999 Stock Option Plan);
- Registration Statements (Form S-3 No. 333-107639 and Amendment 1 thereto) relating to debt securities, common stock and associated preferred share repurchase rights, preferred stock, warrants to purchase debt securities, common stock or preferred stock, securities purchase contracts, securities purchase units and depositary shares of Amgen Inc. and in the related Prospectuses;
- Registration Statement (Form S-8 No. 333-118254) pertaining to the Amgen Inc. Amended and Restated 1997 Equity Incentive Plan (formerly known as the Tularik Inc. 1997 Equity Incentive Plan, as amended);
- Registration Statement (Form S-3 No. 333-132286) relating to the potential resale of securities acquired from Amgen Inc. by selling security holders in unregistered private offerings;
- Registration Statement (Form S-8 No. 333-132932) pertaining to the Amgen Inc. Amended and Restated 1996 Incentive Stock Plan (formerly known as Abgenix, Inc. 1996 Incentive Stock Plan, as amended and restated), the Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (formerly known as Abgenix, Inc. 1999 Nonstatutory Stock Option Plan, as amended and restated);
- Registration Statement (Form S-8 No. 333-133002) pertaining to the Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (formerly known as Abgenix, Inc. 1999 Nonstatutory Stock Option Plan, as amended and restated);

- Registration Statement (Form S-8 No. 333-138325) pertaining to the Amgen Inc. Amended and Restated Assumed Avidia Equity Incentive Plan (formerly known as the Avidia, Inc. Amended and Restated 2003 Equity Incentive Plan);
- Registration Statement (Form S-4 No. 333-147482) relating to the possible exchange of unregistered Senior Floating Notes for registered Senior Floating Notes relating to the Prospectus of Amgen Inc. for the registration of Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017, 6.375% Senior Notes Due 2037;
- Registration Statements (Form S-3 Nos. 333-150290 and 333-172617) relating to debt securities, common stock, preferred stock, warrants to purchase debt securities, common stock, preferred stock or depositary shares, rights to purchase common stock or preferred stock, securities purchase contracts, securities purchase units and depositary shares of Amgen Inc. and in the related Prospectuses; and
- Registration Statement (Form S-8 No. 333-176240) pertaining to the Amgen Profit Sharing Plan for Employees in Ireland;

of our reports dated February 27, 2013, with respect to the consolidated financial statements and schedule of Amgen Inc. and the effectiveness of internal control over financial reporting of Amgen Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2012.

/s/ Ernst & Young LLP

Los Angeles, California
February 27, 2013

EXHIBIT 24

POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jonathan M. Peacock and Thomas J.W. Dittrich, or either of them, his or her attorney-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may 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	Date
/S/ ROBERT A. BRADWAY **Robert A. Bradway**	Chairman of the Board, President and Chief Executive Officer, and Director (Principal Executive Officer)	2/27/2013
/S/ JONATHAN M. PEACOCK **Jonathan M. Peacock**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	2/27/2013
/S/ THOMAS J.W. DITTRICH **Thomas J.W. Dittrich**	Vice President Finance and Chief Accounting Officer (Principal Accounting Officer)	2/27/2013
/S/ DAVID BALTIMORE **David Baltimore**	Director	2/27/2013
/S/ FRANK J. BIONDI, JR. **Frank J. Biondi, Jr.**	Director	2/27/2013
/S/ FRANÇOIS DE CARBONNEL **François de Carbonnel**	Director	2/27/2013
/S/ VANCE D. COFFMAN **Vance D. Coffman**	Director	2/27/2013
/S/ ROBERT A. ECKERT **Robert A. Eckert**	Director	2/27/2013
/S/ REBECCA M. HENDERSON **Rebecca M. Henderson**	Director	2/27/2013
/S/ FRANK C. HERRINGER **Frank C. Herringer**	Director	2/27/2013
/S/ TYLER JACKS **Tyler Jacks**	Director	2/27/2013
/S/ GILBERT S. OMENN **Gilbert S. Omenn**	Director	2/27/2013
/S/ JUDITH C. PELHAM **Judith C. Pelham**	Director	2/27/2013
/S/ J. PAUL REASON **J. Paul Reason**	Director	2/27/2013
/S/ LEONARD D. SCHAEFFER **Leonard D. Schaeffer**	Director	2/27/2013
/S/ RONALD D. SUGAR **Ronald D. Sugar**	Director	2/27/2013

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Amgen Inc.

We have audited the accompanying Consolidated Balance Sheets of Amgen Inc. (the "Company") as of December 31, 2012 and 2011, and the related Consolidated Statements of Income, Comprehensive Income, Stockholders' Equity and Cash Flows for each of the three years in the period ended December 31, 2012. Our audits also included the financial statement schedule listed in the Index at Item 15(a) 2. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Amgen Inc. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Amgen Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 27, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California
February 27, 2013

AMGEN INC.

CONSOLIDATED STATEMENTS OF INCOME

Years ended December 31, 2012, 2011 and 2010

(In millions, except per share data)

	2012	2011	2010
Revenues:			
Product sales	$ 16,639	$ 15,295	$ 14,660
Other revenues	626	287	393
Total revenues	17,265	15,582	15,053
Operating expenses:			
Cost of sales (excludes amortization of certain acquired intangible assets presented separately)	2,918	2,427	2,220
Research and development	3,380	3,167	2,894
Selling, general and administrative	4,801	4,486	3,983
Amortization of certain acquired intangible assets	294	294	294
Other	295	896	117
Total operating expenses	11,688	11,270	9,508
Operating income	5,577	4,312	5,545
Interest expense, net	1,053	610	604
Interest and other income, net	485	448	376
Income before income taxes	5,009	4,150	5,317
Provision for income taxes	664	467	690
Net income	$ 4,345	$ 3,683	$ 4,627
Earnings per share:			
Basic	$ 5.61	$ 4.07	$ 4.82
Diluted	$ 5.52	$ 4.04	$ 4.79
Shares used in the calculation of earnings per share:			
Basic	775	905	960
Diluted	787	912	965

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Years ended December 31, 2012, 2011 and 2010

(In millions)

	2012	2011	2010
Net income	$ 4,345	$ 3,683	$ 4,627
Other comprehensive income (loss), net of reclassification adjustments and taxes:			
Foreign currency translation losses	(9)	(1)	(18)
Gains (losses) on the effective portion of cash flow hedges	(78)	40	85
Net unrealized gains (losses) on available-for-sale securities	63	(15)	40
Other gains (losses)	(1)	(6)	1
Other comprehensive income (loss), net of tax	(25)	18	108
Comprehensive income	$ 4,320	$ 3,701	$ 4,735

See accompanying notes.

AMGEN INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2012 and 2011

(In millions, except per share data)

	2012	2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,257	$ 6,946
Marketable securities	20,804	13,695
Trade receivables, net	2,518	2,896
Inventories	2,744	2,484
Other current assets	1,886	1,572
Total current assets	31,209	27,593
Property, plant and equipment, net	5,326	5,420
Intangible assets, net	3,968	2,584
Goodwill	12,662	11,750
Other assets	1,133	1,524
Total assets	$ 54,298	$ 48,871
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 905	$ 642
Accrued liabilities	4,791	5,028
Current portion of long-term debt	2,495	84
Total current liabilities	8,191	5,754
Long-term debt	24,034	21,344
Other noncurrent liabilities	3,013	2,744
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding — 756.3 shares in 2012 and 795.6 shares in 2011	29,337	27,777
Accumulated deficit	(10,423)	(8,919)
Accumulated other comprehensive income	146	171
Total stockholders' equity	19,060	19,029
Total liabilities and stockholders' equity	$ 54,298	$ 48,871

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended December 31, 2012, 2011 and 2010

(In millions)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income	Total
Balance at December 31, 2009	994.6	$ 26,944	$ (4,322)	$ 45	$ 22,667
Net income	—	—	4,627	—	4,627
Other comprehensive income, net of tax	—	—	—	108	108
Issuance of common stock in connection with the Company's equity award programs	4.0	69	—	—	69
Stock-based compensation	—	357	—	—	357
Tax impact related to employee stock-based compensation	—	(71)	—	—	(71)
Repurchases of common stock	(66.5)	—	(3,800)	—	(3,800)
Other	—	—	(13)	—	(13)
Balance at December 31, 2010	932.1	27,299	(3,508)	153	23,944
Net income	—	—	3,683	—	3,683
Other comprehensive income, net of tax	—	—	—	18	18
Dividends	—	—	(787)	—	(787)
Issuance of common stock in connection with the Company's equity award programs	7.8	230	—	—	230
Stock-based compensation	—	337	—	—	337
Tax impact related to employee stock-based compensation	—	(89)	—	—	(89)
Repurchases of common stock	(144.3)	—	(8,307)	—	(8,307)
Balance at December 31, 2011	795.6	27,777	(8,919)	171	19,029
Net income	—	—	4,345	—	4,345
Other comprehensive loss, net of tax	—	—	—	(25)	(25)
Dividends	—	—	(1,187)	—	(1,187)
Issuance of common stock in connection with the Company's equity award programs	23.0	1,288	—	—	1,288
Stock-based compensation	—	359	—	—	359
Tax impact related to employee stock-based compensation	—	(87)	—	—	(87)
Repurchases of common stock	(62.3)	—	(4,662)	—	(4,662)
Balance at December 31, 2012	756.3	$ 29,337	$ (10,423)	$ 146	$ 19,060

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2012, 2011 and 2010

(In millions)

	2012	2011	2010
Cash flows from operating activities:			
Net income	$ 4,345	$ 3,683	$ 4,627
Depreciation and amortization	1,088	1,060	1,017
Stock-based compensation expense	362	341	353
Deferred income taxes	28	(328)	(151)
Property, plant and equipment impairments	178	6	118
Other items, net	(74)	63	140
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	348	(557)	(210)
Inventories	(150)	(383)	153
Other assets	124	(204)	20
Accounts payable	161	(95)	142
Accrued income taxes	87	(20)	(656)
Legal reserve	(780)	780	—
Other liabilities	165	773	234
Net cash provided by operating activities	5,882	5,119	5,787
Cash flows from investing activities:			
Purchases of property, plant and equipment	(689)	(567)	(580)
Cash paid for acquisitions, net of cash acquired	(2,390)	(701)	—
Purchases of marketable securities	(26,241)	(21,183)	(14,602)
Proceeds from sales of marketable securities	17,372	20,871	10,485
Proceeds from maturities of marketable securities	1,994	749	642
Other	(36)	45	(97)
Net cash used in investing activities	(9,990)	(786)	(4,152)
Cash flows from financing activities:			
Net proceeds from issuance of debt	4,933	10,387	2,471
Repayment of debt	(123)	(2,500)	—
Net proceeds from issuance of commercial paper	—	762	—
Repayments of commercial paper	—	(762)	—
Repurchases of common stock	(4,607)	(8,315)	(3,786)
Dividends paid	(1,118)	(500)	—
Net proceeds from issuance of common stock in connection with the Company's equity award programs	1,288	242	80
Other	46	12	3
Net cash provided by (used in) financing activities	419	(674)	(1,232)
Increase (decrease) in cash and cash equivalents	(3,689)	3,659	403
Cash and cash equivalents at beginning of period	6,946	3,287	2,884
Cash and cash equivalents at end of period	$ 3,257	$ 6,946	$ 3,287

See accompanying notes.

1. Summary of significant accounting policies

Business

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. Our medicines help millions of patients in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses. We operate in one business segment: human therapeutics.

Principles of consolidation

The consolidated financial statements include the accounts of Amgen as well as its majority-owned subsidiaries. We do not have any significant interests in variable interest entities that require consolidation. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

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

Product sales

Sales of our products are recognized when shipped and title and risk of loss have passed. Product sales are recorded net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively "sales deductions") and returns. Taxes collected from customers and remitted to government authorities related to the sales of the Company's products, primarily in Europe, are excluded from revenues.

With regard to EPOGEN® (epoetin alfa), we have the exclusive right to sell epoetin alfa for dialysis, certain diagnostics and all non-human, non-research uses in the United States. We granted to Ortho Pharmaceutical Corporation (which has assigned its rights under the product license agreement to Janssen Biotech, Inc., formerly known as Centocor Ortho Biotech Products, L.P.), a subsidiary of Johnson & Johnson (J&J), a license relating to epoetin alfa for sales in the United States for all human uses except dialysis and diagnostics. This license agreement, which is perpetual, may be terminated for various reasons, including upon mutual agreement of the parties, or default. The parties are required to compensate each other for epoetin alfa sales that either party makes into the other party's exclusive market, sometimes referred to as "spillover." Accordingly, we do not recognize product sales we make into the exclusive market of J&J and do recognize product sales made by J&J into our exclusive market. Sales in our exclusive market are derived from our sales to our customers, as adjusted for spillover. We are employing an arbitrated audit methodology to measure each party's spillover based on estimates of and subsequent adjustments thereto of third-party data on shipments to and usage by end users.

Other revenues

Other revenues consist primarily of royalty income and corporate partner revenues. Royalties from licensees are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectability is reasonably assured. Royalty estimates are made in advance of amounts collected using historical and forecasted trends. Corporate partner revenues are comprised of amounts earned from Kirin-Amgen, Inc. (K-A) for certain research and development (R&D) activities, which are earned as the R&D activities are performed. Corporate partner revenues also include license fees and milestone payments earned from K-A and from third parties. See Multiple-deliverable revenue arrangements, discussed below, Note 6, Collaborative arrangements, and Note 7, Related party transactions.

Multiple-deliverable revenue arrangements

From time to time, we enter into arrangements for the R&D, manufacture and/or commercialization of products and product candidates. These arrangements may require us to deliver various rights, services and/or goods across the entire life cycle of a product or product candidate, including (i) intellectual property rights/licenses, (ii) R&D services, (iii) manufacturing services and/or (iv) commercialization services. The underlying terms of these arrangements generally provide for consideration to Amgen

in the form of non-refundable upfront license payments, R&D and commercial performance milestone payments, cost sharing and/or royalty payments.

Effective January 1, 2011, we adopted a new accounting standard that amends the guidance on the accounting for arrangements involving the delivery of more than one element. Pursuant to the new standard, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. For Amgen this determination is generally based on whether the deliverable has "stand-alone value" to the customer. The arrangement's consideration that is fixed and determinable is then allocated to each separate units of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price (TPE) and (iii) best estimate of selling price (BESP). The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis. In most cases we expect to use TPE or BESP for allocating consideration to each deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. The Company adopted this new accounting standard on a prospective basis for all multiple-deliverable revenue arrangements (MDRAs) entered into on or after January 1, 2011, and for any MDRAs that were entered into prior to January 1, 2011, but materially modified on or after that date. Had the standard been adopted January 1, 2010, the impact on our consolidated financial statements would have been immaterial.

For MDRAs entered into prior to January 1, 2011, and not materially modified thereafter, we continue to apply our prior accounting policy with respect to such arrangements. Under this policy, in general, revenue from non-refundable, up-front fees related to intellectual property rights/licenses where we have continuing involvement is recognized ratably over the estimated period of ongoing involvement. In general, the consideration with respect to the other deliverables is recognized when the goods or services are delivered.

Under all of our MDRAs, consideration associated with at-risk substantive performance milestones is recognized as revenue upon the achievement of the related milestone, as defined in the respective contracts.

Research and development costs

R&D costs are expensed as incurred and include primarily salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems' costs and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs and cost recoveries associated with third-party R&D arrangements such as with K-A, including upfront fees and milestones paid to third parties in connection with technologies which had not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 6, Collaborative arrangements, and Note 7, Related party transactions.

Selling, general and administrative costs

Selling, general and administrative (SG&A) expenses are comprised primarily of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses; and other general and administrative costs. Advertising costs are expensed as incurred. SG&A expenses also include costs and cost recoveries associated with marketing and promotion efforts under certain collaboration arrangements. Net payment or reimbursement of SG&A costs is recognized when the obligations are incurred or we become entitled to the cost recovery. See Note 6, Collaborative arrangements.

Beginning January 1, 2011, SG&A expenses also include amortization of the annual fee mandated by the Patient Protection and Affordable Care Act and the companion Health Care and Education Reconciliation Act (the U.S. healthcare reform federal excise fee). The liability for the annual U.S. healthcare reform federal excise fee is estimated and recorded in full upon the first qualifying sale of our covered products with a corresponding deferred cost established that is amortized on a straight-line basis over the calendar year that it is payable.

Stock-based compensation

We have stock-based compensation plans under which various types of equity-based awards are granted, including restricted stock units (RSUs), performance units and stock options. The estimated fair values of RSUs and stock option awards which are subject only to service conditions with graded vesting are generally recognized as compensation expense on a straight-line basis over the service period. The estimated fair values of performance unit awards are generally recognized as compensation expense as the awards vest ratably from the grant date to the end of the performance period. See Note 3, Stock-based compensation.

Income taxes

We provide for income taxes based on pretax income, applicable tax rates and tax planning opportunities available in the various jurisdictions in which we operate.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits (UTBs) is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense. See Note 4, Income taxes.

Business combinations

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method, assets acquired, including in-process research and development (IPR&D) projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with a business combination are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in earnings. See Note 2, Business combinations, and Note 16, Fair value measurement.

Cash equivalents

We consider cash equivalents to be only those investments which are highly liquid, readily convertible to cash and which mature within three months from the date of purchase.

Available-for-sale investments

We consider our investment portfolio available-for-sale and, accordingly, these investments are recorded at fair value with unrealized gains and losses generally recorded in other comprehensive income. See Note 9, Available-for-sale investments, and Note 16, Fair value measurement.

Inventories

Inventories are stated at the lower of cost or market. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner that approximates the first-in, first-out method. Cost also includes the Puerto Rico excise tax enacted in 2011 related to our manufacturing operations in Puerto Rico. See Note 10, Inventories.

Derivatives

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Consolidated Balance Sheets. The accounting for changes in the fair value of a derivative instrument depends upon whether it has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of hedging relationship. For derivatives formally designated as hedges, we assess both at inception and quarterly thereafter, whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item. Our derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings. See Note 16, Fair value measurement, and Note 17, Derivative instruments.

Property, plant and equipment, net

Property, plant and equipment is recorded at historical cost, net of accumulated depreciation, amortization and, if applicable, impairment charges. We review our property, plant and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Depreciation is provided over the assets' useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms. See Note 11, Property, plant and equipment.

Goodwill and other intangible assets

Finite-lived intangible assets are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is provided over their estimated useful lives on a straight-line basis. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note 12, Goodwill and other intangible assets.

The estimated fair values of IPR&D projects acquired in a business combination which have not reached technological feasibility are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related R&D efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written-off immediately. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market these products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its estimated fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods.

Capitalized IPR&D projects are tested for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. We consider various factors for potential impairment including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays in obtaining market approval and the inability to bring a product to market could result in the related intangible assets to be partially or fully impaired.

We perform an impairment test of goodwill annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. To date, an impairment of goodwill has not been recorded. See Note 12, Goodwill and other intangible assets.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings and other matters such as intellectual property disputes, contractual disputes, governmental investigations and class action suits which are complex in nature and have outcomes that are difficult to predict. Certain of these proceedings are discussed in Note 18, Contingencies and commitments. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We consider all relevant factors when making assessments regarding these contingencies.

While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Convertible debt

The debt and equity components of convertible debt instruments that may be partially or wholly cash settled (cash settleable convertible notes), including our 0.375% 2013 Convertible Notes, are bifurcated and accounted for separately. The debt component of cash settleable convertible notes, which excludes the associated equity conversion option, is recorded at fair value as of the issuance date. The difference between the amount allocated to the debt component and the proceeds received upon issuance of the debt is allocated to the equity component and recorded in Common stock and additional paid-in capital in the Consolidated Balance Sheets. The reduced or discounted carrying value of cash settleable convertible notes resulting from bifurcation is subsequently accreted back to its principal amount through the recognition of non-cash interest expense. This results in recognizing interest expense on the borrowing at an effective rate approximating what would have been incurred had nonconvertible debt with otherwise similar terms been issued. See Note 14, Financing arrangements.

Foreign currency translation

The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating net assets of these subsidiaries at changing rates are recognized in other comprehensive income. The earnings of these subsidiaries are translated into U.S. dollars using average exchange rates.

Reclassifications

Certain prior-period amounts shown within Cash flows from operating activities in our Consolidated Statements of Cash Flows and Note 4, Income taxes have been reclassified to conform to the current-period presentation.

Recent accounting pronouncements

In January 2012, we adopted a new accounting standard that requires additional disclosures for comprehensive income. As permitted under the standard, we have elected to present comprehensive income in two separate but consecutive financial statements, consisting of a statement of income followed by a separate statement of comprehensive income. The standard was required to be applied retrospectively beginning January 1, 2012.

In February 2013, a new accounting standard was issued that requires increased disclosure requirements regarding amounts that are reclassified out of accumulated other comprehensive income. The standard is required to be adopted prospectively beginning on January 1, 2013.

2. Business combinations

deCODE Genetics

On December 10, 2012, we acquired all of the outstanding stock of deCODE Genetics (deCODE), a privately held company that is a global leader in human genetics, for total consideration of $401 million in cash. The transaction, which was accounted for as a business combination, provides us with an opportunity to enhance our efforts to identify and validate human disease targets. deCODE's operations have been included in our consolidated financial statements commencing on the acquisition date.

We allocated the consideration to acquire deCODE to finite-lived intangible assets of $401 million comprised of databases and other proprietary information with an estimated useful life of 10 years, $93 million to goodwill which is not deductible for tax purposes, deferred tax liabilities of $80 million and other net liabilities of $13 million.

Our accounting for the acquisition is preliminary and will be finalized upon completion of our analysis to determine the acquisition date fair values of certain assets acquired, liabilities assumed and tax-related items.

KAI Pharmaceuticals

On July 5, 2012, we acquired all of the outstanding stock of KAI Pharmaceuticals (KAI), a privately held biotechnology company that is developing AMG 416 (formerly referred to as KAI-4169), its lead product candidate, which is in phase 2 clinical development for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease who are on dialysis. The transaction, which was accounted for as a business combination, provides us with an opportunity to further expand our nephrology pipeline. KAI's operations have been included in our consolidated financial statements commencing on the acquisition date.

The consideration to acquire KAI totaled $332 million in cash which was allocated to the acquisition date fair values of assets acquired and liabilities assumed as follows (in millions):

Indefinite-lived intangible assets - IPR&D	$	240
Goodwill		125
Deferred tax assets (liabilities), net		(59)
Other assets (liabilities), net		26
Total consideration	$	332

The estimated fair value of acquired IPR&D is related to AMG 416. The estimated fair value was determined using a probability-weighted income approach, which discounts expected future cash flows to present value by using a discount rate that represents the estimated rate that market participants would use to value this intangible asset. The projected cash flows from AMG 416 were based on certain assumptions, including estimates of future revenues and expenses, the time and resources needed to complete development and the probabilities of obtaining marketing approval from the U.S. Food and Drug Administration (FDA) and other regulatory agencies.

The excess of the acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $125 million was recorded as goodwill, which is not deductible for tax purposes. Goodwill is attributable primarily to expected

synergies and other benefits from combining KAI with our nephrology development and commercialization activities and the deferred tax consequences of indefinite-lived intangible assets recorded for financial statement purposes.

Our accounting for this acquisition is preliminary and will be finalized upon completion of our analysis to determine the acquisition date fair values of certain assets acquired, liabilities assumed and tax-related items.

Mustafa Nevzat Pharmaceuticals

On June 12, 2012, we acquired substantially all of the outstanding stock of Mustafa Nevzat Pharmaceuticals (MN), a privately held company that is a leading supplier of pharmaceuticals to the hospital sector and a major supplier of injectable medicines in Turkey. The transaction, which was accounted for as a business combination, provides us with the opportunity to expand our presence in Turkey and the surrounding region. MN's operations have been included in our consolidated financial statements commencing on the acquisition date.

The consideration to acquire MN totaled $677 million in cash which was allocated to the acquisition date fair values of assets acquired and liabilities assumed as follows (in millions):

Finite-lived intangible assets	$	163
Property, plant and equipment		100
Trade receivables		79
Inventories		52
Goodwill		380
Deferred tax assets (liabilities), net		(45)
Other assets (liabilities), net		(52)
Total consideration	$	677

The finite-lived intangible assets acquired are related primarily to the fair values of MN's regulatory approvals and customer relationships with regard to the marketing of pharmaceutical products and are being amortized on a straight-line basis over their estimated useful lives. The weighted-average useful life of these intangible assets is eight years.

The excess of the acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $380 million was recorded as goodwill, which is not deductible for tax purposes. Goodwill is attributable primarily to MN's expected continued commercial presence in Turkey and other benefits.

Our accounting for the acquisition is preliminary and will be finalized upon completion of our analysis to determine the acquisition date fair values of certain assets acquired, liabilities assumed and tax-related items.

Micromet, Inc.

On March 7, 2012, we acquired Micromet, Inc. (Micromet), a publicly held biotechnology company focused on the discovery, development and commercialization of innovative antibody-based therapies for the treatment of cancer, which became a wholly owned subsidiary of Amgen. This transaction, which was accounted for as a business combination, provides us with an opportunity to further expand our oncology pipeline. Micromet's operations have been included in our consolidated financial statements commencing on the acquisition date.

The consideration to acquire Micromet totaled $1,146 million in cash which was allocated to the acquisition date fair values of assets acquired and liabilities assumed as follows (in millions):

Indefinite-lived intangible assets:		
IPR&D	$	440
Contract assets		170
Finite-lived intangible assets — Developed technology		350
Goodwill		330
Cash and marketable securities		154
Deferred tax assets (liabilities), net		(274)
Other assets (liabilities), net		(24)
Total consideration	$	1,146

The estimated fair value of acquired IPR&D is related to blinatumomab, which is in phase 2 clinical development for the treatment of acute lymphoblastic leukemia. The estimated fair value was determined using a probability-weighted income approach, which discounts expected future cash flows to present value by using a discount rate that represents the estimated rate that market participants would use to value this intangible asset. The projected cash flows from blinatumomab were based on certain assumptions, including estimates of future revenues and expenses, the time and resources needed to complete development and the probabilities of obtaining marketing approval from the FDA and other regulatory agencies.

Contract assets acquired represent the aggregate estimated fair values of receiving future milestone and royalty payments associated with various outlicensing arrangements entered into by Micromet prior to our acquisition of the company. The fair values of these contracts were determined by estimating the probability-weighted net cash flows associated with the agreements that may be received from the other parties discounted to present value by using a discount rate that represents the estimated rate that market participants would use to value these intangible assets. These contract assets are considered indefinite-lived intangible assets and their assigned values will be expensed when the related revenues are earned or the associated R&D efforts are abandoned by the licensees. During 2012, a non-key program under one of these outlicensing arrangements was terminated and resulted in an impairment charge of $19 million which was included in Other operating expenses.

The developed technology acquired relates to Micromet's bi-specific T-cell engager technology platform which has produced various product candidates that are currently being developed as cancer treatments by Micromet and others and may lead to the development of additional product candidates. The fair value of this technology was determined by estimating the probability-weighted net cash flows attributable to this technology discounted to present value by using a discount rate that represents the estimated rate that market participants would use to value this intangible asset. The fair value of this technology is being amortized on a straight-line basis over its estimated useful life of 10 years.

The excess of the acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $330 million was recorded as goodwill, which is not deductible for tax purposes. Goodwill is attributable primarily to expected synergies and other benefits from combining Micromet with our oncology development and commercialization activities and the deferred tax consequences of indefinite-lived and finite-lived intangible assets recorded for financial statement purposes.

BioVex Group, Inc.

On March 4, 2011, we acquired all of the outstanding stock of BioVex Group, Inc. (BioVex), a privately held biotechnology company developing treatments for cancer and for the prevention of infectious disease, including talimogene laherparepvec, a novel oncolytic vaccine in phase 3 clinical development for the treatment of malignant melanoma. The transaction, which was accounted for as a business combination, provides us with an opportunity to expand our efforts to bring novel therapeutics to market. Upon its acquisition, BioVex became a wholly owned subsidiary of Amgen, and its operations have been included in our consolidated financial statements commencing on the acquisition date.

The aggregate acquisition date consideration to acquire BioVex consisted of (in millions):

Cash paid to former shareholders of BioVex	$	407
Fair value of contingent consideration obligations		190
Total consideration	$	597

In connection with this acquisition, we are obligated to make additional payments to the former shareholders of BioVex of up to $575 million contingent upon the achievement of various regulatory and sales milestones with regard to talimogene laherparepvec, including the filing of a Biologics License Application (BLA) with the FDA; the first commercial sale in each of the United States and the European Union (EU) following receipt of marketing approval, which includes use of the product in specified patient populations; and upon achieving specified levels of sales. The estimated fair values of the contingent consideration obligations aggregated $190 million as of the acquisition date and were determined using a combination of valuation techniques. (See Note 16, Fair value measurement for information regarding the estimated fair values of these obligations as of December 31, 2012.) The contingent consideration obligations to make regulatory milestone payments were valued based on assumptions regarding the probability of achieving the milestones and making the related payments, with such amounts discounted to present value based on our credit risk. The contingent consideration obligations to make sales milestone payments were valued based on assumptions regarding the probability of achieving specified product sales thresholds to determine the required payments, with such amounts discounted to present value based on our credit risk.

We allocated the total consideration to the acquisition date fair values of assets acquired and liabilities assumed as follows (in millions):

Indefinite-lived intangible assets — IPR&D	$	675
Goodwill		170
Deferred tax assets (liabilities), net		(246)
Other assets (liabilities), net		(2)
Total consideration	$	597

The estimated fair value of acquired IPR&D is related to talimogene laherparepvec. The estimated fair value was determined using a probability-weighted income approach, which discounts expected future cash flows to present value by using a discount rate that represents the estimated rate that market participants would use to value this intangible asset. The projected cash flows from talimogene laherparepvec were based on certain assumptions, including estimates of future revenue and expenses, the time and resources needed to complete development and the probabilities of obtaining marketing approval from the FDA and other regulatory agencies.

The excess of the acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $170 million was recorded as goodwill, which is not deductible for tax purposes. Goodwill is attributable primarily to the deferred tax consequences of acquired IPR&D recorded for financial statement purposes.

Other acquisitions

We also acquired the businesses described below, which were accounted for as business combinations, and accordingly, their operations have been included in our consolidated financial statements commencing on their respective acquisition dates.

On April 7, 2011, we acquired all of the outstanding stock of Laboratório Químico Farmacêutico Bérgamo Ltda (Bergamo), a privately held Brazilian pharmaceutical company. Upon its acquisition, Bergamo became a wholly owned subsidiary of Amgen.

On May 16, 2011, we acquired a manufacturing facility in Dun Laoghaire, Ireland, from Pfizer Inc. (Pfizer) (Dun Laoghaire). Under the terms of the agreement, most staff at the facility became Amgen employees, and we agreed to manufacture certain products for Pfizer at the facility for a certain period.

On June 15, 2011, we reacquired rights to distribute certain of our products in the Brazilian pharmaceutical market from our local distributor in Brazil and its parent company, Hypermarcas, and in connection therewith acquired all business operations related to these products in Brazil.

The aggregate acquisition date consideration for these businesses was approximately $453 million, composed primarily of cash paid to the former owners of the businesses. The aggregate acquisition date consideration was allocated to (i) goodwill of $265 million, of which $130 million related to Bergamo was tax deductible: (ii) property, plant and equipment of $99 million; (iii) amortizable intangible assets composed primarily of licenses to distribute products and customer contracts of $58 million; and (iv) other assets, net of $31 million. Goodwill resulting from these acquisitions is attributable primarily to the benefits of immediate, direct access to the Brazilian market for expediting our international expansion efforts and geographic diversification to assist in risk mitigation efforts related to our manufacturing operations.

The estimated incremental R&D costs to be incurred to obtain necessary regulatory approvals for the IPR&D projects in the acquisitions discussed above, including AMG 416, blinatumomab and talimogene laherparepvec, are individually immaterial in any given year. The major risks and uncertainties associated with the timely and successful completion of development and commercialization of these product candidates include our ability to confirm their safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not able to market a human therapeutic without obtaining regulatory approvals, and such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value, if any, of these acquired IPR&D projects may vary from their estimated fair values at the dates of acquisition.

The preliminary fair value estimates of assets acquired and liabilities assumed with respect to the acquisitions of deCODE, KAI, and MN were based on preliminary calculations and valuations. Our estimates and assumptions for each of these acquisitions, particularly with respect to identifiable intangible assets acquired and tax-related items, are subject to change as we obtain additional information for our estimates during the respective measurement periods (up to one year from the respective acquisition dates).

The operations of each of the acquired businesses discussed above were not material individually or in the aggregate to our consolidated financial statements. Pro forma supplemental consolidated results of operations for the years ended December 31, 2012, 2011 and 2010, that assumes the acquisitions of the businesses discussed above all occurred on January 1 of the year prior to the year of acquisition are not provided because the impact would not be material to our consolidated results of operations either individually or in the aggregate.

3. Stock-based compensation

Our 2009 Equity Incentive Plan (the 2009 Plan) authorizes the issuance of 100 million shares of our common stock through grants of equity-based awards, including RSUs, stock options and performance units to employees and consultants of Amgen, its subsidiaries and non-employee members of our Board of Directors. The 2009 Plan, which was approved by our stockholders on May 6, 2009, replaced our prior equity plans (the Prior Plans), and no further awards may be made under these Prior Plans. Under the terms of the 2009 Plan, the pool of available shares that may be used for all types of awards, including those issued under our Prior Plans after December 31, 2008, and before May 6, 2009 (the stub period), is reduced by one share for each stock option granted and by 1.9 shares for other types of awards granted, including RSUs and performance units. If any shares subject to an award granted under our Prior Plans during the stub period or any awards granted under the 2009 Plan expire, or are forfeited, terminated or cancelled without the issuance of shares, the shares subject to such awards are added back to the pool of available shares under the 2009 Plan on the same basis that they were removed. As of December 31, 2012, the 2009 Plan provides for future grants and/or issuances of up to approximately 48 million shares of our common stock. Stock-based awards under our employee compensation plans are made with newly issued shares reserved for this purpose.

The following table reflects the components of stock-based compensation expense recognized in our Consolidated Statements of Income for the years ended December 31, 2012, 2011 and 2010 (in millions):

	2012	2011	2010
Stock options	$ 59	$ 85	$ 124
RSUs	186	188	182
Performance units	117	68	47
Total stock-based compensation expense, pretax	362	341	353
Tax benefit from stock-based compensation expense	(134)	(124)	(120)
Total stock-based compensation expense, net of tax	$ 228	$ 217	$ 233

Restricted stock units and stock options

Eligible employees generally receive a grant of RSUs annually with the size and type of award generally determined by the employee's salary grade and performance level. In addition, certain management and professional level employees typically receive RSU grants upon commencement of employment. Prior to 2012, eligible employees also received a grant of stock options annually. Prior to February 2013, non-employee members of our Board of Directors (outside directors) received a grant of RSUs and stock options annually and received a grant of stock options in connection with their appointment to the Board of Directors. Beginning in April 2013, outside directors will receive only annual grants of RSUs.

Our RSU and stock option grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including upon death, disability, a change in control, termination in connection with a change

in control and the retirement of employees who meet certain service and/or age requirements. RSUs and stock options granted prior to April 25, 2011, generally vest in equal amounts on each of the first four anniversaries of the grant date. Stock options and RSUs granted on and after April 25, 2011, generally vest in approximately equal amounts on the second, third and fourth anniversaries of the grant date. RSUs granted on and after April 27, 2012, accrue dividend equivalents which are typically payable in shares only when and to the extent the underlying RSUs vest and are issued to the recipient.

Stock options

The exercise price for stock options is set at the closing price of our common stock on the date of grant and the related number of shares granted is fixed at that point in time. Awards granted to employees on and after April 26, 2010, expire 10 years from the date of grant; options granted to employees prior to that date expire seven years from the date of grant.

We use an option valuation model to estimate the grant date fair value of stock options. The weighted-average assumptions used in the option valuation model and the resulting weighted-average estimated grant date fair values of stock options were as follows for the years ended December 31, 2012, 2011 and 2010:

	2012	2011	2010
Closing price of our common stock on grant date	$ 74.56	$ 54.66	$ 58.32
Expected volatility	22.2%	23.5%	28.0%
Expected life (in years)	8.1	5.9	6.6
Risk-free interest rate	1.6%	2.5%	3.2%
Expected dividend yield	2.1%	2.0%	0%
Fair value of stock options granted	$ 14.65	$ 11.39	$ 20.97

The expected volatility reflects consideration of the implied volatility in publicly traded instruments associated with Amgen's common stock during the period the options were granted. We believe implied volatility in these instruments is more indicative of expected future volatility than the historical volatility in the price of our common stock. We use historical data to estimate the expected life of the options. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period the options were granted. The expected dividend yield for options granted on and after April 25, 2011, was based on expectations regarding our policy of paying dividends announced in April 2011.

The following summarizes select information regarding our stock options during the year ended December 31, 2012:

	Options (in millions)	Weighted-average exercise price	Weighted-average remaining contractual life (years)	Aggregate intrinsic value (in millions)
Balance unexercised at December 31, 2011	34.2	$ 59.11		
Granted	0.1	$ 74.56		
Exercised	(20.9)	$ 60.67		
Expired/forfeited	(1.1)	$ 63.97		
Balance unexercised at December 31, 2012	12.3	$ 56.09	4.9	$ 371
Vested or expected to vest at December 31, 2012	12.2	$ 56.10	4.9	$ 367
Exercisable at December 31, 2012	6.3	$ 56.59	3.1	$ 187

The total intrinsic values of options exercised during the years ended December 31, 2012, 2011 and 2010, were $320 million, $47 million and $15 million, respectively. The actual tax benefits realized from tax deductions from option exercises during the three years ended December 31, 2012, 2011 and 2010, were $117 million, $14 million and $5 million, respectively.

Restricted stock units

The grant date fair value of an RSU equaled the closing price of our common stock on the grant date for RSUs granted prior to April 25, 2011, and on and after April 27, 2012. Prior to April 2011, we did not have a policy of paying dividends, and beginning April 27, 2012, RSUs granted accrue dividend equivalents during the vesting period. The fair values of RSUs granted on April 25, 2011 through April 26, 2012, are based on the closing price of our common stock on the grant date reduced by the weighted-

average expected dividend yield of 2.0% over the weighted-average vesting period, discounted at a weighted-average risk-free interest rate of 1.0%. The weighted-average grant date fair values of RSUs granted in 2012, 2011 and 2010 were $72.99, $51.83 and $58.19, respectively. The following summarizes select information regarding our RSUs during the year ended December 31, 2012:

	Units (in millions)	Weighted-average grant date fair value
Balance nonvested at December 31, 2011	9.0	$ 52.64
Granted	3.9	$ 72.99
Vested	(2.8)	$ 50.64
Forfeited	(0.7)	$ 58.38
Balance nonvested at December 31, 2012	9.4	$ 61.14

The total fair values of shares associated with RSUs that vested during the years ended December 31, 2012, 2011 and 2010, were $139 million, $176 million and $184 million, respectively.

As of December 31, 2012, there was approximately $388 million of unrecognized compensation costs related to nonvested stock option and RSU awards, which is expected to be recognized over a weighted-average period of 1.7 years.

Performance units

Certain management-level employees also receive annual grants of performance units, which give the recipient the right to receive common stock that is contingent upon achievement of specified pre-established goals over the performance period, which is generally three years. The performance goals for the units granted in 2012, 2011 and 2010, which are accounted for as equity awards, are based upon Amgen's stockholder return compared with a comparator group of companies, which are considered market conditions and are reflected in the grant date fair value of the units, and for units granted in 2010, Amgen's standalone financial performance, which are considered performance conditions. The expense recognized for the awards granted in 2012 and 2011 is based on the grant date fair value of a unit multiplied by the number of units granted, net of estimated forfeitures. The expense recognized for the awards granted in 2010 was based on the grant date fair value of a unit multiplied by the number of units expected to be earned with respect to the performance conditions, net of estimated forfeitures. Depending on the outcome of these performance goals, a recipient may ultimately earn a number of units greater or less than the number of units granted. Shares of our common stock are issued on a one-for-one basis for each performance unit earned. In general, participants vest in their performance unit awards at the end of the performance period. The performance award program provides for accelerated or continued vesting in certain circumstances as defined in the plan, including upon death, disability, a change in control and retirement of employees who meet certain service and/or age requirements. Performance units granted in 2012 and later accrue dividend equivalents which are typically payable in shares only when and to the extent the underlying performance units vest and are issued to the recipient, including with respect to market conditions that affect the number of performance units earned.

We used payout simulation models to estimate the grant date fair value of performance units granted in 2012, 2011 and 2010. The weighted-average assumptions used in these models and the resulting weighted-average grant date fair values of our performance units were as follows for the years ended December 31, 2012, 2011 and 2010:

	2012	2011	2010
Closing price of our common stock on grant date	$ 68.75	$ 51.67	$ 56.90
Volatility	22.9%	32.8%	34.7%
Risk-free interest rate	0.5%	1.2%	1.3%
Expected dividend yield	2.2%	0.1%	0%
Fair value of unit	$ 78.21	$ 49.50	$ 62.06

The payout simulation models also assumed correlations of returns of the stock prices of our common stock and the common stocks of the comparator groups of companies and stock price volatilities of the comparator groups of companies.

As of December 31, 2012 and 2011, a total of 5.8 million and 4.1 million performance units were outstanding with weighted-average grant date fair values of $65.15 and $51.92 per unit, respectively. During the year ended December 31, 2012, 2.9 million performance units with a weighted-average grant date fair value of $78.21 were granted, 1.2 million performance units with a

grant date fair value of $62.06 vested and 0.4 million performance units with a weighted-average grant date fair value of $62.60 were forfeited.

The total fair values of performance units that vested during 2012, 2011 and 2010 were $100 million, $25 million and $34 million, respectively, based upon the number of performance units earned multiplied by the closing stock price of our common stock on the last day of the performance period.

As of December 31, 2012, there was approximately $179 million of unrecognized compensation cost related to the 2012 and 2011 performance unit grants that is expected to be recognized over a weighted-average period of approximately 1.0 years.

4. Income taxes

The provision for income taxes includes the following for the years ended December 31, 2012, 2011 and 2010 (in millions):

	2012	2011	2010
Current provision:			
Federal	$ 438	$ 551	$ 620
State	47	54	52
Foreign	158	148	153
Total current provision	643	753	825
Deferred provision (benefit):			
Federal	83	(273)	(180)
State	(43)	(12)	43
Foreign	(19)	(1)	2
Total deferred provision (benefit)	21	(286)	(135)
Total provision	$ 664	$ 467	$ 690

Deferred income taxes reflect the tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards and the tax effects of net operating loss (NOL) carryforwards.

In 2012, we reclassified the prepaid taxes associated with intercompany profit in ending inventory from current deferred income tax assets to current prepaid tax. This change resulted in a reclassification of approximately $71 million and $16 million for 2011 and 2010, respectively, from the deferred provision to the current provision.

Significant components of our deferred tax assets and liabilities are as follows as of December 31, 2012 and 2011 (in millions):

	2012	2011
Deferred income tax assets [1]:		
Expense accruals	$ 805	$ 751
NOL and credit carryforwards	427	206
Expenses capitalized for tax	195	193
Stock-based compensation	115	241
Deferred revenue	40	133
Other	83	70
Total deferred income tax assets	1,665	1,594
Valuation allowance	(273)	(126)
Net deferred income tax assets	1,392	1,468
Deferred income tax liabilities:		
Acquired intangibles	(1,249)	(832)
Fixed assets	(117)	(219)
Unremitted foreign earnings	(106)	(61)
Other	(145)	(110)
Total deferred income tax liabilities	(1,617)	(1,222)
Total deferred income taxes, net	$ (225)	$ 246

[1] In 2012, we reclassified certain prior period amounts to conform with current period reporting, primarily in connection with reclassifying prepaid taxes associated with intercompany profit in ending inventory from current deferred tax assets to prepaid taxes. Prepaid taxes are not included in the net deferred income tax table above; therefore, amounts related to these prepaid taxes which totaled $349 million for 2011 have been removed from the above table.

Valuation allowances are provided to reduce the amounts of our deferred tax assets to an amount that is more likely than not to be realized based on an assessment of positive and negative evidence, including estimates of future taxable income necessary to realize future deductible amounts.

The valuation allowance for deferred tax assets increased by $147 million and $46 million in 2012 and 2011, respectively, due primarily to valuation allowances established as part of acquisitions and the Company's expectation that some state R&D credits will not be utilized, offset partially by the release of valuation allowance related to state investment credits.

At December 31, 2012, we had $242 million of tax credit carryforwards available to reduce future state income taxes and have provided a valuation allowance for $110 million of those state tax credit carryforwards. The majority of the state tax credit carryforwards have no expiry; the remainder expires between 2013 and 2019.

At December 31, 2012, we had $233 million of NOL carryforwards available to reduce future federal income taxes and have provided a valuation allowance for $75 million of those federal NOL carryforwards. The federal NOL carryforwards for which no valuation allowance has been provided expire between 2023 and 2032. We had $301 million of NOL carryforwards available to reduce future state income taxes and have provided a valuation allowance for $48 million of those state NOL carryforwards. The state NOLs for which no valuation allowance has been provided expire between 2014 and 2018. We had $383 million of NOL carryforwards available to reduce future foreign income taxes for which a full valuation allowance has been provided. The majority of the foreign NOLs have no expiry; the remainder of the foreign NOLs expire between 2017 and 2022.

The reconciliation of the total gross amounts of UTBs (excluding interest, penalties, foreign tax credits and the federal tax benefit of state taxes related to UTBs) for the years ended December 31, 2012, 2011 and 2010 is as follows (in millions):

	2012	2011	2010
Balance at beginning of year	$ 975	$ 920	$ 1,140
Additions based on tax positions related to the current year	300	283	305
Reductions for tax positions of prior years	(45)	(7)	(110)
Settlements	(30)	(221)	(415)
Balance at end of year	$ 1,200	$ 975	$ 920

Substantially all of the UTBs as of December 31, 2012, if recognized, would affect our effective tax rate.

During the year ended December 31, 2012, we settled examinations with various state and foreign tax authorities for prior tax years. As a result of these developments, we remeasured our UTBs accordingly.

During the year ended December 31, 2011, we settled our examination with the Internal Revenue Service (IRS) related to certain transfer pricing tax positions for the years ended December 31, 2007, 2008 and 2009. As a result of these developments, we remeasured our UTBs accordingly.

During the year ended December 31, 2010, we settled our examination with the IRS related to certain transfer pricing tax positions for the years ended December 31, 2007 and 2008. In addition, we also settled issues under appeal with the IRS for the years ended December 31, 2005 and 2006, primarily related to the impact of transfer pricing adjustments on the repatriation of funds. During the year ended December 31, 2010, the IRS also agreed to Competent Authority relief for certain transfer pricing tax positions for the years ended December 31, 2002, through December 31, 2006. As a result of these developments, we remeasured our UTBs accordingly.

As of December 31, 2012, we believe it is reasonably possible that our gross liabilities for UTBs may decrease by approximately $280 million within the succeeding twelve months due to the resolution of federal and state audits, including a decrease related to the IRS settlement described below.

Interest and penalties related to UTBs are included in our provision for income taxes. During 2012, 2011 and 2010, we accrued approximately $30 million, $23 million and $41 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. At December 31, 2012 and 2011, accrued interest and penalties associated with UTBs totaled approximately $102 million and $105 million, respectively.

The reconciliation between the federal statutory tax rate applied to income before income taxes and our effective tax rate for the years ended December 31, 2012, 2011 and 2010, is as follows:

	2012	2011	2010
Federal statutory tax rate	35.0 %	35.0 %	35.0 %
Foreign earnings, including earnings invested indefinitely	(17.8)%	(19.4)%	(19.1)%
State taxes	0.6 %	0.7 %	1.6 %
Credits, Puerto Rico Excise Tax	(5.2)%	(6.5)%	0.0 %
Credits, primarily federal R&D	0.0 %	(1.5)%	(0.9)%
Legal settlements	(0.2)%	2.2 %	0.0 %
Audit settlements (federal, state, foreign)	0.3 %	0.0 %	(3.1)%
Other, net	0.6 %	0.8 %	(0.5)%
Effective tax rate	13.3 %	11.3 %	13.0 %

Because the American Taxpayer Relief Act of 2012 was not enacted until 2013, certain provisions of the Act benefiting the Company's 2012 federal taxes, including the retroactive extension of the R&D tax credit for 2012, cannot be recognized in the Company's 2012 financial results and instead will be reflected in the Company's 2013 financial results for the first quarter. The tax benefit of the retroactive extension of the 2012 R&D tax credit that will be recognized in the first quarter of 2013 is approximately $65 million.

The effective tax rates for the years ended December 31, 2012, 2011 and 2010, are different from the federal statutory rates primarily as a result of indefinitely invested earnings of our foreign operations. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be invested indefinitely outside the United States. Substantially all of the benefit from foreign earnings on our effective tax rate results from foreign income associated with the Company’s operation conducted in Puerto Rico that is subject to a tax incentive grant that expires in 2020. At December 31, 2012, the cumulative amount of these earnings was approximately $22.2 billion. If these earnings were repatriated to the United States, we would be required to accrue and pay approximately $7.9 billion of additional income taxes based on the current tax rates in effect.

Our total foreign income before income taxes was approximately $3.3 billion, $3.0 billion and $3.5 billion for the years ended December 31, 2012, 2011 and 2010, respectively.

Commencing January 1, 2011, Puerto Rico imposes a temporary excise tax on the purchase of goods and services from a related manufacturer in Puerto Rico. The excise tax is imposed on the gross intercompany purchase price of the goods and services and is effective for a six-year period beginning in 2011, with the excise tax rate declining in each year (4% in 2011, 3.75% in 2012, 2.75% in 2013, 2.5% in 2014, 2.25% in 2015 and 1% in 2016). In February 2013, the Puerto Rico government proposed an amendment to the excise tax legislation which, if approved, would increase the excise tax rate to 4% effective July 1, 2013 through 2017. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in cost of sales when the related products are sold. For U.S. income tax purposes, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes when the excise tax is incurred.

Income taxes paid during the years ended December 31, 2012, 2011 and 2010, totaled $502 million, $595 million and $1,344 million, respectively.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely audited by the tax authorities in those jurisdictions. Significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions, the use of tax credits and allocations of income among various tax jurisdictions because of differing interpretations of tax laws and regulations. We are no longer subject to U.S. federal income tax examinations for tax years ending on or before December 31, 2009, or to California state income tax examinations for tax years ending on or before December 31, 2005.

Subsequent to December 31, 2012, we settled the examination of our U.S. tax returns with the IRS relating to years ended December 31, 2007, 2008, and 2009. We will remeasure our UTBs and recognize the tax impact of this settlement in the first quarter of 2013. We expect the settlement to result in a tax benefit of approximately $185 million.

5. Earnings per share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which include principally shares that may be issued under: our stock option, restricted stock and performance unit awards, determined using the treasury stock method; our outstanding convertible notes, as discussed below; and our outstanding warrants (collectively “dilutive securities”). The convertible note hedges purchased in connection with the issuance of our convertible notes are excluded from the calculation of diluted EPS because their impact is always anti-dilutive. For further information regarding our convertible notes and warrants, see Note 14, Financing arrangements.

Prior to the conversion/maturity of our 0.375% 2013 Convertible Notes in February 2013 (see Note 14, Financing arrangements), the principal amount of the notes had to be settled in cash, and the excess of the conversion value, as defined, over the principal amount could have been settled in cash and/or shares of our common stock upon conversion. Therefore, only the shares of our common stock potentially issuable with respect to the excess of the notes’ conversion value over their principal amount, if any, are considered as dilutive potential common shares for purposes of calculating diluted EPS. For the year ended December 31, 2012, the conversion value of our convertible notes due in 2013 exceeded the related principal amount resulting in the assumed issuance of an additional one million shares calculated on a weighted-average basis for purposes of computing diluted

EPS. For the years ended December 31, 2011 and 2010, the conversion values of our convertible notes were less than the related principal amounts, and accordingly, no shares were assumed to be issued for purposes of computing diluted EPS.

The computation for basic and diluted EPS was as follows (in millions, except per share data):

	2012	2011	2010
Income (Numerator):			
Net income for basic and diluted EPS	$ 4,345	$ 3,683	$ 4,627
Shares (Denominator):			
Weighted-average shares for basic EPS	775	905	960
Effect of dilutive securities	12	7	5
Weighted-average shares for diluted EPS	787	912	965
Basic EPS	$ 5.61	$ 4.07	$ 4.82
Diluted EPS	$ 5.52	$ 4.04	$ 4.79

For the years ended December 31, 2012, 2011 and 2010, there were employee stock-based awards, calculated on a weighted-average basis, to acquire 6 million, 33 million and 43 million shares of our common stock, respectively, that are not included in the computation of diluted EPS because their impact would have been anti-dilutive. In addition, shares of our common stock that may be issued upon exercise of our warrants are not included in the computation of diluted EPS for any of the periods presented above because their impact would have been anti-dilutive.

6. Collaborative arrangements

A collaborative arrangement is a contractual arrangement that involves a joint operating activity which involves two or more parties who are both: (i) active participants in the activity; and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and product candidates. These collaborations generally provide for non-refundable upfront license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration agreements are performed with no guarantee of either technological or commercial success and each is unique in nature. Our significant arrangements are discussed below.

Pfizer Inc.

We are in a collaboration with Pfizer to co-promote Enbrel® in the United States and Canada. The rights to market ENBREL outside the United States and Canada are reserved to Pfizer. Under the agreement, a management committee comprised of equal representation from Amgen and Pfizer is responsible for overseeing the marketing and sales of ENBREL, including strategic planning, the approval of an annual marketing plan, product pricing and the establishment of a brand team. Amgen and Pfizer share in the agreed-upon selling and marketing expenses approved by the joint management committee. We currently pay Pfizer a percentage of annual gross profits on our ENBREL sales in the United States and Canada attributable to all approved indications on a scale that increases as gross profits increase; however, we maintain a majority share of ENBREL profits. After expiration of the co-promotion term on October 31, 2013, we will be required to pay Pfizer residual royalties based on a declining percentage of annual net ENBREL sales in the United States and Canada for three years, ranging from 12% to 10%. The amounts of such payments are anticipated to be significantly less than what would be owed based on the terms of the current ENBREL profit share. Effective November 1, 2016, there will be no further royalty payments.

We have determined that we are the principal participant in the collaboration with Pfizer to market ENBREL in the United States and Canada. Accordingly, we record our product sales of ENBREL to third parties net of estimated returns, rebates and other deductions. For the years ended December 31, 2012, 2011 and 2010, ENBREL sales aggregated $4.2 billion, $3.7 billion and $3.5 billion, respectively.

During the years ended December 31, 2012, 2011 and 2010, the ENBREL profit share expense was $1,495 million, $1,288 million and $1,184 million, respectively. In addition, cost recoveries from Pfizer for their share of the selling and marketing

expense were $35 million, $84 million and $87 million for the years ended December 31, 2012, 2011 and 2010, respectively. Both the profit share expenses and the cost recoveries are included in Selling, general and administrative expense in the Consolidated Statements of Income.

Glaxo Group Limited

We are in a collaboration with Glaxo Group Limited (Glaxo), a wholly owned subsidiary of GlaxoSmithKline plc, for the commercialization of denosumab for osteoporosis indications in Europe, Australia, New Zealand and Mexico (the Primary Territories). We have retained the rights to commercialize denosumab for all indications in the United States and Canada and for oncology indications in the Primary Territories. Under a related agreement, Glaxo will commercialize denosumab for all indications in countries, excluding Japan, where we did not have a commercial presence at the commencement of the agreement, including China, Brazil, India, Taiwan and South Korea (the Expansion Territories). In the Expansion Territories, Glaxo is responsible for all development and commercialization costs and will purchase denosumab from us to meet demand. We have the option of expanding our role in the commercialization of denosumab in the Primary Territories and certain of the Expansion Territories.

In the Primary Territories, we share equally in the commercialization profits and losses related to the collaboration after accounting for expenses, including an amount payable to us in recognition of our discovery and development of denosumab. Glaxo is also responsible for bearing a portion of the cost of certain specified development activities in the Primary Territories.

The collaboration agreement with Glaxo for the Primary Territories will expire in 2022 and the related agreement for the Expansion Territories will expire in 2024, unless either agreement is terminated earlier in accordance with its terms.

As the principal participant in the Primary Territories, Amgen records related product sales to third parties net of estimated returns, rebates and other deductions. During the years ended December 31, 2012, 2011 and 2010, product sales in the Primary Territories for osteoporosis indications were $139 million, $62 million and $5 million, respectively. In the Expansion Territories, we record product sales to Glaxo. During the years ended December 31, 2012, 2011 and 2010, product sales of denosumab to Glaxo for the Expansion Territories were not material.

During the years ended December 31, 2012, 2011 and 2010, the net cost recoveries from Glaxo were $10 million, $30 million and $46 million, respectively, and are included in Selling, general and administrative expense in the Consolidated Statements of Income. In addition, during 2010, we received payments from Glaxo aggregating $75 million for the achievement of certain commercial milestones, which were recognized as Other revenues in our Consolidated Statement of Income.

AstraZeneca Plc.

We are in a collaboration with AstraZeneca Plc. (AstraZeneca) to jointly develop and commercialize certain monoclonal antibodies from Amgen's clinical inflammation portfolio, including brodalumab, AMG 139, AMG 157, AMG 181 and AMG 557. The agreement covers the worldwide development and commercialization, except for certain Asian countries for brodalumab and Japan for AMG 557, that are licensed to other third parties.

Under the terms of the agreement, approximately 65% of related development costs for the 2012-2014 periods will be funded by AstraZeneca, thereafter, the companies will share costs equally. If approved for sale, Amgen would receive a low-single-digit royalty rate for brodalumab and a mid-single-digit royalty rate for the rest of the portfolio, after which the worldwide commercialization profits and losses related to the collaboration products would be shared equally. In 2012, we received a payment of $50 million, in connection with the transfer of technology rights, which was recognized in Other revenues in the Consolidated Statement of Income. During the year ended December 31, 2012, cost recoveries recognized for development costs were $28 million, which are included in Research and development expense in the Consolidated Statement of Income**.**

The collaboration agreement will continue in effect unless terminated in accordance with its terms.

Takeda Pharmaceutical Company Limited

In 2008, we entered into an arrangement with Takeda Pharmaceutical Company Limited (Takeda), that provided Takeda both: (i) the exclusive rights to develop and commercialize for the Japanese market up to 12 molecules from our portfolio across a range of therapeutic areas, including oncology and inflammation (collectively the “Japanese market products”) and (ii) the right to collaborate with us on the worldwide (outside Japan) development and commercialization of our product candidate, motesanib. The Japanese market products include Vectibix® and certain product candidates. In connection with this 2008 arrangement, we received upfront payments of $300 million that were deferred and were being recognized as Other revenues in our Consolidated Statements of Income over the estimated period of continuing involvement of approximately 20 years. Additionally, during 2010,

we received payments aggregating $55 million for the achievement of certain regulatory milestones which were recognized as Other revenues in our Consolidated Statement of Income upon the achievement of the related milestone events.

In 2011, we announced that the motesanib pivotal phase 3 trial (MONET1) had not met its primary objective of demonstrating an improvement in overall survival in patients with advanced non-squamous non small cell lung cancer (NSCLC).

In June 2012, the parties materially modified this arrangement such that Amgen licensed all of its rights to motesanib to Takeda which now has control over the worldwide development and commercialization of motesanib. Takeda subsequently announced initiation of a new phase 3 clinical trial in non-squamous NSCLC patients in Japan, Hong Kong, South Korea and Taiwan based on the prospectively-defined Asian subgroup analysis of the MONET1 data. Based on the modification of the parties' arrangement, we will no longer participate in the development of motesanib and our obligations with respect to motesanib are limited primarily to closing the MONET1 clinical trial and transitioning certain existing development data and manufacturing capabilities (collectively “transition services”) from our contract manufacturer to Takeda. In exchange for licensing motesanib to Takeda, we received an additional upfront payment of $3 million and will receive incremental cost recoveries of approximately $21 million. We may also receive substantive success-based regulatory approval milestones and royalties on global sales of motesanib, if approved for sale, that are substantially lower than those under the 2008 arrangement. As of the date of modification, $230 million of the up-front payment we received in 2008 remained in deferred revenue on the Consolidated Balance Sheet.

Upon the modification of the arrangement, we determined that the remaining deliverables are: (i) the additional license rights to motesanib granted to Takeda and related transition services, (ii) commercial supply of Vectibix® and (iii) clinical and commercial supply and data relating to certain development activities, to the extent undertaken by Amgen, for the Japanese market products other than Vectibix®. We considered several factors in determining whether stand-alone value exists for each deliverable, including the rights and ability to perform the R&D activities, as well as the ability of parties to use a third party to perform their respective designated activities under the arrangement. The estimated selling prices for the undelivered items were determined by using third party evidence and BESP where applicable as of the date of modification. BESP was determined primarily using a probability-weighted discounted cash flow analysis. The fixed or determinable arrangement consideration was allocated to the undelivered items based on the relative selling price method and will be recognized as the services are performed or product is delivered. This amount was deducted from the sum of the consideration to be received in the future plus deferred revenue from the original 2008 arrangement as of the date of the modification of $230 million with the remainder of $206 million recognized as Other revenues in our Consolidated Statements of Income upon modification. Subsequently during 2012, deferred revenue of $24 million was recognized as the related services were completed. In addition, the arrangement allows for the receipt of royalties and milestone payments upon the achievement of various substantive success-based development and regulatory approval milestones which are immaterial, individually and in the aggregate, with regard to product candidates that remain under development. The receipt of these amounts, however, is contingent upon the occurrence of various future events that have a high degree of uncertainty of occurring.

During the years ended December 31, 2012, 2011 and 2010, cost recoveries from Takeda were $74 million, $83 million and $91 million, respectively, and are included in Research and development expense in the Consolidated Statements of Income. In addition, for the years December 31, 2012, 2011 and 2010, we recognized royalties on sales of Vectibix® in Japan of $21 million, $20 million and $7 million respectively, in Other revenues in the Consolidated Statements of Income.

UCB

We are in a collaboration with UCB for the development and commercialization of romosozumab. We have the rights to commercialize romosozumab for all indications in the United States, Canada, Mexico and Japan. UCB has the rights for all EU members at the time of first regulatory approval, Australia and New Zealand. Prior to commercialization, countries that have not been initially designated will be designated to Amgen or UCB in accordance with the terms of the agreement.

Generally, development costs are shared equally and we will share equally in the worldwide commercialization profits and losses related to the collaboration after accounting for expenses.

The collaboration agreements will continue in effect unless terminated earlier in accordance with their terms.

During the years ended December 31, 2012, 2011 and 2010, the net costs recovered from UCB were $71 million, $35 million, and $28 million, respectively, and are included in Research and development expense in the Consolidated Statements of Income.

Other

In addition to the collaborations discussed above, we have various others that are not individually significant to our business at this time. Pursuant to the terms of those agreements, we may be required to pay or we may receive additional amounts upon the achievement of various development and commercial milestones which in the aggregate could be significant. We may also incur or have reimbursed to us significant R&D costs if the related product candidate were to advance to late stage clinical trials. In addition, if any products related to these collaborations are approved for sale, we may be required to pay or we may receive significant royalties on future sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring.

7. Related party transactions

We own a 50% interest in K-A, a corporation formed in 1984 with Kirin Holdings Company, Limited (Kirin) for the development and commercialization of certain products based on advanced biotechnology. All of our rights to manufacture and market certain products including pegfilgrastim, granulocyte colony-stimulating factor, darbepoetin alfa, recombinant human erythropoietin and romiplostim are pursuant to exclusive licenses from K-A, which we currently market under the brand names Neulasta®, NEUPOGEN®, Aranesp®, EPOGEN®, and Nplate®, respectively.

We account for our interest in K-A using the equity method and include our share of K-A's profits or losses in Selling, general and administrative expense in the Consolidated Statements of Income. Our share of K-A's profits and losses was a loss of $24 million, and profits of $47 million and $71 million, for the years ended December 31, 2012, 2011 and 2010, respectively. At both December 31, 2012 and 2011, the carrying value of our equity method investment in K-A, net of dividends received, was approximately $0.4 billion and is included in noncurrent Other assets in the Consolidated Balance Sheets.

K-A's revenues consist of royalty income related to its licensed technology rights. K-A receives royalty income from us, as well as from Kirin, J&J and F. Hoffmann-La Roche Ltd. under separate product license contracts for certain geographic areas outside the United States. During the years ended December 31, 2012, 2011 and 2010, K-A earned royalties from us of $274 million, $298 million and $322 million, respectively. These amounts are included in Cost of sales (excludes amortization of certain acquired intangible assets) in the Consolidated Statements of Income.

K-A's expenses consist primarily of costs related to R&D activities conducted on its behalf by Amgen and Kirin. K-A pays Amgen and Kirin for such services at negotiated rates. During the years ended December 31, 2012, 2011 and 2010, we earned revenues from K-A of $115 million, $130 million and $96 million, respectively, for certain R&D activities performed on K-A's behalf. These amounts are recognized as Other revenues in the Consolidated Statements of Income. We may also receive numerous individually immaterial milestones aggregating $85 million upon the achievement of various substantive success-based development and regulatory approval milestones contingent upon the occurrence of various future events, most of which have a high degree of uncertainty of occurring. During the years ended December 31, 2012, 2011 and 2010, we recorded cost recoveries from K-A of $142 million, $85 million and $88 million, respectively, related to certain third-party costs. These amounts are included in Research and development expense in the Consolidated Statements of Income.

As of December 31, 2012 and 2011, we owed K-A $31 million and $75 million, respectively, which are included in Accrued liabilities in the Consolidated Balance Sheets.

8. Cost savings initiatives

Manufacturing operations optimization

In order to optimize our network of manufacturing facilities and improve cost effectiveness, we determined that certain manufacturing facilities located in Boulder, Colorado, were no longer needed and accordingly, they were abandoned during the fourth quarter of 2012. This resulted in the write-off of the carrying value of the facility, which aggregated $118 million, during the year ended December 31, 2012. The amount is included in Cost of sales (excludes amortization of certain acquired intangible assets) in the Consolidated Statement of Income.

On January 18, 2011, we entered into an agreement whereby Boehringer Ingelheim (BI) agreed to acquire our rights in and substantially all assets at our manufacturing facility located in Fremont, California. The transaction closed in March 2011. In connection with the closing of the transaction, BI assumed our obligations under certain of the facility's operating lease contracts and entered into an agreement to manufacture certain quantities of our marketed product Vectibix® for us at this facility through December 31, 2012 (the supply period).

As a result of the transaction with BI, an impairment analysis was performed on this facility which determined that a manufacturing line that had not yet been completed was impaired, and we wrote off its entire carrying value, which aggregated $118 million, during the year ended December 31, 2010. This amount is included in Other operating expenses in the Consolidated Statement of Income.

Due to the lack of sufficient initial investment by BI in the acquisition of this facility and our ongoing involvement with these operations, the transaction did not meet the accounting requirements to be treated as a sale involving real estate. As a result, the related assets continued to be carried on our Consolidated Balance Sheets with reduced estimated useful lives of the remaining fixed assets to coincide with the supply period. During each of the years ended December 31, 2012 and 2011, we recorded incremental depreciation of approximately $42 million in excess of what otherwise would have been recorded. In addition, due to the assignment to BI of the obligations under certain of the facility's operating leases, we recorded charges of approximately $23 million during the year ended December 31, 2011, with respect to the lease period beyond the end of the supply period. These amounts are recorded in Cost of sales (excludes amortization of certain acquired intangible assets) in the Consolidated Statements of Income.

Other cost savings initiatives

As part of our continuing efforts to improve cost efficiencies in our operations, we recorded certain charges aggregating approximately $175 million and $109 million during the years ended December 31, 2012 and 2011, respectively, which are included in Other operating expenses in the Consolidated Statements of Income. The 2012 expenses are primarily severance-related and charges related to exiting leased facilities, and the 2011 expenses are primarily severance-related.

9. Available-for-sale investments

The amortized cost, gross unrealized gains, gross unrealized losses and estimated fair values of available-for-sale investments by type of security were as follows (in millions):

Type of security as of December 31, 2012	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. Treasury securities	$ 4,443	$ 15	$ —	$ 4,458
Other government-related debt securities:				
U.S.	1,018	12	—	1,030
Foreign and other	1,549	60	(1)	1,608
Corporate debt securities:				
Financial	3,266	96	(1)	3,361
Industrial	4,283	100	(3)	4,380
Other	441	11	—	452
Residential mortgage-backed securities	1,828	9	(8)	1,829
Other mortgage- and asset-backed securities	1,769	7	(9)	1,767
Money market mutual funds	2,620	—	—	2,620
Other short-term interest-bearing securities	2,186	—	—	2,186
Total interest-bearing securities	23,403	310	(22)	23,691
Equity securities	52	2	—	54
Total available-for-sale investments	$ 23,455	$ 312	$ (22)	$ 23,745

Type of security as of December 31, 2011	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. Treasury securities	$ 3,878	$ 68	$ —	$ 3,946
Other government-related debt securities:				
U.S.	1,548	23	—	1,571
Foreign and other	441	9	—	450
Corporate debt securities:				
Financial	2,493	30	(15)	2,508
Industrial	3,077	79	(10)	3,146
Other	280	9	—	289
Residential mortgage-backed securities	518	3	(3)	518
Other mortgage- and asset-backed securities	1,271	3	(7)	1,267
Money market mutual funds	6,266	—	—	6,266
Total interest-bearing securities	19,772	224	(35)	19,961
Equity securities	42	—	—	42
Total available-for-sale investments	$ 19,814	$ 224	$ (35)	$ 20,003

The fair values of available-for-sale investments by classification in the Consolidated Balance Sheets were as follows as of December 31, 2012 and 2011 (in millions):

Classification in the Consolidated Balance Sheets	2012	2011
Cash and cash equivalents	$ 2,887	$ 6,266
Marketable securities	20,804	13,695
Other assets — noncurrent	54	42
Total available-for-sale investments	$ 23,745	$ 20,003

Cash and cash equivalents in the table above excludes cash of $370 million and $680 million as of December 31, 2012 and 2011, respectively.

The fair values of available-for-sale interest-bearing security investments by contractual maturity, except for mortgage- and asset-backed securities that do not have a single maturity date, were as follows as of December 31, 2012 and 2011 (in millions):

Contractual maturity	2012	2011
Maturing in one year or less	$ 7,175	$ 6,791
Maturing after one year through three years	5,014	5,855
Maturing after three years through five years	6,286	5,379
Maturing after five years through ten years	1,620	151
Mortgage- and asset-backed securities	3,596	1,785
Total interest-bearing securities	$ 23,691	$ 19,961

For the years ended December 31, 2012, 2011 and 2010, realized gains totaled $186 million, $191 million and $115 million, respectively, and realized losses totaled $54 million, $37 million and $25 million, respectively. The cost of securities sold is based on the specific identification method.

The primary objective of our investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment grade credit ratings and places restrictions on maturities and concentration by asset class and issuer.

We review our available-for-sale investments for other-than-temporary declines in fair value below our cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. This evaluation is based on a number of factors including, the length of time and the extent to which the fair value has been below our cost basis and adverse conditions related specifically to the security, including any changes to the credit rating of the security. As of December 31, 2012 and 2011, we believe the cost bases for our available-for-sale investments were recoverable in all material respects.

10. Inventories

Inventories consisted of the following as of December 31, 2012 and 2011 (in millions):

	2012	2011
Raw materials	$ 192	$ 158
Work in process	1,723	1,802
Finished goods	829	524
Total inventories	$ 2,744	$ 2,484

11. Property, plant and equipment

Property, plant and equipment consisted of the following as of December 31, 2012 and 2011 (dollar amounts in millions):

	Useful life (in years)	2012	2011
Land	—	$ 412	$ 366
Buildings and improvements	10-40	3,510	3,463
Manufacturing equipment	8-12	2,007	1,897
Laboratory equipment	8-12	1,056	1,016
Other	3-15	3,891	3,745
Construction in progress	—	1,071	744
Property, plant and equipment, gross		11,947	11,231
Less accumulated depreciation and amortization		(6,621)	(5,811)
Property, plant and equipment, net		$ 5,326	$ 5,420

During the years ended December 31, 2012, 2011 and 2010, we recognized depreciation and amortization charges associated with our property, plant and equipment of $689 million, $679 million and $594 million, respectively.

12. Goodwill and other intangible assets

Goodwill

The changes in the carrying amounts of goodwill for the years ended December 31, 2012 and 2011, were as follows (in millions):

	2012	2011
Beginning balance	$ 11,750	$ 11,334
Goodwill resulting from acquisitions of businesses	928	435
Currency translation	(16)	(19)
Ending balance	$ 12,662	$ 11,750

Identifiable intangible assets

Identifiable intangible assets consisted of the following as of December 31, 2012 and 2011 (in millions):

	2012			2011		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
Finite-lived intangible assets:						
Acquired product technology rights:						
Developed product technology	$ 2,872	$ (2,003)	$ 869	$ 2,872	$ (1,811)	$ 1,061
Core technology	1,348	(940)	408	1,348	(850)	498
Trade name	190	(133)	57	190	(120)	70
Acquired R&D technology rights	1,094	(381)	713	350	(350)	—
Other acquired intangible assets	896	(477)	419	686	(406)	280
Total finite-lived intangible assets	6,400	(3,934)	2,466	5,446	(3,537)	1,909
Indefinite-lived intangible assets:						
IPR&D	1,346	—	1,346	675	—	675
Contract assets	156	—	156	—	—	—
Total indefinite-lived intangible assets	1,502	—	1,502	675	—	675
Total identifiable intangible assets	$ 7,902	$ (3,934)	$ 3,968	$ 6,121	$ (3,537)	$ 2,584

Amortization of finite-lived intangible assets is provided over their estimated useful lives ranging from 3 to 15 years on a straight-line basis.

Acquired product technology rights relate to the identifiable intangible assets acquired in connection with the 2002 Immunex Corporation acquisition, and the related amortization expense is included in Amortization of certain acquired intangible assets in the Consolidated Statements of Income. Acquired R&D technology rights, Other acquired intangible assets, IPR&D and Contract assets as of December 31, 2012 and 2011, included the identifiable intangible assets acquired in connection with the acquisitions of businesses that occurred during the years ended December 31, 2012 and 2011. (See Note 2, Business combinations.) Acquired R&D technology rights consist of technology used in R&D with alternative future uses and the related amortization expense is included in Research and development expense in the Consolidated Statements of Income. The amortization expense related to other acquired intangible assets is included principally in Cost of sales (excludes amortization of certain acquired intangible assets) and Selling, general and administrative expense in the Consolidated Statements of Income. During the years ended December 31, 2012, 2011 and 2010, we recognized amortization charges associated with our finite-lived intangible assets of $397 million, $380 million and $423 million, respectively. The total estimated amortization for each of the next five years for our intangible assets is $464 million, $446 million, $434 million, $413 million and $271 million in 2013, 2014, 2015, 2016 and 2017, respectively.

13. Accrued liabilities

Accrued liabilities consisted of the following as of December 31, 2012 and 2011 (in millions):

	2012	2011
Sales deductions	$ 1,129	$ 1,326
Employee compensation and benefits	1,010	916
Sales returns reserve	346	339
Legal reserve	—	780
Other	2,306	1,667
Total accrued liabilities	$ 4,791	$ 5,028

14. Financing arrangements

The carrying values and the fixed contractual coupon rates of our long-term borrowings were as follows as of December 31, 2012 and 2011 (in millions):

	2012	2011
0.375% convertible notes due 2013 (0.375% 2013 Convertible Notes)	$ 2,488	$ 2,346
1.875% notes due 2014 (1.875% 2014 Notes)	1,000	1,000
4.85% notes due 2014 (4.85% 2014 Notes)	1,000	1,000
2.30% notes due 2016 (2.30% 2016 Notes)	749	748
2.50% notes due 2016 (2.50% 2016 Notes)	999	999
2.125% notes due 2017 (2.125% 2017 Notes)	1,248	—
5.85% notes due 2017 (5.85% 2017 Notes)	1,099	1,099
6.15% notes due 2018 (6.15% 2018 Notes)	499	499
4.375% euro denominated notes due 2018 (4.375% 2018 euro Notes)	723	714
5.70% notes due 2019 (5.70% 2019 Notes)	999	998
2.125% euro denominated notes due 2019 (2.125% 2019 euro Notes)	887	—
4.50% notes due 2020 (4.50% 2020 Notes)	300	300
3.45% notes due 2020 (3.45% 2020 Notes)	897	897
4.10% notes due 2021 (4.10% 2021 Notes)	998	998
3.875% notes due 2021 (3.875% 2021 Notes)	1,745	1,745
3.625% notes due 2022 (3.625% 2022 Notes)	747	—
5.50% pound sterling denominated notes due 2026 (5.50% 2026 pound sterling Notes)	763	739
4.00% pound sterling denominated notes due 2029 (4.00% 2029 pound sterling Notes)	1,117	—
6.375% notes due 2037 (6.375% 2037 Notes)	899	899
6.90% notes due 2038 (6.90% 2038 Notes)	499	499
6.40% notes due 2039 (6.40% 2039 Notes)	996	996
5.75% notes due 2040 (5.75% 2040 Notes)	697	697
4.95% notes due 2041 (4.95% 2041 Notes)	595	595
5.15% notes due 2041 (5.15% 2041 Notes)	2,232	2,232
5.65% notes due 2042 (5.65% 2042 Notes)	1,244	1,244
5.375% notes due 2043 (5.375% 2043 Notes)	1,000	—
Other, including our zero-coupon convertible notes	109	184
Total debt	26,529	21,428
Less current portion	(2,495)	(84)
Total noncurrent debt	$ 24,034	$ 21,344

Debt repayments

During the year ended December 31, 2012, we repaid $123 million of debt, including the redemption of all of our outstanding zero-coupon convertible notes due in 2032 and debt assumed in the acquisition of MN and deCODE. In February 2011, our 0.125%

2011 Convertible Notes became due, and we repaid the $2.5 billion aggregate principal amount. No debt was due or repaid in 2010.

Debt issuances

We issued debt securities in various offerings during the three years ended December 31, 2012, including:

- In 2012, we issued $5.0 billion aggregate principal amount of notes, comprised of the 2.125% 2017 Notes, the 2.125% 2019 euro Notes (€675 million aggregate principal amount), the 3.625% 2022 Notes, the 4.00% 2029 pound sterling Notes (£700 million aggregate principal amount) and the 5.375% 2043 Notes.
- In 2011, we issued $10.5 billion aggregate principal amount of notes, comprised of the 1.875% 2014 Notes, the 2.30% 2016 Notes, the 2.50% 2016 Notes, the 4.375% 2018 euro Notes (€550 million aggregate principal amount), the 4.10% 2021 Notes, the 3.875% 2021 Notes, the 5.50% 2026 pound sterling Notes (£475 million aggregate principal amount), the 5.15% 2041 Notes and the 5.65% 2042 Notes.
- In 2010, we issued $2.5 billion aggregate principal amount of notes, comprised of the 4.50% 2020 Notes, the 3.45% 2020 Notes, the 5.75% 2040 Notes and the 4.95% 2041 Notes.

Debt issuance costs incurred in connection with these debt offerings in 2012, 2011 and 2010 totaled $25 million, $55 million and $17 million, respectively. These debt issuance costs are being amortized over the respective lives of the notes, and the related charge is included in Interest expense, net, in the Consolidated Statements of Income.

All of our debt issuances other than our Other notes may be redeemed at any time at our option, in whole or in part, at the principal amount of the notes being redeemed plus accrued interest and a make-whole amount, as defined. In addition, except with respect to our 4.85% 2014 Notes and Other notes, in the event of a change-in-control triggering event, as defined, we may be required to purchase for cash all or a portion of these debt issuances at a price equal to 101% of the principal amount of the notes plus accrued interest.

Convertible Notes

In 2006, we issued $5.0 billion principal amount of convertible notes at par, including the 0.125% 2011 Convertible Notes and the 0.375% 2013 Convertible Notes. While outstanding, these notes were convertible into shares of our common stock upon the occurrence of specified events. The conversion rate on the $2.5 billion principal amount of the 0.375% 2013 Convertible Notes was 12.8809 shares per $1,000 principal amount of notes at December 31, 2012, which represents a conversion price of approximately $77.63 per share. While these notes were outstanding, this conversion rate was adjusted for certain transactions with respect to our common stock, including payment of cash dividends. Prior to their maturity, the 0.375% 2013 Convertible Notes could only be converted: (i) during any calendar quarter if the closing price of our common stock exceeded 130% of the then conversion price per share during a defined period at the end of the previous quarter, (ii) if we made specified distributions to holders of our common stock or specified corporate transactions occurred or (iii) within one month prior to the maturity date. Upon conversion, a holder would receive the conversion value equal to the conversion rate multiplied by the volume weighted-average price of our common stock during a specified conversion period following the conversion date. The conversion value was payable in: (i) cash equal to the lesser of the principal amount of the note or the conversion value, as defined, and (ii) cash, shares of our common stock, or a combination of cash and shares of our common stock, at our option, to the extent the conversion value exceeded the principal amount of the note (the excess conversion value). In February 2013, our 0.375% 2013 Convertible Notes matured/converted, and accordingly, the $2.5 billion principal amount was settled in cash. We also elected to pay the note holders who converted their notes $99 million of cash for the excess conversion value, as allowed by the original terms of the notes.

Concurrent with the issuance of the 0.375% 2013 Convertible Notes in February 2006, we purchased a convertible note hedge. The convertible note hedge allowed us to receive shares of our common stock and/or cash from the counterparty to the transaction equal to the amounts of common stock and/or cash related to the excess conversion value that we would issue and/or pay to the holders of the 0.375% 2013 Convertible Notes upon conversion. As a result of the conversion of the 0.375% 2013 Convertible Notes, we received $99 million of cash from the counterparty to offset the corresponding amount paid to the note holders. We also purchased a convertible note hedge with similar terms in connection with the issuance of the 0.125% 2011 Convertible Notes, which terminated unexercised when these notes were repaid.

Also concurrent with the issuance of the 0.375% 2013 Convertible Notes, we sold warrants to acquire 31.5 million shares of our common stock in May 2013 (the settlement date) that have an exercise price of $105.48 per share as of December 31, 2012. If the average price of our common stock during a defined period ending on or about the settlement date exceeds the exercise price of the warrants, the warrants will be net settled, at our option, in cash or shares of our common stock. In connection with the

issuance of the 0.125% 2011 Convertible Notes, we sold warrants to purchase 31.3 million shares of our stock on similar terms, which expired unexercised in May 2011.

Because the convertible note hedges and warrants could be settled at our option in cash or shares of our common stock, and these contracts met all of the applicable criteria for equity classification under the applicable accounting standards, the cost of the convertible note hedges and net proceeds from the sale of the warrants are classified in Stockholders' equity in the Consolidated Balance Sheets. In addition, because both of these contracts are classified in Stockholders' equity and are indexed to our common stock, they are not accounted for as derivatives.

Because these convertible notes were cash settleable, their debt and equity components were bifurcated and accounted for separately. The discounted carrying value of the debt component resulting from the bifurcation was accreted back to the principal amount over the period the notes were outstanding, resulting in the recognition of non-cash interest expense. The total aggregate amount repaid, including the amount related to the debt discount, is included in Cash flows from financing activities in the Consolidated Statement of Cash Flows. After giving effect to this bifurcation, the effective interest rate on the 0.375% 2013 Convertible Notes was 6.35%. For the years ended December 31, 2012, 2011 and 2010, total interest expenses for the 0.375% 2013 Convertibles Notes were $151 million, $143 million and $134 million, respectively, including non-cash interest expenses of $142 million, $133 million and $125 million, respectively. While outstanding, the 0.125% 2011 Convertible Notes were accounted for in the same manner, resulting in an effective interest rate of 6.24%. For the years ended December 31, 2011 and 2010, total interest expenses for the 0.125% 2011 Convertible Notes were $13 million and $149 million, respectively, including non-cash interest expenses of $12 million and $146 million, respectively.

The principal balance, unamortized discount and net carrying amount of the liability and equity components of our 0.375% 2013 Convertible Notes were as follows as of December 31, 2012 and 2011 (in millions):

	Liability component			Equity component
0.375% 2013 Convertible Notes	**Principal balance**	**Unamortized discount**	**Net carrying amount**	**Net carrying amount**
December 31, 2012	$ 2,500	$ 12	$ 2,488	$ 829
December 31, 2011	$ 2,500	$ 154	$ 2,346	$ 829

Other

Other notes include our notes due in 2097 with carrying value of $100 million, debt assumed in the acquisition of MN with a carrying value of $9 million at December 31, 2012, and the zero-coupon convertible notes due in 2032 which had a carrying value of $84 million at December 31, 2011.

Interest rate swaps

To achieve a desired mix of fixed and floating interest rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating London Interbank Offered Rate (LIBOR)-based coupon over the life of the respective note. These interest rate swap contracts qualified and were designated as fair value hedges. As of December 31, 2011, we had interest rate swap contracts with aggregate notional amounts of $3.6 billion with respect to our 4.85% 2014 Notes, 5.85% 2017 Notes, 6.15% 2018 Notes and 5.70% 2019 Notes. While outstanding, the rates on these swaps ranged from LIBOR plus 0.3% to LIBOR plus 2.6%. Due to historically low interest rates, we terminated all of these swap contracts in May 2012. See Note 17, Derivative instruments.

Cross-currency swaps

In order to hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. The terms of these contracts effectively convert the interest payments and principal repayment on our 2.125% 2019 euro Notes, 5.50% 2026 pound sterling Notes and 4.00% 2029 pound sterling Notes from euros/pounds sterling to U.S. dollars. These cross-currency swap contracts have been designated as cash flow hedges. For information regarding the terms of these contracts, see Note 17, Derivative instruments.

Shelf registration statements and other facilities

As of December 31, 2012, we have a commercial paper program that allows us to issue up to $2.5 billion of unsecured commercial paper to fund our working capital needs. At December 31, 2012 and 2011, we had no amounts outstanding under our commercial paper program.

In December 2011, we entered into a $2.5 billion syndicated, unsecured, revolving credit agreement which is available for general corporate purposes or as a liquidity backstop to our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $500 million with the agreement of the banks. Each bank which is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.1% based on our current credit rating. Generally, we would be charged interest at LIBOR plus 0.9% for any amounts borrowed under this facility. As of December 31, 2012 and 2011, no amounts were outstanding under this facility. In connection with the new revolving credit agreement we terminated our prior $2.3 billion revolving credit agreement that was scheduled to expire in November 2012.

In March 2011, we filed a shelf registration statement with the U.S. Securities and Exchange Commission to replace an existing shelf registration statement that was scheduled to expire in April 2011. This shelf registration statement allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depository shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depository shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. This shelf registration statement expires in March 2014.

In 1997, we established a $400 million medium-term note program under which medium-term debt securities may be offered from time to time with terms to be determined at the time of issuance. As of December 31, 2012 and 2011, no securities were outstanding under this medium-term note program.

Certain of our financing arrangements contain non-financial covenants. In addition, our revolving credit agreement includes a financial covenant with respect to the level of our borrowings in relation to our equity, as defined. We were in compliance with all applicable covenants under these arrangements as of December 31, 2012.

Contractual maturities of long-term debt obligations

The aggregate contractual maturities of all long-term debt obligations due subsequent to December 31, 2012, are as follows (in millions):

Maturity date	Amount
2013[(1)]	$ 2,507
2014	2,002
2015	—
2016	1,750
2017	2,350
Thereafter	18,017
Total	$ 26,626

(1) This amount includes the$2.5 billion principal amount for our 0.375% 2013 Convertible Notes after full accretion of the debt discount.

Interest costs

Interest costs are expensed as incurred, except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest expenses, net, for the years ended December 31, 2012, 2011 and 2010, were $1.1 billion, $610 million and $604 million, respectively. Interest costs capitalized for the years ended December 31, 2012, 2011 and 2010, were $26 million, $22 million and $33 million, respectively. Interest paid, net of interest rate swaps, during the years ended December 31, 2012, 2011 and 2010, totaled $406 million, $446 million and $323 million, respectively. Interest paid in 2012 is net of the $397 million received upon settlement of the interest rate swaps. See Note 17, Derivative instruments.

15. Stockholders' equity

Stock repurchase program

Activity under our stock repurchase program was as follows for the years ended December 31, 2012, 2011 and 2010 (in millions):

	2012		2011		2010	
	Shares	Dollars	Shares	Dollars	Shares	Dollars
First quarter	21.0	$ 1,429	—	$ —	29.1	$ 1,684
Second quarter	17.4	1,203	12.9	732	10.3	616
Third quarter	9.7	797	45.4	2,421	6.6	364
Fourth quarter	14.2	1,233	86.0	5,154 [(1)]	20.5	1,136
Total stock repurchases	62.3	$ 4,662	144.3	$ 8,307	66.5	$ 3,800

[(1)] Includes the repurchase of 83.3 million shares of our common stock at an average price paid per share of $60.08, including related expenses, for an aggregate cost of $5.0 billion, under a modified Dutch auction tender offer.

In December 2012, the Board of Directors approved an increase in the share repurchase authorization by $2.0 billion, and as of December 31, 2012, $2.3 billion remained available under this stock repurchase program.

Dividends

On July 28 and October 13, 2011, the Board of Directors declared quarterly cash dividends of $0.28 per share of common stock, which were paid on September 8 and December 8, 2011, respectively. On December 15, 2011, and March 15, July 19 and October 10, 2012, the Board of Directors declared quarterly cash dividends of $0.36 per share of common stock, which were paid on March 7, June 7, September 7 and December 7, 2012, respectively. Additionally, on December 13, 2012, the Board of Directors declared a quarterly cash dividend of $0.47 per share of common stock, which will be paid on March 7, 2013.

Accumulated other comprehensive income

The components of Accumulated other comprehensive income (AOCI) are as follows for the years ended December 31, 2012, 2011 and 2010 (in millions):

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2009	$ 40	$ (82)	$ 95	$ (8)	$ 45
Foreign currency translation adjustments	(29)	—	—	—	(29)
Unrealized gains	—	186	155	1	342
Reclassification adjustments to income	—	(46)	(90)	—	(136)
Income taxes	11	(55)	(25)	—	(69)
Balance as of December 31, 2010	22	3	135	(7)	153
Foreign currency translation adjustments	(6)	—	—	—	(6)
Unrealized (losses) gains	—	(51)	125	2	76
Reclassification adjustments to income	—	112	(154)	—	(42)
Other	—	—	—	(8)	(8)
Income taxes	5	(21)	14	—	(2)
Balance as of December 31, 2011	21	43	120	(13)	171
Foreign currency translation adjustments	(13)	—	—	—	(13)
Unrealized (losses) gains	—	15	233	(1)	247
Reclassification adjustments to income	—	(134)	(132)	—	(266)
Income taxes	4	41	(38)	—	7
Balance as of December 31, 2012	$ 12	$ (35)	$ 183	$ (14)	$ 146

Income tax expenses/benefits for unrealized gains and losses and the related reclassification adjustments to income for cash flow hedges were an $8 million expense and $49 million benefit in 2012, a $20 million benefit and $41 million expense in 2011 and a $71 million expense and $16 million benefit in 2010, respectively. Income tax expenses/benefits for unrealized gains and losses and the related reclassification adjustments to income for available-for-sale securities were an $87 million expense and $49 million benefit for 2012, a $45 million expense and $59 million benefit in 2011 and a $60 million expense and $35 million benefit in 2010, respectively.

Other

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. As of December 31, 2012 and 2011, no shares of preferred stock were issued or outstanding.

16. Fair value measurement

To estimate the fair value of our financial assets and liabilities we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

Level 1	— Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access
Level 2	— Valuations for which all significant inputs are observable, either directly or indirectly, other than level 1 inputs
Level 3	— Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

The fair value of each major class of the Company's financial assets and liabilities measured at fair value on a recurring basis was as follows (in millions):

Fair value measurement as of December 31, 2012, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale investments:				
U.S. Treasury securities	$ 4,458	$ —	$ —	$ 4,458
Other government-related debt securities:				
U.S.	—	1,030	—	1,030
Foreign and other	—	1,608	—	1,608
Corporate debt securities:				
Financial	—	3,361	—	3,361
Industrial	—	4,380	—	4,380
Other	—	452	—	452
Residential mortgage-backed securities	—	1,829	—	1,829
Other mortgage- and asset-backed securities	—	1,767	—	1,767
Money market mutual funds	2,620	—	—	2,620
Other short-term interest-bearing securities	—	2,186	—	2,186
Equity securities	54	—	—	54
Derivatives:				
Foreign currency contracts	—	46	—	46
Cross-currency swap contracts	—	65	—	65
Total assets	$ 7,132	$ 16,724	$ —	$ 23,856
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 59	$ —	$ 59
Cross-currency swap contracts	—	6	—	6
Contingent consideration obligations in connection with a business combination	—	—	221	221
Total liabilities	$ —	$ 65	$ 221	$ 286

Fair value measurement as of December 31, 2011, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale investments:				
U.S. Treasury securities	$ 3,946	$ —	$ —	$ 3,946
Other government-related debt securities:				
U.S.	—	1,571	—	1,571
Foreign and other	—	450	—	450
Corporate debt securities:				
Financial	—	2,508	—	2,508
Industrial	—	3,146	—	3,146
Other	—	289	—	289
Residential mortgage-backed securities	—	518	—	518
Other mortgage- and asset-backed securities	—	1,267	—	1,267
Money market mutual funds	6,266	—	—	6,266
Equity securities	42	—	—	42
Derivatives:				
Foreign currency contracts	—	172	—	172
Interest rate swap contracts	—	377	—	377
Total assets	$ 10,254	$ 10,298	$ —	$ 20,552
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 48	$ —	$ 48
Cross-currency swap contracts	—	26	—	26
Contingent consideration obligations in connection with a business combination	—	—	190	190
Total liabilities	$ —	$ 74	$ 190	$ 264

The fair values of our U.S. Treasury securities, money market mutual funds and equity securities are based on quoted market prices in active markets with no valuation adjustment.

Most of our other-government related and corporate debt securities are investment grade with maturity dates of five years or less from the balance sheet date. Our other-government related debt securities portfolio is composed of securities with weighted-average credit ratings of A+ by Standard & Poor's (S&P) or Fitch, Inc. (Fitch) and AA- or equivalent by Moody's Investors Service, Inc. (Moody's); and our corporate debt securities portfolio has a weighted-average credit rating of A- or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

Our residential mortgage-, other mortgage- and asset-backed securities portfolio is composed entirely of senior tranches, with credit ratings of AA+ by S&P and AAA or equivalent by Moody's or Fitch. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

We value our other short-term interest-bearing securities at amortized cost, which approximates fair value given their near term maturity dates.

Substantially all of our foreign currency forward and option derivatives contracts have maturities of three years or less and all are with counterparties that have minimum credit ratings of A- or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable, either directly or indirectly. These inputs include foreign currency rates, LIBOR cash and swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts also include implied volatility measures. These inputs, where applicable, are at commonly quoted intervals. See Note 17, Derivative instruments.

Our cross-currency swap contracts are with counterparties that have minimum credit ratings of A- or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include foreign currency exchange rates, LIBOR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. See Note 17, Derivative instruments.

All of our interest rate swap contracts were terminated in May 2012. (See Note 17, Derivative instruments.) While outstanding, our interest rate swap contracts were with counterparties that had minimum credit ratings of A- or equivalent by S&P, Moody's or Fitch. We estimated the fair values of these contracts by using an income-based industry standard valuation model for which all significant inputs were observable either directly or indirectly. These inputs included LIBOR, swap rates and obligor credit default swap rates.

As a result of our acquisition of BioVex in March 2011, we are obligated to pay its former shareholders up to $575 million of additional consideration contingent upon achieving up to eight separate regulatory and sales-related milestones with regard to talimogene laherparepvec, which was acquired in the acquisition and is currently in phase 3 clinical development for the treatment of malignant melanoma. The three largest of these potential payments are $125 million each, including the amount due upon completion of the filing of a BLA with the FDA. Potential payments are also due upon the first commercial sale in each of the United States and the EU following receipt of marketing approval which includes use of the product in specified patient populations and upon achievement of specified levels of sales within specified periods of time.

These contingent consideration obligations are recorded at their estimated fair values with any changes in fair value recognized in earnings. The fair value measurements of these obligations are based on significant unobservable inputs, including the estimated probabilities and timing of achieving the related regulatory events in connection with these milestones and, as applicable, estimated annual sales. Significant changes (increases or decreases) in these inputs would result in corresponding changes in the fair values of the contingent consideration obligations.

We revalue these contingent consideration obligations each reporting period until the related contingencies are resolved. We estimate the fair values of these obligations by using a combination of probability-adjusted discounted cash flows, option pricing techniques and a simulation model of expected annual sales. Quarterly, management in our R&D and commercial sales organizations review key assumptions used in the fair value measurements of these obligations. In the absence of any significant changes in key assumptions, the changes in fair values of these contingent consideration obligations reflect the passage of time and changes in our credit risk adjusted rate used to discount obligations to present value. During the year ended December 31, 2012, the increase in the estimated aggregate fair value of these obligations was $31 million, which was recorded in Other operating expenses in the Consolidated Statement of Income.

There have been no transfers of assets or liabilities between the fair value measurement levels, and there were no material remeasurements to fair value during the years ended December 31, 2012 and 2011, of assets and liabilities that are not measured at fair value on a recurring basis, except as discussed in Note 2, Business combinations, regarding an impairment of an indefinite-lived intangible asset and Note 8, Cost savings initiatives, regarding an impairment of fixed assets which were recognized during the year ended December 31, 2012.

Summary of the fair value of other financial instruments

Cash equivalents

The estimated fair values of cash equivalents approximate their carrying values due to the short-term nature of these financial instruments.

Borrowings

We estimate the fair values of our convertible notes (Level 2) by using an income-based industry standard valuation model for which all significant inputs are observable either directly or indirectly, including benchmark yields adjusted for our credit risk. The fair value of our convertible notes represents only the liability components of these instruments, because their equity components are included in Common stock and additional paid-in capital in the Consolidated Balance Sheets. We estimate the fair values of our other long-term notes (Level 2) by taking into consideration indicative prices obtained from a third-party financial institution that utilizes industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; credit spreads; benchmark yields; foreign currency exchange rates, as applicable; and other observable inputs. As of December 31, 2012 and 2011, the aggregate fair values of our long-term debt were $29.9 billion and $23.0 billion, respectively, and the carrying values were $26.5 billion and $21.4 billion, respectively.

17. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to these exposures, we utilize or have utilized certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We do not use derivatives for speculative trading purposes.

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, associated primarily with our euro-denominated international product sales. Increases and decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are offset partially by the corresponding increases and decreases in our international operating expenses resulting from these foreign currency exchange rate movements. To further reduce our exposure to foreign currency exchange rate fluctuations on our international product sales, we enter into foreign currency forward and option contracts to hedge a portion of our projected international product sales over a three-year time horizon, with, at any given point in time, a higher percentage of nearer-term projected product sales being hedged than in successive periods. As of December 31, 2012, 2011 and 2010, we had open foreign currency forward contracts with notional amounts of $3.7 billion, $3.5 billion and $3.2 billion, respectively, and open foreign currency option contracts with notional amounts of $200 million, $292 million and $398 million, respectively. These foreign currency forward and option contracts, primarily euro based, have been designated as cash flow hedges, and accordingly, the effective portions of the unrealized gains and losses on these contracts are reported in AOCI and reclassified to earnings in the same periods during which the hedged transactions affect earnings.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. Under the terms of these contracts, we paid euros/pounds sterling and received U.S. dollars for the notional amounts at the inception of the contracts, and we exchange interest payments based on these notional amounts at fixed rates over the lives of the contracts in which we pay U.S. dollars and receive euros/pounds sterling. In addition, we will pay U.S. dollars to and receive euros/pounds sterling from the counterparties at the maturities of the contracts for these same notional amounts. The terms of these contracts correspond to the related hedged notes, effectively converting the interest payments and principal repayment on these notes from euros/pounds sterling to U.S. dollars. These cross-currency swap contracts have been designated as cash flow hedges, and accordingly, the effective portions of the unrealized gains and losses on these contracts are reported in AOCI and reclassified to earnings in the same periods during which the hedged debt affects earnings. The notional amounts and interest rates of our cross-currency swaps are as follows (notional amounts in millions):

	Foreign currency		U.S. dollars	
Hedged notes	**Notional Amount**	**Interest rate**	**Notional Amount**	**Interest rate**
2.125% 2019 euro Notes	€ 675	2.125%	$ 864	2.6%
5.50% 2026 pound sterling Notes	£ 475	5.50%	$ 748	5.8%
4.00% 2029 pound sterling Notes	£ 700	4.00%	$ 1,122	4.3%

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on such contracts, which are designated as cash flow hedges, are reported in AOCI and amortized into earnings over the lives of the associated debt issuances.

The effective portion of the unrealized gain/(loss) recognized in other comprehensive income for our derivative instruments designated as cash flow hedges was as follows (in millions):

	Years ended December 31,		
Derivatives in cash flow hedging relationships	**2012**	**2011**	**2010**
Foreign currency contracts	$ (63)	$ (25)	$ 191
Cross-currency swap contracts	85	(26)	—
Forward interest rate contracts	(7)	—	(5)
Total	$ 15	$ (51)	$ 186

The location in the Consolidated Statements of Income and the effective portion of the gain/(loss) reclassified from AOCI into earnings for our derivative instruments designated as cash flow hedges were as follows (in millions):

		Years ended December 31,		
Derivatives in cash flow hedging relationships	**Statements of Income location**	**2012**	**2011**	**2010**
Foreign currency contracts	Product sales	$ 74	$ (108)	$ 47
Cross-currency swap contracts	Interest and other income, net	61	(3)	—
Forward interest rate contracts	Interest expense, net	(1)	(1)	(1)
Total		$ 134	$ (112)	$ 46

No portions of our cash flow hedge contracts are excluded from the assessment of hedge effectiveness, and the ineffective portions of these hedging instruments were approximately $1 million of losses for both the years ended December 31, 2012 and 2010, and approximately $1 million of gain for the year ended December 31, 2011. As of December 31, 2012, the amounts expected to be reclassified from AOCI into earnings over the next 12 months are approximately $20 million of net losses on our foreign currency and cross-currency swap contracts and approximately $1 million of losses on forward interest rate contracts.

Fair value hedges

To achieve a desired mix of fixed and floating interest rates on our long-term debt, we entered into interest rate swap contracts, which qualified and were designated as fair value hedges. The terms of these interest rate swap contracts corresponded to the related hedged debt instruments and effectively converted a fixed interest rate coupon to a floating LIBOR-based coupon over the lives of the respective notes. While outstanding, the rates on these swaps ranged from LIBOR plus 0.3% to LIBOR plus 2.6%. As of December 31, 2011 and 2010, we had interest rate swap contracts with aggregate notional amounts of $3.6 billion with respect to our 4.85% 2014 Notes, 5.85% 2017 Notes, 6.15% 2018 Notes and 5.70% 2019 Notes. Due to historically low interest rates, in May 2012 we terminated all of these interest rate swap contracts resulting in the receipt of $397 million from the counterparties, which was included in Net cash provided by operating activities in the Consolidated Statements of Cash Flows for the current year period. This amount is being recognized in Interest expense, net in the Consolidated Statements of Income over the remaining lives of the related debt issuances.

For derivative instruments that are designated and qualify as fair value hedges, the unrealized gain or loss on the derivative resulting from the change in fair value during the period as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk is recognized in current earnings. While the interest rate swaps were outstanding during the year ended December 31, 2012, and the years ended December 31, 2011 and 2010, we included unrealized losses on the hedged debt of $20 million, $182 million and $105 million, respectively, in the same line item, Interest expense, net, in the Consolidated Statements of Income, as the offsetting unrealized gains of $20 million, $182 million and $105 million, respectively, on the related interest rate swap agreements.

Derivatives not designated as hedges

We enter into foreign currency forward contracts that are not designated as hedging transactions to reduce our exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies. These exposures are hedged on a month-to-month basis. As of December 31, 2012, 2011 and 2010, the total notional amounts of these foreign currency forward contracts were $629 million, $389 million and $670 million, respectively.

The location in the Consolidated Statements of Income and the amount of gain/(loss) recognized in earnings for our derivative instruments not designated as hedging instruments were as follows (in millions):

		Years ended December 31,		
Derivatives not designated as hedging instruments	**Statements of Income location**	**2012**	**2011**	**2010**
Foreign currency contracts	Interest and other income, net	$ 19	$ (1)	$ 32

The fair values of derivatives included in the Consolidated Balance Sheets were as follows (in millions):

	Derivative assets		Derivative liabilities	
December 31, 2012	**Balance Sheet location**	**Fair value**	**Balance Sheet location**	**Fair value**
Derivatives designated as hedging instruments:				
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	$ 65	Accrued liabilities/ Other noncurrent liabilities	$ 6
Foreign currency contracts	Other current assets/ Other noncurrent assets	45	Accrued liabilities/ Other noncurrent liabilities	58
Total derivatives designated as hedging instruments		110		64
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	1	Accrued liabilities	1
Total derivatives not designated as hedging instruments		1		1
Total derivatives		$ 111		$ 65

	Derivative assets		Derivative liabilities	
December 31, 2011	**Balance Sheet location**	**Fair value**	**Balance Sheet location**	**Fair value**
Derivatives designated as hedging instruments:				
Interest rate swap contracts	Other current assets/ Other noncurrent assets	$ 377	Accrued liabilities/ Other noncurrent liabilities	$ —
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	26
Foreign currency contracts	Other current assets/ Other noncurrent assets	172	Accrued liabilities/ Other noncurrent liabilities	48
Total derivatives designated as hedging instruments		549		74
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	—	Accrued liabilities	—
Total derivatives not designated as hedging instruments		—		—
Total derivatives		$ 549		$ 74

Our derivative contracts that were in liability positions as of December 31, 2012, contain certain credit-risk-related contingent provisions that would be triggered if: (i) we were to undergo a change in control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts.

The cash flow effects of our derivatives contracts for the three years ended December 31, 2012, are included within Net cash provided by operating activities in the Consolidated Statements of Cash Flows.

18. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings and other matters, including those discussed in this Note, that are complex in nature and have outcomes that are difficult to predict.

We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Our legal proceedings range from cases brought by a single plaintiff to a class action with thousands of putative class members. These legal proceedings, as well as other matters, involve various aspects of our business and a variety of claims (including but not limited to patent infringement, marketing, pricing and trade practices and securities law), some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing, plaintiffs seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process (which in complex proceedings of the sort faced by us often extend for several years). As a result, none of the matters described in these filings have progressed sufficiently through discovery and/or development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain of our legal proceedings and other matters are discussed below:

Federal Securities Litigation - In re Amgen Inc. Securities Litigation

The six federal class action stockholder complaints filed against Amgen Inc., Kevin W. Sharer, Richard D. Nanula, Dennis M. Fenton, Roger M. Perlmutter, Brian M. McNamee, George J. Morrow, Edward V. Fritzky, Gilbert S. Omenn and Franklin P. Johnson, Jr., (the Federal Defendants) in the U.S. District Court for the Central District of California (the California Central District Court) on April 17, 2007 (*Kairalla v. Amgen Inc., et al.*), May 1, 2007 (*Mendall v. Amgen Inc., et al., & Jaffe v. Amgen Inc., et al.*), May 11, 2007 (*Eldon v. Amgen Inc., et al.*), May 21, 2007 (*Rosenfield v. Amgen Inc., et al.*) and June 18, 2007 (*Public Employees' Retirement Association of Colorado v. Amgen Inc., et al.*) were consolidated by the California Central District Court into one action captioned *In re Amgen Inc. Securities Litigation*. The consolidated complaint was filed with the California Central District Court on October 2, 2007. The consolidated complaint alleges that Amgen and these officers and directors made false statements that resulted in: (i) deceiving the investing public regarding Amgen's prospects and business; (ii) artificially inflating the prices of Amgen's publicly traded securities and (iii) causing plaintiff and other members of the class to purchase Amgen publicly traded securities at inflated prices. The complaint also makes off-label marketing allegations that, throughout the class period, the Federal Defendants improperly marketed Aranesp® and EPOGEN® for off-label uses while aware that there were alleged safety signals with these products. The plaintiffs seek class certification, compensatory damages, legal fees and other relief deemed proper. The Federal Defendants filed a motion to dismiss on November 8, 2007. On February 4, 2008, the California Central District Court granted in part, and denied in part, the Federal Defendants' motion to dismiss the consolidated amended complaint. Specifically, the California Central District Court granted the Federal Defendants' motion to dismiss as to individual defendants Fritzky, Omenn, Johnson, Fenton and McNamee, but denied the Federal Defendants' motion to dismiss as to individual defendants Sharer, Nanula, Perlmutter and Morrow.

A class certification hearing before the California Central District Court, was held on July 17, 2009 and on August 12, 2009, the California Central District Court granted plaintiffs' motion for class certification. On August 28, 2009, Amgen filed a petition for permission to appeal with the U.S. Court of Appeals for the Ninth Circuit (the Ninth Circuit Court) under Rule 23(f), regarding the Order on Class Certification and the Ninth Circuit Court granted Amgen's permission to appeal on December 11, 2009. On February 2, 2010, the California Central District Court granted Amgen's motion to stay the underlying action pending the outcome of the Ninth Circuit Court 23(f) appeal. On October 14, 2011, the appeal under Rule 23(f) was argued before the Ninth Circuit Court and on December 28, 2011, the Ninth Circuit Court denied the appeal. Amgen filed a petition for certiorari with the U.S. Supreme Court on March 3, 2012, and on June 11, 2012, the Court granted Amgen's petition. Oral argument occurred on November

5, 2012. On February 27, 2013, the U.S. Supreme Court affirmed the decision of the Ninth Circuit Court and remanded the case back to the California Central District Court for further proceedings.

State Derivative Litigation

Larson v. Sharer, et al.

The three state stockholder derivative complaints filed against Amgen Inc., Kevin W. Sharer, George J. Morrow, Dennis M. Fenton, Brian M. McNamee, Roger M. Perlmutter, David Baltimore, Gilbert S. Omenn, Judith C. Pelham, Frederick W. Gluck, Jerry D. Choate, J. Paul Reason, Frank J. Biondi, Jr., Leonard D. Schaeffer, Frank C. Herringer, Richard D. Nanula, Willard H. Dere, Edward V. Fritzky, Franklin P. Johnson, Jr. and Donald B. Rice as defendants (the State Defendants) on May 1, 2007 (*Larson v. Sharer, et al.*, & *Anderson v. Sharer, et al.*), and August 13, 2007 (*Weil v. Sharer, et al.*) in the Superior Court of the State of California, Ventura County (the Superior Court) were consolidated by the Superior Court under one action captioned *Larson v. Sharer, et al*. The consolidated complaint was filed on July 5, 2007. The complaint alleges that the State Defendants breached their fiduciary duties, wasted corporate assets, were unjustly enriched and violated the California Corporations Code. Plaintiffs allege that the State Defendants failed to disclose and/or misrepresented results of Aranesp® clinical studies, marketed both Aranesp® and EPOGEN® for off-label uses and that these actions or inactions caused stockholders to suffer damages. The complaints also allege insider trading by the State Defendants. The plaintiffs seek treble damages based on various causes of action, reformed corporate governance, equitable and/or injunctive relief, restitution, disgorgement of profits, benefits and other compensation, and legal costs.

An amended consolidated complaint was filed on March 13, 2008, adding Anthony Gringeri as a State Defendant and removing the causes of action for insider selling and misappropriation of information, violation of California Corporations Code Section 25402 and violation of California Corporations Code Section 25403. On July 14, 2008, the Superior Court dismissed without prejudice the consolidated state derivative class action. The judge also ordered a stay of any re-filing of an amended complaint until the federal court has determined in the *In re Amgen Inc. Securities Litigation* action whether any securities fraud occurred.

Birch v. Sharer, et al.

On January 23, 2009, a stockholder derivative lawsuit titled *Birch v. Sharer, et al.* was filed in the Superior Court of the State of California, Los Angeles County (the Los Angeles Superior Court) naming Amgen Inc., Kevin W. Sharer, David Baltimore, Frank J. Biondi, Jr., Jerry D. Choate, Vance D. Coffman, Frederick W. Gluck, Frank C. Herringer, Gilbert S. Omenn, Judith C. Pelham, J. Paul Reason, Leonard D. Schaeffer and Tom Zindrick as defendants. The complaint alleges derivative claims for breach of fiduciary duty based on a purported failure to implement adequate internal controls and to oversee the Company's operations, which plaintiff claims resulted in numerous lawsuits and investigations over a number of years. Plaintiff seeks damages on behalf of Amgen, including costs and expenses, allegedly incurred, among other things, in connection with wrongful termination lawsuits and potential violations of the Health Insurance Portability and Accountability Act. On February 25, 2009, the case was reassigned to a judge in the Complex Department of the Los Angeles Superior Court. Amgen and the individual defendants filed motions to dismiss on June 23, 2009.

Oral argument on Amgen and the individual defendants' motions to dismiss were heard on September 25, 2009 before the Los Angeles Superior Court and the court granted the motions to dismiss but allowed the plaintiff an opportunity to amend her complaint by October 21, 2009. Plaintiff filed a request for dismissal without prejudice with the court on October 23, 2009. On October 29, 2009, Amgen received from plaintiff a stockholder demand on the Board of Directors to take action to remedy breaches of fiduciary duties by the directors and certain executive officers of the Company. Ms. Birch alleged that the directors and certain executive officers violated their core fiduciary principles, causing Amgen to suffer damages. She demanded that the Board of Directors take action against each of the officers and directors to recover damages and to correct deficiencies in the Company's internal controls that allowed the misconduct to occur. The Board of Directors completed its investigation and determined in its business judgment that it was not in the best interests of the Company to pursue the claims made in the demand against any of the individuals mentioned in the demand. Therefore, the Board voted to reject the demand and communicated this to Ms. Birch on May 19, 2010.

On February 8, 2010, plaintiff filed another stockholder demand lawsuit in the Los Angeles Superior Court against the same defendants in the original lawsuit but also added Board of Director members François de Carbonnel and Rebecca Henderson. The allegations in the new complaint are nearly identical to those in the previously filed complaint. The case filed on February 8, 2010

by plaintiff Birch was assigned to the Complex Division of the Los Angeles Superior Court. On June 30, 2010, Amgen filed its demurrer to plaintiff's complaint with the Complex Division of the Los Angeles Superior Court. On September 29, 2010, the Complex Division of the Los Angeles Superior Court denied Amgen's and the individual defendants' demurrers finding that the plaintiff had adequately pled wrongful refusal. Amgen and the individual defendants filed answers on October 29, 2010. On December 9, 2010, the Complex Division of the Los Angeles Superior Court stayed the underlying action and Amgen and the individual defendants filed a motion for judgment on the pleadings/motion for summary judgment. The motion for the judgment on the pleadings was heard on January 31, 2011 and the Complex Division of the Los Angeles Superior Court dismissed the entire lawsuit with prejudice against both Amgen and the individual defendants without leave to amend. Following an appeal by plaintiff, on June 21, 2012, the California State Appellate Court reversed the decision of the Complex Division of the Los Angeles Superior Court. The case has been re-assigned to Judge Kenneth Freeman and Amgen and the individual defendants filed motions for summary judgment on November 19, 2012. The motions for summary judgment will be heard on April 16, 2013.

Purnell v. Sharer, et al.

On January 24, 2013, a stockholder derivative lawsuit titled *Purnell v. Sharer, et al.* was filed in the Superior Court against Amgen Inc., Kevin W. Sharer, Robert A. Bradway, David Baltimore, Frank J. Biondi, Jr., Vance D. Coffman, François de Carbonnel, Rebecca M. Henderson, Frank C. Herringer, Leroy M. Hood, Tyler Jacks, Gilbert S. Omenn, Judith C. Pelham, J. Paul Reason, Leonard D. Schaeffer and Ronald D. Sugar as defendants. The lawsuit alleges that the individual defendants breached their fiduciary duties by failing to implement adequate internal controls which resulted on December 19, 2012 in the civil settlement, corporate integrity agreement and criminal misdemeanor plea in connection with the Federal Investigations (see *Government Investigations and Qui Tam Actions* below).

Federal Derivative Litigation

On May 7, 2007, the stockholder derivative lawsuit of *Durgin v. Sharer, et al.*, was filed in the California Central District Court and named Amgen Inc., Kevin W. Sharer, George J. Morrow, Dennis M. Fenton, Brian M. McNamee, Roger M. Perlmutter, David Baltimore, Gilbert S. Omenn, Judith C. Pelham, Frederick W. Gluck, Jerry D. Choate, J. Paul Reason, Frank J. Biondi, Jr., Leonard D. Schaeffer, Frank C. Herringer, Richard D. Nanula, Edward V. Fritzky and Franklin P. Johnson, Jr. as defendants. The complaint alleges the same claims and requests the same relief as in the three state stockholder derivative complaints now consolidated as *Larson v. Sharer, et al*. The case has been stayed for all purposes until thirty days after a final ruling on the motion to dismiss by the California Central District Court in the *In re Amgen Inc. Securities Litigation* action.

On September 21, 2007, the stockholder derivative lawsuit of *Rosenblum v. Sharer, et al.*, was filed in the California Central District Court. This lawsuit was brought by a stockholder who previously made a demand on the Amgen Board on May 14, 2007. The complaint alleges that the defendants breached their fiduciary duties, wasted corporate assets and were unjustly enriched. Plaintiffs allege that the defendants failed to disclose and/or misrepresented results of Aranesp® clinical studies, marketed both Aranesp® and EPOGEN® for off-label uses and that these actions or inactions as well as the Amgen market strategy caused damage to the Company resulting in several inquiries, investigations and lawsuits that are costly to defend. The complaint also alleges insider trading by the defendants. The plaintiffs seek treble damages based on various causes of action, reformed corporate governance, equitable and/or injunctive relief, restitution, disgorgement of profits, benefits and other compensation, and legal costs. The case was stayed for all purposes until thirty days after a final ruling on the motion to dismiss by the California Central District Court in the *In re Amgen Inc. Securities Litigation* action.

Thereafter, on May 1, 2008, plaintiff in *Rosenblum v. Sharer, et al.*, filed an amended complaint which removed Dennis Fenton as a defendant and also eliminated the claims for insider selling by defendants. On July 28, 2008, the California Central District Court heard Amgen and the defendants' motion to dismiss and motion to stay. On July 30, 2008, the California Central District Court granted Amgen and the defendants' motion to dismiss without prejudice and also granted a stay of the case pending resolution of the *In re Amgen Inc. Securities Litigation* action.

ERISA Litigation

On August 20, 2007, the ERISA class action lawsuit of *Harris v. Amgen Inc., et al.,* was filed in the California Central District Court and named Amgen Inc., Kevin W. Sharer, Frank J. Biondi, Jr., Jerry Choate, Frank C. Herringer, Gilbert S. Omenn, David Baltimore, Judith C. Pelham, Frederick W. Gluck, Leonard D. Schaeffer, Jacqueline Allred, Raul Cermeno, Jackie Crouse, Lori Johnston, Michael Kelly and Charles Bell as defendants. Plaintiffs claim that Amgen and the individual defendants breached their fiduciary duties by failing to inform current and former employees who participated in the Amgen Retirement and Savings Plan

and the Retirement and Savings Plan for Amgen Manufacturing Limited of the alleged off-label promotion of both Aranesp® and EPOGEN® while a number of studies allegedly demonstrated safety concerns in patients using ESAs. On February 4, 2008, the California Central District Court dismissed the complaint with prejudice as to plaintiff Harris, who had filed claims against Amgen Inc. The claims alleged by the second plaintiff, Ramos, were also dismissed but the court granted the plaintiff leave to amend his complaint. On February 1, 2008, the plaintiffs appealed the decision by the California Central District Court to dismiss the claims of both plaintiffs Harris and Ramos to the Ninth Circuit Court. On May 19, 2008, plaintiff Ramos in the *Harris v. Amgen Inc., et al.*, action filed another lawsuit captioned *Ramos v. Amgen Inc., et al.*, in the California Central District Court. The lawsuit is another ERISA class action. The *Ramos v. Amgen Inc., et al*., matter names the same defendants in the *Harris v. Amgen Inc., et al.*, matter plus four new defendants: Amgen Manufacturing Limited, Richard Nanula, Dennis Fenton and the Fiduciary Committee. On July 14, 2009, the Ninth Circuit Court reversed the California Central District Court's decision in the *Harris* matter and remanded the case back to the California Central District Court. In the meantime, a third ERISA class action was filed by Don Hanks on June 2, 2009 in the California Central District Court alleging the same ERISA violations as in the *Harris* and *Ramos* lawsuits.

On August 10, 2009, the *Harris*, *Ramos* and *Hanks* matters were consolidated by the California Central District Court into one action captioned *Harris, et. al. v. Amgen Inc.* On October 13, 2009, the California Central District Court granted plaintiffs Harris' and Ramos' motion to be appointed interim co-lead counsel. Plaintiffs filed an amended complaint on November 11, 2009 and added two additional plaintiffs, Jorge Torres and Albert Cappa. Amgen filed a motion to dismiss the amended/consolidated complaint, and on March 2, 2010, the California Central District Court dismissed the entire lawsuit without prejudice. Plaintiffs filed an amended complaint on March 23, 2010. Amgen then filed another motion to dismiss on April 20, 2010. On June 16, 2010, the California Central District Court entered an order dismissing the entire lawsuit with prejudice. On June 24, 2010, the plaintiffs filed a notice of appeal with the Ninth Circuit Court. Petitioner's opening brief was served on December 20, 2010 and Amgen's answering brief was filed on February 2, 2011. Oral argument occurred on February 17, 2012.

Government Investigations and Qui Tam Actions

On May 10, 2007, Amgen received a subpoena from the Attorney General of the State of New York seeking documents related to Amgen's promotional activities, sales and marketing activities, medical education, clinical studies, pricing and contracting, license and distribution agreements and corporate communications. Amgen fully cooperated in responding to the subpoena.

Beginning in late 2007, Amgen received a number of subpoenas from the U.S. Attorney's Offices for the Eastern District of New York and the Western District of Washington, pursuant to the Health Insurance Portability and Accountability Act (18 U.S.C. 3486), for broad production of documents relating to its products and clinical trials. Amgen fully cooperated with the government's document requests. Over the next several years, numerous current and former Amgen employees received civil and grand jury subpoenas to provide testimony on a wide variety of subjects. We refer herein to these investigations conducted by the U.S. Attorney's Offices for the Eastern District of New York and the Western District of Washington as the Federal Investigations.

On January 14, 2008, Amgen received a subpoena from the New Jersey Attorney General's Office for production of documents relating to one of its products. Amgen completed its response per the terms of the subpoena.

A U.S. government filing in the U.S. District Court for the District of Massachusetts (the Massachusetts District Court) concerning the partially unsealed complaint filed pursuant to the Qui Tam provisions of the Federal Civil False Claims Act and on behalf of 17 named states and the District of Columbia under their respective State False Claims Acts (the Massachusetts Qui Tam Action) became public on or about May 7, 2009. The filing represented that, in addition to the Massachusetts Qui Tam Action, there were nine other actions under the False Claim Act pending under seal against Amgen, including eight pending in the U.S. District Court for the Eastern District of New York (the New York Eastern District Court) and one pending in the U.S. District Court for the Western District of Washington. Together, with the Massachusetts Qui Tam Action, we refer to these actions as the Original Qui Tam Actions. In the filing made public on May 7, 2009, the U.S. government represented that these ten Original Qui Tam Actions alleged that Amgen engaged in a wide variety of illegal marketing practices with respect to various Amgen products and that these were joint civil and criminal investigations being conducted by a wide variety and large number of federal and state agencies.

On September 1, 2009, the U.S. government filed a notice of non-intervention and 14 states and the District of Columbia filed notices of intervention in the Massachusetts Qui Tam Action. On October 30, 2009, 14 states and the District of Columbia filed an amended complaint in the Massachusetts District Court entitled *The United States of America, States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Nevada, New Hampshire, New Mexico, New York, Tennessee and Texas and the Commonwealths of Massachusetts and Virginia and the District of Columbia, ex rel Kassie*

Westmoreland v. Amgen Inc., Integrated Nephrology Network, AmerisourceBergen Specialty Group, ASD Healthcare and AmerisourceBergen Corporation. The relator, Kassie Westmoreland, also filed a second amended complaint with the Massachusetts District Court on the same day. The complaints alleged violations of the federal Anti-Kickback Statute and violations of state false claims act statutes with regard to Amgen's marketing of overfill in vials of Aranesp® and with regard to Amgen's relationship with the Integrated Nephrology Network (INN), a group purchasing organization. The relator's seconded amended complaint also alleged that Amgen retaliated against and wrongfully terminated Ms. Westmoreland.

On January 20, 2010, the states of Florida and Texas voluntarily dismissed their complaints against Amgen. On February 12, 2010, February 16, 2010 and February 18, 2010, respectively, the states of New Hampshire, Louisiana and Nevada voluntarily dismissed their complaints against Amgen. On February 23, 2010, the state of Delaware voluntarily dismissed its complaint against Amgen. Also, on February 23, 2010, the Massachusetts District Court granted Amgen's motion to stay and sever the relator's employment claims.

On April 23, 2010, the Massachusetts District Court dismissed all of the claims of the relator, on behalf of the federal government and the states of New Mexico and Georgia, and all of the claims of the remaining states, for failure to state valid legal grounds upon which relief could be granted. On May 26, 2010, the Massachusetts District Court granted leave for the relator to file a fourth amended complaint. On May 24, 2010, the states of New York, Massachusetts, Michigan, California, Illinois, and Indiana filed notices of intent to appeal the Massachusetts District Court's judgment to the U.S. Court of Appeals for the First Circuit (the First Circuit Court).

On September 20, 2010, the Massachusetts District Court entered a written ruling denying Amgen's motions to dismiss the relator's fourth amended complaint. On April 11, 2011, the Massachusetts District Court heard summary judgment arguments on the fourth amended complaint from Amgen, INN and the relator. On July 22, 2011, the First Circuit Court issued a written decision reversing the Massachusetts District Court's dismissal of the claims of the states of California, Illinois, Indiana, Massachusetts, New Mexico, and New York and affirming the dismissal of the claims of Georgia.

In March 2011, the U.S. Attorney's Office of the Western District of Washington informed Amgen that the subject matter of its investigation would be transferred to the U.S. Attorney's Office of the Eastern District of New York.

In October 2011, Amgen announced it had reached an agreement in principle to settle allegations relating to its sales and marketing practices arising out of the Federal Investigations, and on December 19, 2012, Amgen announced that it had finalized a settlement agreement (the Settlement Agreement), with the U.S. government, 49 states and the District of Columbia. The Settlement Agreement resolved the Federal Investigations, the related state Medicaid claims (except for those of the State of South Carolina) and the claims of nine of the ten Original Qui Tam Actions. The Settlement Agreement also resolved the claims of one of the other civil qui tam actions that had not been included in the agreement in principle but of which Amgen was made aware during settlement discussions (see below). This additional qui tam action resolved by the Settlement Agreement (the Additional Qui Tam) included allegations that Amgen's promotional, contracting, sales and marketing activities and arrangements relating to ENBREL caused the submission of various false claims under the Federal Civil False Claims Act and various State False Claims Acts. Under the Settlement Agreement, Amgen paid approximately $612 million to resolve its civil liability related to certain promotional practices related to the drugs Aranesp®, EPOGEN®, NEUPOGEN®, Neulasta®, ENBREL and Sensipar® as alleged in the unsealed qui tam complaints and $150 million to resolve its criminal liability relating to the marketing of Aranesp®, as well as accrued interest.

As part of the Settlement Agreement, Amgen pled guilty to a single misdemeanor count of misbranding Aranesp® by promoting it in a way that was different from the dosages in the label. The plea was entered on December 18, 2012 in the New York Eastern District Court and was accepted by the court on December 19, 2012. In connection with entering into the Settlement Agreement, Amgen also entered into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services that requires Amgen to maintain its corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years. In February 2013, Amgen resolved the state Medicaid claims of the State of South Carolina related to the Federal Investigations for an immaterial amount. Amgen has accrued an immaterial amount to resolve the remaining Original Qui Tam Action, which remains pending in the New York Eastern District Court.

As part of the settlement described above, Amgen was made aware that it was a defendant in several other civil qui tam actions **(**the Other Qui Tams) in addition to those included in the October 2011 agreement in principle. As stated above, the Additional Qui Tam was resolved by the Settlement Agreement. Amgen has been dismissed from two of the Other Qui Tams: *U.S. ex rel. May v. Amgen, et al.* and another matter that continues under seal against other defendants. Amgen has reached a separate

agreement in principle and continues to expect to enter into a written settlement agreement to resolve a fourth Other Qui Tam, for which Amgen has accrued an immaterial amount; that matter will remain under seal in the U.S. federal court where it was filed until the settlement agreement is signed. The fifth and final Other Qui Tam action remains under seal in the U.S. federal court in which it was filed and includes allegations that Amgen's promotional, contracting, sales and marketing activities and arrangements relating to Aranesp®, NEUPOGEN®, Neulasta®, XGEVA®, Prolia®, Vectibix® and Nplate® caused the submission of various false claims under the Federal Civil False Claims Act and various State False Claims Acts. Amgen continues to cooperate fully with the government in its investigation of these allegations.

Commitments

We lease certain facilities and equipment related primarily to administrative, R&D, sales and marketing activities under non-cancelable operating leases that expire through 2032. The following table summarizes the minimum future rental commitments under non-cancelable operating leases as of December 31, 2012 (in millions):

2013	$	121
2014		97
2015		90
2016		79
2017		67
Thereafter		287
Total minimum operating lease commitments	$	741

Included in the table above are future rental commitments for abandoned leases in the amount of $331 million. Rental expense on operating leases for the years ended December 31, 2012, 2011 and 2010, was $117 million, $131 million and $115 million, respectively.

In addition, we have minimum contractual purchase commitments with third-party manufacturers through 2014 that total $39 million as of December 31, 2012. Amounts purchased under these contractual purchase commitments for the years ended December 31, 2012, 2011 and 2010, were $123 million, $87 million and $68 million, respectively.

19. Segment information

We operate in one business segment — human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Enterprise-wide disclosures about product sales; revenues and long-lived assets by geographic area; and revenues from major customers are presented below.

Revenues

Revenues were as follows for the years ended December 31, 2012, 2011 and 2010 (in millions):

	2012	2011	2010
Product sales:			
Neulasta®	$ 4,092	$ 3,952	$ 3,558
NEUPOGEN®	1,260	1,260	1,286
ENBREL	4,236	3,701	3,534
Aranesp®	2,040	2,303	2,486
EPOGEN®	1,941	2,040	2,524
Sensipar®/Mimpara®	950	808	714
Vectibix®	359	322	288
Nplate®	368	297	229
XGEVA®	748	351	8
Prolia®	472	203	33
Other	173	58	—
Total product sales	16,639	15,295	14,660
Other revenues	626	287	393
Total revenues	$ 17,265	$ 15,582	$ 15,053

Geographic information

Outside the United States, we sell products principally in Europe and Canada. The geographic classification of product sales was based on the location of the customer. The geographic classification of all other revenues was based on the domicile of the entity from which the revenues were earned.

Certain geographic information with respect to revenues and long-lived assets (consisting of property, plant and equipment) was as follows (in millions):

	Years ended December 31,		
	2012	2011	2010
Revenues:			
United States	$ 13,415	$ 11,985	$ 11,636
ROW	3,850	3,597	3,417
Total revenues	$ 17,265	$ 15,582	$ 15,053

	December 31,	
	2012	2011
Long-lived assets:		
United States	$ 2,906	$ 3,144
Puerto Rico	1,908	1,993
ROW	512	283
Total long-lived assets	$ 5,326	$ 5,420

Major customers

In the United States, we sell primarily to pharmaceutical wholesale distributors. We utilize those wholesale distributors as the principal means of distributing our products to healthcare providers. In Europe, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country. We monitor the financial condition of our larger customers, and we limit our credit exposure by setting credit limits and, for certain customers, by requiring letters of credit.

We had product sales to three customers each accounting for more than 10% of total revenues for the years ended December 31, 2012, 2011 and 2010. For 2012, on a combined basis, these customers accounted for 76% and 94% of worldwide gross revenues and U.S. gross product sales, respectively, as noted in the following table. Certain information with respect to these customers for the years ended December 31, 2012, 2011 and 2010, was as follows (dollar amounts in millions):

	2012	2011	2010
AmerisourceBergen Corporation:			
Gross product sales	$ 7,556	$ 7,574	$ 7,678
% of total gross revenues	34%	36%	38%
% of U.S. gross product sales	43%	45%	47%
McKesson Corporation:			
Gross product sales	$ 5,898	$ 4,591	$ 3,913
% of total gross revenues	27%	22%	19%
% of U.S. gross product sales	32%	27%	24%
Cardinal Health, Inc.:			
Gross product sales	$ 3,245	$ 3,021	$ 2,813
% of total gross revenues	15%	14%	14%
% of U.S. gross product sales	19%	18%	17%

At December 31, 2012 and 2011, amounts due from these three customers each exceeded 10% of gross trade receivables and accounted for 61% and 60%, respectively, of net trade receivables on a combined basis. At December 31, 2012 and 2011, 36% and 39%, respectively, of trade receivables, net were due from customers located outside the United States, primarily in Europe. Our total allowance for doubtful accounts as of December 31, 2012 and 2011, was not material.

20. Quarterly financial data (unaudited)

	2012 Quarters ended			
(In millions, except per share data)	December 31	September 30	June 30	March 31
Product sales	$ 4,337	$ 4,201	$ 4,200	$ 3,901
Gross profit from product sales	3,485	3,496	3,518	3,222
Net income	788	1,107	1,266	1,184
Earnings per share:				
Basic	$ 1.03	$ 1.44	$ 1.63	$ 1.50
Diluted	$ 1.01	$ 1.41	$ 1.61	$ 1.48

	2011 Quarters ended			
(In millions, except per share data)	December 31	September 30[1]	June 30	March 31
Product sales	$ 3,907	$ 3,877	$ 3,893	$ 3,618
Gross profit from product sales	3,251	3,272	3,291	3,054
Net income	934	454	1,170	1,125
Earnings per share:				
Basic	$ 1.09	$ 0.50	$ 1.26	$ 1.21
Diluted	$ 1.08	$ 0.50	$ 1.25	$ 1.20

(1) We recorded a $780 million legal settlement charge ($705 million, net of tax) in connection with an agreement in principle to settle allegations related to our sales and marketing practices.

SCHEDULE II

AMGEN INC.

VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2012, 2011 and 2010

(In millions)

Allowance for doubtful accounts	Balance at beginning of period	Additions charged to costs and expenses	Other additions	Deductions	Balance at end of period
Year ended December 31, 2012	$ 54	$ 7	$ —	$ —	$ 61
Year ended December 31, 2011	$ 42	$ 17	$ —	$ 5	$ 54
Year ended December 31, 2010	$ 32	$ 10	$ —	$ —	$ 42

Exhibit 3.5

CERTIFICATE OF CHANGE OF LOCATION OF REGISTERED OFFICE
AND OF REGISTERED AGENT

OF

AMGEN INC.

It is hereby certified that:

1. The name of the corporation (hereinafter called the "corporation") is

AMGEN INC.

2. The registered office of the corporation within the State of Delaware is hereby changed to 2711 Centerville Road, Suite 400, City of Wilmington 19808, County of New Castle.

3. The registered agent of the corporation within the State of Delaware is hereby changed to Corporation Service Company, the business office of which is identical with the registered office of the corporation as hereby changed.

4. The corporation has authorized the changes hereinbefore set forth by resolution of its Board of Directors.

Signed on January 2, 2009.

/s/ Mark A. Schlossberg
Name: Mark A. Schlossberg
Title: Asst. Secretary and V.P.

AMGEN INC. 2009
PERFORMANCE AWARD PROGRAM
(Effective March 3, 2009)

As Amended December 13, 2012

ARTICLE I

PURPOSE

The purpose of this document is to set forth the general terms and conditions applicable to the Amgen Inc. 2009 Performance Award Program (the "Program") established by the Compensation and Management Development Committee of the Board of Directors of Amgen Inc. (the "Company") pursuant to, and in implementation of, Articles 5 and 9 of the Company's 2009 Equity Incentive Plan (the "2009 Plan"). The Program is intended to carry out the purposes of the 2009 Plan and provide a means to reinforce objectives for sustained long-term performance and value creation by awarding selected key employees of the Company with payments in Company stock based on the level of achievement of pre-established performance goals during performance periods through the award of Performance Awards pursuant to Articles 5 and 9 of the 2009 Plan, subject to the restrictions and other provisions of the Program and the 2009 Plan.

ARTICLE II

DEFINITIONS

Unless otherwise defined herein, capitalized terms used herein shall have the meanings assigned to such terms in the 2009 Plan.

"Award" shall mean the earned Performance Units payable in Common Stock under the Program for a Performance Period.

"Board" shall mean the Board of Directors of the Company.

"Change of Control" shall mean the occurrence of any of the following:

(i) the acquisition (other than from the Company) by any person, entity or "group," within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (excluding, for this purpose, the Company or any of its Affiliates, or any employee benefit plan of the Company or any of its Affiliates which acquires beneficial ownership of voting securities of the Company), of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of fifty percent (50%) or more of either the then outstanding shares of Common Stock or the combined voting power of the Company's then outstanding voting securities entitled to vote generally in the election of directors; or

(ii) individuals who, as of April 2, 1991, constitute the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board, provided that any person becoming a director subsequent to April 2, 1991, whose election, or nomination for election by the Company's stockholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board (other than an election or nomination of an individual whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of the Directors of the Company, as such terms are used in Rule 14a-11 of Regulation 14A promulgated under the Exchange Act) shall be, for purposes of the Plan, considered as though such person were a member of the Incumbent Board; or

(iii) the consummation by the Company of a reorganization, merger, consolidation, (in each case, with respect to which persons who were the stockholders of the Company immediately prior to such reorganization, merger or consolidation do not, immediately thereafter, own more than fifty percent (50%) of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities) or a liquidation or dissolution of the Company or of the sale of all or substantially all of the assets of the Company; or

(iv) any other event which the Incumbent Board in its sole discretion determines constitutes a Change of Control.

Notwithstanding anything herein or in any Award Agreement to the contrary, if a Change of Control constitutes a payment event with respect to any Award that is subject to United States income tax and which provides for a deferral of compensation that is subject to Section 409A of the Code, the transaction or event described in subsection (i), (ii), (iii) or (iv) must also constitute a "change in control event," as defined in Treasury Regulation §1.409A-3(i)(5), in order to constitute a Change of Control for purposes of payment of such Award.

"Code" shall mean the Internal Revenue Code of 1986, as amended from time to time, together with the regulations and official guidance promulgated thereunder.

"Common Stock" shall mean the common stock, par value $0.0001 per share, of the Company.

"Determination Date" shall have the meaning ascribed to it in Section 4.1.

"Participant" shall mean a key employee of the Company or an Affiliate who participates in this Program pursuant to the provisions of Article III hereof.

"Performance Period" shall mean a period of time with respect to which performance is measured as determined by the Committee. Performance Periods may overlap.

"Performance Goals" shall have the meaning ascribed to it in Section 5.2.

"Performance Unit" shall mean a right granted to a Participant pursuant to the Program to receive Common Stock, the payment of which is contingent upon achieving the Performance Goals.

"Permanent and Total Disability" shall have the meaning ascribed to such term under Section 22(e)(3) of the Code and with such permanent and total disability being certified prior to termination of a Participant's employment by (i) the Social Security Administration, (ii) the comparable governmental authority applicable to an Affiliate of the Company, (iii) such other body having the relevant decision-making power applicable to an Affiliate of the Company, or (iv) an independent medical advisor appointed by the Company in its sole discretion, as applicable, in any such case.

"Retirement-Eligible" shall mean when a Participant is at least sixty-five (65) years of age, or when a Participant is at least fifty-five (55) years of age and has been an employee of the Company and/or an Affiliate of the Company for at least ten (10) years in the aggregate as determined by the Company in its sole discretion according to Company policies and practices as in effect from time to time.

"Section 162(m) Participant" shall mean any Participant designated by the Committee as a "covered employee" within the meaning of Section 162(m) of the Code whose compensation for the fiscal year in which the Participant is so designated or a future fiscal year may be subject to the limit on deductible compensation imposed by Section 162(m) of the Code.

"Voluntary Retirement" shall mean voluntary termination of employment that is not the result of Permanent and Total Disability.

ARTICLE III

PARTICIPATION

3.1 Participants. Participants for any Performance Period shall be those active key employees of the Company or an Affiliate who are designated in writing as eligible for participation by the Committee no later than the ninetieth (90th) day after the beginning of such Performance Period.

3.2 No Right to Participate. No Participant or other employee of the Company or an Affiliate shall, at any time, have a right to participate in this Program for any Performance Period, notwithstanding having previously participated in this Program.

ARTICLE IV

ADMINISTRATION

4.1 Generally. The Committee shall establish the basis for payments under this Program in relation to specified Performance Goals, as more fully described in Article V hereof. With respect to the 162(m) Participants, the Committee shall establish the basis for payments under this Program in relation to specified Performance Goals no later than the ninetieth (90th) day after the beginning of such Performance Period, but in no event after 25 percent of the Performance Period has lapsed. Following the end of each Performance Period, once all of the information necessary for the Committee to determine the Company's performance is made available to the Committee, the Committee shall determine the amount of the Award payable to each Participant; *provided, however*, that any such determination shall be made no later than six months following the end of such Performance Period (the date of such determination shall hereinafter be called the "Determination Date"). The Committee shall have the power and authority granted it under Article 12 of the 2009 Plan, including, without limitation, the authority to construe and interpret this Program, to prescribe, amend and rescind rules, regulations and procedures relating to its administration and to make all other determinations necessary or advisable for administration of this Program. Decisions of the Committee in accordance with the authority granted hereby shall be conclusive and binding. Subject only to compliance with the express provisions hereof, the Committee may act in its sole and absolute discretion with respect to matters within its authority under this Program.

4.2 Provisions Applicable to Section 162(m) Participants. Subject to the sole discretion of the Committee, any Awards paid hereunder to a Section 162(m) Participant shall satisfy and shall be interpreted in a manner that satisfies any applicable requirements as "qualified performance-based compensation" within the meaning of Section 162(m) of the Code and any provisions, application or interpretation of the Program or the 2009 Plan that is inconsistent with this intent shall be disregarded. To the extent that any Award (i) is deemed to constitute "nonqualified deferred compensation" (within the meaning of Code Section 409A) and (ii) would nevertheless be subject to the deduction limitations imposed by Section 162(m) of the Code in the year in which such Award would otherwise be paid under this Program, the payment of such Award may, in the Committee's discretion, be delayed until the earlier of (A) the first year in which such Award would not be subject to the deduction limitations imposed by Section 162(m) or (B) such time as the Participant ceases to be a "service provider" to the Company (within the meaning of Section 409A of the Code).

4.3 Provisions Applicable to Participants in Foreign Jurisdictions. Notwithstanding any provision of the Program to the contrary, in order to comply with the laws in other countries in which the Company and its Affiliates operate or have employees, the Committee, in its sole discretion, shall have the power and authority to:

(i) modify the terms and conditions of any award of Performance Units granted to employees outside the United States to comply with applicable foreign laws;

(ii) condition the effectiveness of any award of Performance Units upon approval or compliance with any applicable foreign laws, regulations, rules or local governmental regulatory exemption or approvals;

(iii) provide for payment of any Award in cash or Common Stock, at the Company's election, to the extent necessary to comply with applicable foreign laws; and

(iv) take any other action, before or after an award of Performance Units is made, that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals.

Notwithstanding the foregoing, the Committee may not take any actions hereunder, and no award of Performance Units shall be granted, that would violate the Securities Act, the Exchange Act, the Code, or any other securities or tax or other applicable law or regulation.

ARTICLE V

AWARD DETERMINATIONS

5.1 Award of Performance Units. The Committee shall determine the number of Performance Units (rounded down to the nearest whole number) to be awarded under this Program to each Participant with respect to such Performance Period. With respect to the Section 162(m) Participants, the Committee shall determine the number of Performance Units (rounded down to the nearest whole number) to be awarded under this Program to each Section 162(m) Participant with respect to such Performance Period no later than the ninetieth (90th) day after the beginning of such Performance Period, but in no event after 25 percent of the Performance Period has elapsed. Performance Units granted under the Program shall constitute Performance Awards under Article 9 of the 2009 Plan.

5.2 Performance Requirements. The Committee shall approve the performance goals (collectively, the "Performance Goals") with respect to any of the business criteria permitted under the 2009 Plan, each subject to such adjustments as the Committee

may specify in writing at such time, and shall establish a formula, standard or schedule which aligns the level of achievement of the Performance Goals with the earned Performance Units.

With respect to the Section 162(m) Participants, the Committee shall approve the Performance Goals no later than the ninetieth (90th) day after the beginning of such Performance Period, but in no event after 25 percent of the Performance Period has elapsed, and the Performance Goals may not be changed during the Performance Period, but the thresholds, targets and multiplier measures of the Performance Goals shall be subject to such adjustments as the Committee may specify in writing no later than the ninetieth (90th) day after the beginning of such Performance Period, but in no event after 25 percent of the Performance Period has elapsed.

5.3 Dividend Equivalents. The Committee shall determine whether Dividend Equivalents shall be credited with respect to Performance Units awarded under the Program pursuant to Section 9.2 of the 2009 Plan on such terms and conditions determined by the Committee. Any such Dividend Equivalents shall be credited in cash or additional shares of Common Stock by such formula and at such time and subject to such limitations as may be determined by the Committee.

ARTICLE VI

PAYMENT OF AWARDS

6.1 Form and Timing of Payment. Except as set forth in Section 8.1 below, no Award payable pursuant to this Program shall be paid unless and until the Committee certifies, in writing, the extent to which the Performance Goals have been achieved and the corresponding number of Performance Units earned. The specified payment date applicable to such Awards shall be the year immediately following the tax year including the end of the Performance Period. Shares of Common Stock issued in respect of an Award shall be deemed to be issued in consideration for future services to be rendered or past services actually rendered to the Company or for its benefit, by the Participant, which the Committee deems to have a value at least equal to the aggregate par value thereof.

6.2 Tax Withholding. Regardless of any action the Company or its Affiliate takes with respect to any or all income tax (including federal, state and local taxes), social insurance, payroll tax, payment on account or other tax-related items related to participation in the Program and legally applicable to the Participant ("Tax Obligations"), the Participant acknowledges that the ultimate liability for all Tax Obligations is and remains the Participant's responsibility and may exceed the amount actually withheld by the Company and/or its Affiliate. The Participant further acknowledges that the Company and/or its Affiliate (i) make no representations or undertakings regarding the treatment of any Tax Obligations in connection with any aspect of the Performance Units, including the grant of the Performance Units, the vesting of Performance Units, the conversion of the Performance Units into shares or the receipt of an equivalent cash payment, the subsequent sale of any shares acquired at vesting and the receipt of any dividends; and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Performance Units to reduce or eliminate the Participant's liability for Tax Obligations or achieve any particular tax result. Furthermore, if the Participant becomes subject to tax in more than one jurisdiction between the Grant Date and the date of any relevant taxable event, the Participant acknowledges that the Company and/or its Affiliate may be required to withhold or account for Tax Obligations in more than one jurisdiction.

Prior to any relevant taxable or tax withholding event, as applicable, the Participant shall pay, or make adequate arrangements satisfactory to the Company or to its Affiliate (in their sole discretion) to satisfy all Tax Obligations. In this regard, the Participant authorizes the Company and/or its Affiliate or their respective agents, at their discretion, to satisfy all applicable Tax Obligations by one or a combination of the following:

(a) withholding from the Participant's wages or other cash compensation paid to the Participant by the Company and/or its Affiliate; or

(b) withholding from proceeds of the sale of shares of Common Stock acquired upon vesting or payment of the Performance Units either through a voluntary sale or through a mandatory sale arranged by the Company (on the Participant's behalf pursuant to this authorization); or

(c) withholding in shares of Common Stock to be issued upon vesting or payment of the Performance Units, provided that the Company and its Affiliate shall only withhold an amount of shares of Common Stock with a fair market value equal to the Tax Obligations.

To avoid adverse accounting treatment, the Company may withhold or account for Tax Obligations not to exceed the applicable minimum statutory withholding rates or other applicable withholding rates. If the Tax Obligations are satisfied by withholding in shares of Common Stock, for tax purposes, the Participant is deemed to have been issued the full number of shares of Common Stock subject to the vested Performance Units, notwithstanding that a number of the shares of Common Stock is held back solely for the purpose of paying the Tax Obligations due as a result of any aspect of the Participant's participation in the Program (any shares of Common Stock withheld by the Company hereunder shall not be deemed to have been issued by the Company for any purpose under the Program and shall remain available for issuance thereunder).

Finally, the Participant shall pay to the Company or its Affiliate any amount of Tax Obligations that the Company or its Affiliate may be required to withhold or account for as a result of the Participant's participation in the Program that cannot be satisfied by the means previously described. The Participant agrees to take any further actions and execute any additional documents as may be necessary to effectuate the provisions of this Section 6.2. Notwithstanding Section 6.1 above, the Company may refuse to issue or deliver the shares or the proceeds of the sale of shares of Common Stock if the Participant fails to comply with its obligations in connection with the Tax Obligations.

ARTICLE VII

TERMINATION OF EMPLOYMENT

7.1 Termination of Employment During Performance Period.

(a) In the event that a Participant's employment with the Company or an Affiliate is terminated prior to the last business day of a Performance Period by reason of such Participant's Voluntary Retirement and such Participant is Retirement-Eligible on the date of such termination, the full or prorated amount of such Participant's Award, if any, applicable to such Performance Period shall be paid in accordance with the provisions of Article VI above. For purposes of the foregoing, the amount of the Participant's Award (rounded down to the nearest whole number) shall be determined based on the Company's performance as compared to the Performance Goals for such Performance Period and (i) if the Award was granted with respect to a Performance Period commencing in a calendar year prior to the calendar year in which such Voluntary Retirement occurs, the full amount of the Award is payable, and (ii) if the Award was granted with respect to the Performance Period commencing in the calendar year in which such Voluntary Retirement occurs, the Award otherwise payable is multiplied by a fraction (rounded to two decimal places), the numerator of which is the number of complete months of employment during the Performance Period, and the denominator of which is twelve (12). Notwithstanding the foregoing, a Participant shall not be entitled to such full or prorated amount of such Participant's Award pursuant to this Section 7.1(a) unless either such Participant signs a general release and waiver in a form provided by the Company and delivers it to the Company no later than the date specified by the Company, or the Company waives such release requirement in writing; *provided, however*, that in no event shall payment of such full or prorated amount of such Participant's Award be made later than the specified payment date as set forth in Section 6.1 above.

(b) In the event that a Participant's employment with the Company or an Affiliate is terminated prior to the last business day of a Performance Period by reason of such Participant's death or Permanent and Total Disability, the full or prorated amount of such Participant's Award, if any, applicable to such Performance Period shall be paid in accordance with the provisions of Article VI above. For purposes of the foregoing, the amount of the Participant's Award (rounded down to the nearest whole number) shall be determined based on the Company's performance as compared to the Performance Goals for such Performance Period and (i) if the Award was granted with respect to a Performance Period commencing in a calendar year prior to the calendar year in which such termination occurs, the full amount of the Award is payable, and (ii) if the Award was granted with respect to the Performance Period commencing in the calendar year in which such termination occurs, the Award otherwise payable is multiplied by a fraction (rounded to two decimal places), the numerator of which is the number of complete months of employment during the Performance Period, and the denominator of which is twelve (12). Notwithstanding the foregoing, with respect to a Participant whose employment is terminated due to such Participant's Permanent and Total Disability, such Participant shall not be entitled to such full or prorated amount of such Participant's Award pursuant to this Section 7.1(b) unless either such Participant signs a general release and waiver in a form provided by the Company and delivers it to the Company no later than the date specified by the Company, or the Company waives such release requirement in writing; *provided, however*, that in no event shall payment of such full or prorated amount of such Participant's Award be made later than the specified payment date as set forth in Section 6.1 above.

(c) In the event that a Participant's employment with the Company or an Affiliate is terminated prior to the last business day of a Performance Period for any reason other than as specified in Sections 7.1(a) and (b) above, all of such Participant's rights to an Award for such Performance Period shall be forfeited, unless, prior to the payment date described in Article VI above, the Company, in its sole discretion, makes a written determination to otherwise pay the full or prorated amount of the Participant's Award, if any, applicable to such Performance Period, which full or prorated amount shall be paid in accordance

with the provisions of Article VI above. For purposes of the foregoing, if the payment of the Participant's Award is prorated, the amount of the Participant's Award (rounded down to the nearest whole number) shall be determined based on the Company's performance as compared to the Performance Goals for such Performance Period and the Award otherwise payable is multiplied by a fraction (rounded to two decimal places), the numerator of which is the number of complete months of employment during the Performance Period, and the denominator of which is the number of months in the Performance Period. Notwithstanding the foregoing, a Participant shall not be entitled to such full or prorated amount of such Participant's Award pursuant to this Section 7.1(c) unless either such Participant signs a general release and waiver in a form provided by the Company and delivers it to the Company no later than the date specified by the Company, or the Company waives such release requirement in writing; *provided*, *however*, that in no event shall payment of such full or prorated amount of such Participant's Award be made later than the specified payment date as set forth in Section 6.1 above.

7.2 Termination of Employment After End of Performance Period. In the event that a Participant's employment with the Company or an Affiliate is terminated on or after the last business day of the applicable Performance Period but prior to the Determination Date for any reason, the amount of any Award applicable to such Performance Period shall be paid to the Participant in accordance with the provisions of Article VI above.

ARTICLE VIII

CHANGE OF CONTROL

8.1 Change of Control During Performance Period.

(a) Notwithstanding anything to the contrary in the Program, in the event of a Change of Control that occurs during the first fiscal year of a Performance Period that began prior to January 1, 2008, such Performance Period shall be shortened and shall terminate as of the last business day of the last completed fiscal quarter preceding the date of such Change of Control and each Participant employed by the Company immediately prior to such Change of Control shall be entitled to a payment equal to the amount of the Participant's Award (rounded down to the nearest whole number) he or she would have received for such shortened Performance Period using the assumption that the target levels with respect to the Company's Revenue CAGR and EPS CAGR of the Performance Goals have been satisfied. Any such payment shall be made as soon as practicable following such Change of Control (provided, that the Company may elect, in its sole discretion, to make any such payments in a manner that will not subject the payments to penalties under Code Section 409A) and, in the Committee's sole discretion, may be paid in cash.

(b) Notwithstanding anything to the contrary in the Program, in the event of a Change of Control that occurs during the second or third fiscal year of a Performance Period that began prior to January 1, 2008, such Performance Period shall be shortened and shall terminate as of the last business day of the last completed fiscal quarter preceding the date of such Change of Control and each Participant employed by the Company immediately prior to such Change of Control shall be entitled to a payment equal to the greater of (i) the amount of the Participant's Award (rounded down to the nearest whole number) he or she would have received for such shortened Performance Period using the assumption that the targets levels with respect to the Company's Revenue CAGR and EPS CAGR of the Performance Goals have been satisfied, or (ii) the amount of the Participant's Award (rounded down to the nearest whole number) he or she would have been entitled to receive for such shortened Performance Period, determined based on the Company's performance as determined by the Amgen Revenue CAGR and Amgen EPS CAGR and comparative performance as determined by the Peer Group Revenue CAGR and Peer Group EPS CAGR (for the 2006-2008 Performance Period) or the Company's performance as determined by the Amgen Revenue CAGR and Amgen EPS CAGR and Total Stockholder Return (for the 2007-2009 Performance Period) for such shortened Performance Period. Any such payment shall be made as soon as practicable following such Change of Control (provided, that the Company may elect, in its sole discretion, to make any such payments in a manner that will not subject the payments to penalties under Code Section 409A) and, in the Committee's sole discretion, may be paid in cash.

(c) Notwithstanding anything to the contrary in the Program, for Performance Periods beginning on or after January 1, 2008, the Committee shall set forth the terms of any Award payable in the event of Change of Control that occurs during a Performance Period in the Performance Goals.

(d) For purposes of this Section 8.1, the following terms shall have the meanings set forth in the Performance Goals for the relevant Performance Period: “Revenue CAGR,” “EPS CAGR,” “Amgen Revenue CAGR,” “Amgen EPS CAGR,” “Peer Group Revenue CAGR,” “Peer Group EPS CAGR” and “Total Stockholder Return.”

8.2 Change of Control After End of Performance Period. Notwithstanding anything to the contrary in the Program, in the event of a Change of Control that occurs after the end of the applicable Performance Period but prior to the Determination

Date, the amount of any Award applicable to such Performance Period shall be paid to the Participant in accordance with the provisions of Article VI above.

ARTICLE IX

MISCELLANEOUS

9.1 Plan. The Program is subject to all the provisions of the 2009 Plan and its provisions are hereby made a part of the Program, including without limitation the provisions of Articles 5 and 9 thereof (relating to Performance-Based Compensation and Performance Awards) and Section 13.2 thereof (relating to adjustments upon changes in the Common Stock), and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the 2009 Plan. In the event of any conflict between the provisions of the Program and those of the 2009 Plan, the provisions of the 2009 Plan shall control. Notwithstanding any provision of the Program to the contrary, any earned Performance Units paid in cash rather than shares of Common Stock shall not be deemed to have been issued by the Company for any purpose under the 2009 Plan.

9.2 Amendment and Termination. Notwithstanding anything herein to the contrary, the Committee may, at any time, terminate, modify or suspend this Program; *provided, however*, that, without the prior consent of the Participants affected, no such action may adversely affect any rights or obligations with respect to any Awards theretofore earned but unpaid for a completed Performance Period, whether or not the amounts of such Awards have been computed and whether or not such Awards are then payable. Notwithstanding the forgoing, at any time the Committee determines that the Performance Units may be subject to Section 409A of the Code, the Committee shall have the right, in its sole discretion, and without a Participant's prior consent to amend the Program as it may determine is necessary or desirable either for the Performance Units to be exempt from the application of Section 409A or to satisfy the requirements of Section 409A, including by adding conditions with respect to the vesting and/or the payment of the Performance Units, provided that no such amendment may change the Program's "performance goals," within the meaning of Section 162(m) of the Code, with respect to any person who is a "covered employee," within the meaning of Section 162(m) of the Code.

9.3 No Contract for Employment. Nothing contained in this Program or in any document related to this Program or to any Award shall confer upon any Participant any right to continue as an employee or in the employ of the Company or an Affiliate or constitute any contract or agreement of employment for a specific term or interfere in any way with the right of the Company or an Affiliate to reduce such person's compensation, to change the position held by such person or to terminate the employment of such person, with or without cause.

9.4 Nontransferability. No benefit payable under, or interest in, this Program shall be subject in any manner to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or charge and any such attempted action shall be void and no such benefit or interest shall be, in any manner, liable for, or subject to, debts, contracts, liabilities or torts of any Participant or beneficiary; *provided, however*, that, nothing in this Section 9.4 shall prevent transfer (i) by will, or (ii) by applicable laws of descent and distribution.

9.5 Compensation Subject to Recovery. The Awards under this Program and all compensation payable with respect to them shall be subject to recovery by the Company pursuant to any and all of the Company's policies with respect to the recovery of compensation, as they shall be in effect and may be amended from time to time, to the maximum extent permitted by applicable law.

9.6 Nature of Program. No Participant, beneficiary or other person shall have any right, title or interest in any fund or in any specific asset of the Company or any Affiliate by reason of any award hereunder. There shall be no funding of any benefits which may become payable hereunder. Nothing contained in this Program (or in any document related thereto), nor the creation or adoption of this Program, nor any action taken pursuant to the provisions of this Program shall create, or be construed to create, a trust of any kind or a fiduciary relationship between the Company or an Affiliate and any Participant, beneficiary or other person. To the extent that a Participant, beneficiary or other person acquires a right to receive payment with respect to an Award hereunder, such right shall be no greater than the right of any unsecured general creditor of the Company or other employing entity, as applicable. All amounts payable under this Program shall be paid from the general assets of the Company or employing entity, as applicable, and no special or separate fund or deposit shall be established and no segregation of assets shall be made to assure payment of such amounts. Nothing in this Program shall be deemed to give any employee any right to participate in this Program except in accordance herewith.

9.7 Governing Law. This Program shall be construed in accordance with the laws of the State of Delaware, without giving effect to the principles of conflicts of law thereof.

AMGEN INC. 2009 DIRECTOR EQUITY INCENTIVE PROGRAM
(Effective January 1, 2013)

As Amended and Restated December 13, 2012

ARTICLE I

PURPOSE

The purpose of this document is to set forth the general terms and conditions applicable to the Amgen 2009 Director Equity Incentive Program (as amended from time to time, the "Program") established by the Board of Directors of Amgen Inc. (the "Company") pursuant to the Company's 2009 Equity Incentive Plan, as amended (the "2009 Plan"). The Program is intended to carry out the purposes of the 2009 Plan and provide a means to reinforce objectives for sustained long-term performance and value creation by awarding each Non-Employee Director of the Company with stock awards, subject to the restrictions and other provisions of the Program and the 2009 Plan. The Program originally became effective as of the date the 2009 Plan was approved by the Board of Directors of the Company and the Program (as amended and restated on December 13, 2012) shall be effective as of January 1, 2013 (the "Effective Date").

ARTICLE II

DEFINITIONS

Unless otherwise defined herein, capitalized terms used herein shall have the meanings assigned to such terms in the 2009 Plan.

"Alternate Payee" shall mean the spouse, former spouse or child of an Eligible Director.

"Award" shall mean a Restricted Stock Unit granted to an Eligible Director pursuant to the Program.

"Board" shall mean the Board of Directors of the Company.

"Code" shall mean the Internal Revenue Code of 1986, as amended from time to time, together with the regulations and official guidance promulgated thereunder.

"Common Stock" shall mean the common stock, par value $0.0001 per share, of the Company.

"Eligible Director" shall mean a member of the Board who is not an employee of the Company or any Affiliate.

"QDRO" shall mean a court order (i) that creates or recognizes the right of the spouse, former spouse or child of an individual who is granted an Award to an interest in such Award relating to marital property rights or support obligations and (ii) that the Board determines would be a "qualified domestic relations order," as that term is defined in Section 414(p) of the Code and Section 206(d) of the Employee Retirement Income Security Act ("ERISA"), but for the fact that the Program is not a plan described in Section 3(3) of ERISA.

"Restricted Stock Unit" shall mean a restricted right to receive a share of Common Stock granted pursuant to Article III.

ARTICLE III

RESTRICTED STOCK UNITS

3.1 Annual Grants. On the date which is two business days after the release of the Company's quarterly earnings for the first fiscal quarter of each year after the Effective Date (the "Annual Grant Date"), each person who is at that time an Eligible Director shall automatically be granted, without further action by the Company, the Board, or the Company's stockholders, Restricted Stock Units to acquire a number of shares of Common Stock (rounded down to the nearest whole number) equal to the quotient obtained by dividing (x) $200,000, by (y) the closing market price of a share of Common Stock on the date of grant

(rounded to two decimal places) (such Restricted Stock Units, the "Annual RSU Award"). Notwithstanding the foregoing, each person who becomes an Eligible Director following the Annual Grant Date with respect to any year (such year, the "Initial Year") shall automatically be granted, on the date which is two business days after the release of the Company's quarterly or annual earnings for the Initial Year next following such person becoming an Eligible Director, and without further action by the Company, the Board, or the Company's stockholders, a prorated Annual RSU Award (rounded down to the nearest whole number) for the Initial Year based on the number of months during which such person would serve as an Eligible Director during the Initial Year if the Eligible Director were to serve through the end of the Initial Year. Restricted Stock Units shall constitute Restricted Stock Units under Section 9.5 of the 2009 Plan.

3.2 Terms of Restricted Stock Units.

(a) Each Restricted Stock Unit granted pursuant to this Program shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. The provisions of separate Restricted Stock Units need not be identical, but each Restricted Stock Unit shall include (through incorporation of provisions hereof by reference in the Restricted Stock Unit agreement or otherwise) the substance of each of the following provisions as set forth in this Section 3.2 and Section 9.5 of the 2009 Plan.

(b) Each grant of Restricted Stock Units made to an Eligible Director shall be fully vested as of the date of grant of such Restricted Stock Units (such date, "Vesting Date").

(c) A holder's vested Restricted Stock Units shall be paid by the Company in shares of Common Stock (on a one-to-one basis) on, or as soon as practicable after, the Vesting Date (the "Payment Date"), but in any event by the fifteenth day of the third month following the end of the tax year in which such Restricted Stock Units vest, unless the Eligible Director has irrevocably elected in writing by December 31 of the year preceding the grant of such Restricted Stock Units to defer the payment of such Restricted Stock Units, and any dividends paid thereon, to another date under one of the following options, which payment form or forms shall be specified at the time of the deferral election (the "Deferred Payment Date"): (i) full payment of the vested Restricted Stock Units in January of a year specified by the Eligible Director which shall be no earlier than the third calendar year following the calendar year in which the date of grant occurs and no later than the tenth calendar year following such year; (ii) full payment of the vested Restricted Stock Units in January of the calendar year following the year in which the Eligible Director with respect to whom the Restricted Stock Units were granted ceases to be an Eligible Director and ceases to otherwise provide services to the Company in a manner that constitutes a "separation from service" (within the meaning of Code Section 409A) for any reason; (iii) payment of the vested Restricted Stock Units in five substantially equal annual installments, commencing in January of the calendar year following the year in which the Eligible Director with respect to whom the Restricted Stock Units were granted ceases to be an Eligible Director and ceases to otherwise provide services to the Company in a manner that constitutes a "separation from service" (within the meaning Code Section 409A) for any reason; or (iv) payment of the vested Restricted Stock Units in ten substantially equal annual installments, commencing in January of the calendar year following the year in which the Eligible Director with respect to whom the Restricted Stock Units were granted ceases to be an Eligible Director and ceases to otherwise provide services to the Company in a manner that constitutes a "separation from service" (within the meaning Code Section 409A) for any reason. Shares of Common Stock issued in respect of a Restricted Stock Unit shall be deemed to be issued in consideration for future services to be rendered or past services actually rendered to the Company or for its benefit, by the Eligible Director, which the Board deems to have a value not less than the par value of a share of Common Stock.

3.3 Dividend Equivalents.

(a) Crediting and Payment of Dividend Equivalents. Subject to this Section 3.3, Dividend Equivalents shall be credited on each Restricted Stock Unit granted to an Eligible Director under the Program in the manner set forth in the remainder of this Section 3.3. If the Company declares one or more dividends or distributions (each, a "Dividend") on its Common Stock with a record date which occurs during the period commencing on the date of grant through and including the day immediately preceding the day the shares of Common Stock subject to the Restricted Stock Units are issued to the Eligible Director, whether in the form of cash, Common Stock or other property, then on the date such Dividend is paid to the Company's stockholders the Eligible Director shall be credited with an amount equal to the amount or fair market value of such Dividend which would have been payable to the Eligible Director if the Eligible Director held a number of shares of Common Stock equal to the number of the Eligible Director's Restricted Stock Units as of the record date for such Dividend. Any such Dividend Equivalents shall be credited and deemed reinvested in the Common Stock as of the Dividend payment date. Dividend Equivalents shall be payable in full shares of Common Stock, unless the Board determines, at any time prior to payment and in its discretion, that they shall be payable in cash. Dividend Equivalents payable with respect to fractional shares of Common Stock shall be paid in cash.

(b) Treatment of Dividend Equivalents. Except as otherwise expressly provided in this Section 3.3, any Dividend Equivalents credited to an Eligible Director shall be subject to all of the provisions of the Program and the Restricted Stock Unit Agreement which apply to the Restricted Stock Units with respect to which they have been credited and shall be payable, if at all, at the time and to the extent that the underlying Restricted Stock Unit becomes payable.

ARTICLE IV

MISCELLANEOUS

4.1 Administration of the Program. The Program shall be administered by the Board and, to the extent permitted by applicable law or the rules of any Securities Exchange, the Board may delegate to a committee of one or more members of the Board the authority to administer the Program.

4.2 Application of 2009 Plan. The Program is subject to all the provisions of the 2009 Plan, including Section 13.2 thereof (relating to adjustments upon changes in the Common Stock), and its provisions are hereby made a part of the Program, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the 2009 Plan. In the event of any conflict between the provisions of this Program and those of the 2009 Plan, the provisions of the 2009 Plan shall control.

4.3 Amendment and Termination. Notwithstanding anything herein to the contrary, the Board may, at any time, terminate, modify or suspend the Program; *provided, however,* that, without the prior consent of the Eligible Directors affected, no such action may adversely affect any rights or obligations with respect to any Awards theretofore earned but unpaid, whether or not the amounts of such Awards have been computed and whether or not such Awards are then payable. Any amendment of this Program may, in the sole discretion of the Board, be accomplished in a manner calculated to cause such amendment not to constitute an "extension," "renewal" or "modification" (each within the meaning of Code Section 409A) of any Restricted Stock Units that would cause such Restricted Stock Units to be considered "nonqualified deferred compensation" (within the meaning of Code Section 409A).

4.4 No Contract for Employment. Nothing contained in the Program or in any document related to the Program or to any Award shall confer upon any Eligible Director any right to continue as a director or in the service or employment of the Company or an Affiliate or constitute any contract or agreement of service or employment for a specific term or interfere in any way with the right of the Company or an Affiliate to reduce such person's compensation, to change the position held by such person or to terminate the service of such person, with or without cause.

4.5 Nontransferability.

(a) No benefit payable under, or interest in, this Program shall be subject in any manner to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or charge and any such attempted action shall be void and no such benefit or interest shall be, in any manner, liable for, or subject to, debts, contracts, liabilities or torts of any Eligible Director or beneficiary; provided, however, that, nothing in this Section 4.5 shall prevent transfer (i) by will, (ii) by applicable laws of descent and distribution or (iii) to an Alternate Payee to the extent that a QDRO so provides.

(b) The transfer to an Alternate Payee of an Award pursuant to a QDRO shall not be treated as having caused a new grant. If an Award is so transferred, the Alternate Payee generally has the same rights as the Eligible Director under the terms of the Program; *provided however*, that (i) the Award shall be subject to the same terms and conditions, including the vesting terms, termination provisions and exercise period, as if the Award were still held by the Eligible Director, and (ii) such Alternate Payee may not transfer an Award. In the event of the Company Stock Administrator's receipt of a domestic relations order or other notice of adverse claim by an Alternate Payee of an Eligible Director of an Award, transfer of the proceeds of the exercise of such Award, whether in the form of cash, stock or other property, may be suspended. Such proceeds shall thereafter be transferred pursuant to the terms of a QDRO or other agreement between the Eligible Director and Alternate Payee. An Eligible Director's ability to exercise an Award may be barred if the Company Stock Administrator receives a court order directing the Company Stock Administrator not to permit exercise.

4.6 Nature of Program. No Eligible Director, beneficiary or other person shall have any right, title or interest in any fund or in any specific asset of the Company or any Affiliate by reason of any award hereunder. There shall be no funding of any benefits which may become payable hereunder. Nothing contained in this Program (or in any document related thereto), nor the creation or adoption of this Program, nor any action taken pursuant to the provisions of this Program shall create, or be construed to create, a trust of any kind or a fiduciary relationship between the Company or an Affiliate and any Eligible Director, beneficiary or other person. To the extent that an Eligible Director, beneficiary or other person acquires a right to receive payment

with respect to an award hereunder, such right shall be no greater than the right of any unsecured general creditor of the Company or other employing entity, as applicable. All amounts payable under this Program shall be paid from the general assets of the Company or employing entity, as applicable, and no special or separate fund or deposit shall be established and no segregation of assets shall be made to assure payment of such amounts. Nothing in this Program shall be deemed to give any person any right to participate in this Program except in accordance herewith.

4.7 Governing Law. This Program shall be construed in accordance with the laws of the State of Delaware, without giving effect to the principles of conflicts of law thereof.

4.8 Code Section 409A. To the extent that this Program constitutes a "non-qualified deferred compensation plan" within the meaning of with Code Section 409A and Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Effective Date, this Program shall be interpreted and operated in accordance with Code Section 409A. Notwithstanding any provision of this Program to the contrary, in the event that following the grant of any Restricted Stock Units, the Board determines that any Award does or may violate any of the requirements of Code Section 409A, the Board may adopt such amendments to the Program and any affected Award or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Board determines are necessary or appropriate to (a) exempt the Program and any such Award from the application of Code Section 409A and/or preserve the intended tax treatment of the benefits provided with respect to the Award, or (b) comply with the requirements of Code Section 409A; provided, however, that this paragraph shall not create an obligation on the part of the Board to adopt any such amendment, policy or procedure or take any such other action.

RESTRICTED STOCK UNIT AGREEMENT
(Director Equity Incentive Program)

_____, Amgen Inc. Grantee:

On this __ day of _____ (the "Grant Date"), Amgen Inc., a Delaware corporation (the "Company"), pursuant to its Amgen 2009 Director Equity Incentive Program (as amended from time to time, the "Program") which implements the Amgen Inc. 2009 Equity Incentive Plan (the "Plan"), has granted to you, the grantee named above, _____ restricted stock units (the "Units") with respect to _____ Shares on the terms and conditions set forth in this Restricted Stock Unit Agreement, including any appendix hereto (as further described in Section XIV below) containing special terms and conditions applicable to your country (collectively, this "Agreement"), and the Plan. Capitalized terms not defined herein shall have the meanings assigned to such terms in the Plan and/or the Program.

I. Vesting Schedule. Subject to the terms and conditions of this Agreement and in consideration for services previously rendered by you, one hundred percent (100%) of the Units shall vest upon the date hereof (the "Vesting Date").

II. Form and Timing of Payment. Any vested Units shall be paid by the Company in Shares (on a one-to-one basis) on, or as soon as practicable after, the Vesting Date (but in any event by the fifteenth day of the third month following the tax year in which they vest), unless you have irrevocably elected in writing by December 31 of the year preceding the Vesting Date to defer the payment of such Units under one of the following options: (i) full payment of the vested Units in January of a year specified by you which shall be no earlier than the third calendar year following the calendar year in which the date of grant occurs and no later than the tenth calendar year following such year; (ii) full payment of the vested Units in January of the calendar year following the year in which you cease to be an Eligible Director (and experience a "separation from service" with the Company within the meaning of Code Section 409A) for any reason; (iii) payment of the vested Units in five substantially equal annual installments, commencing in January of the calendar year following the year in which you cease to be an Eligible Director (and experience a "separation from service" with the Company within the meaning of Code Section 409A) for any reason; or (iv) payment of the vested Units in ten substantially equal annual installments, commencing in January of the calendar year following the year in which you cease to be an Eligible Director (and experience a "separation from service" with the Company within the meaning of Code Section 409A) for any reason; *provided*, *however*, that no Shares shall be issued hereunder unless the Board determines that the consideration received by the Company in exchange for the issuance of Common Stock has a value not less than the par value thereof. Any deferral election made pursuant to this Section II shall specify the distribution schedule from the options provided in this Section II and shall be irrevocable.

III. Transferability. No benefit payable under, or interest in, this Agreement shall be subject in any manner to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or charge and any such attempted action shall be void and no such benefit or interest shall be, in any manner, liable for, or subject to, your or your beneficiary's debts, contracts, liabilities or torts; *provided*, *however*, nothing in this Section III shall prevent transfer (i) by will, (ii) by applicable laws of descent and distribution or (iii) to an Alternate Payee to the extent that a QDRO so provides, as further described in the Program.

IV. No Contract for Employment. This Agreement is not an employment or service contract and nothing in this Agreement shall be deemed to create in any way whatsoever any obligation on your part to continue in the employ or service of the Company or any Affiliate, or of the Company or any Affiliate to continue your employment or service with the Company or any Affiliate.

V. Notices. Any notices provided for in this Agreement, the Program or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at such address as is currently maintained in the Company's records or at such other address as you hereafter designate by written notice to the Company.

VI. Nature of Grant. In accepting the Units granted hereunder, you acknowledge that:

(a) the Program and Plan are established voluntarily by the Company, are discretionary in nature and may be modified, amended, suspended or terminated by the Company at any time;

(b) the grant of the Units is voluntary and occasional and does not create any contractual or other right to receive future grants of Units, or benefits in lieu of Units, even if Units have been granted repeatedly in the past;

(c) your participation in the Program and Plan is voluntary;

(d) all decisions with respect to future awards, if any, will be at the sole discretion of the Company;

(e) the future value of the underlying Shares is unknown and cannot be predicted with certainty; and

(f) the Units and the benefits under the Program and Plan, if any, will not automatically transfer to another company in the case of a merger, takeover or transfer of liability.

VII. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Program and Plan, or your acquisition or sale of the underlying Shares. You are hereby advised to consult with your own personal tax, legal and financial advisors regarding your participation in the Program and Plan before taking any action related to the Program and Plan.

VIII. ***Data Privacy. You hereby explicitly and unambiguously consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this Agreement by and among, as applicable, the Company or its Affiliates for the exclusive purpose of implementing, administering and managing your participation in the Program and Plan.***

You understand that the Company or its Affiliates may hold certain personal information about you, including, without limitation, your name, home address and telephone number, date of birth, social insurance number (to the extent permitted under applicable local law) or other identification number, salary, nationality, job title, residency status, any shares of stock or directorships held in the Company, details of all equity compensation or any other entitlement to shares awarded, canceled, vested, unvested or outstanding in your favor, for the purpose of implementing, administering and managing the Program and Plan ("Data"). You understand that Data may be transferred to Merrill Lynch Bank & Trust Co., FSB (or any successor thereto) or any third parties assisting in the implementation, administration and management of the Program and Plan, that these recipients may be located in your country or elsewhere including outside the European Economic Area, and that the recipient's country (e.g., the United States) may have different data privacy laws and protections than your country. You understand that you may request a list with the names and addresses of any potential recipients of the Data by contacting the Company. You authorize the Company, its Affiliates, Merrill Lynch Bank & Trust Co., FSB (or any successor thereto) and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering, and managing your participation in the Program and Plan to receive, possess, use, retain and transfer the Data, in electronic or other form, for the sole purposes of implementing, administering and managing your participation in the Program and Plan, including any requisite transfer of such Data as may be required to any other broker, escrow agent or other third party with whom the shares issued upon vesting of the Units may be deposited. You understand that Data will be held only as long as is necessary to implement, administer and manage your participation in the Program and Plan. You understand that you may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing the Company. You understand that refusal or withdrawal of consent may affect your ability to participate in the Program and Plan. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact the Company.

IX. Language. If you have received this Agreement or any other document related to the Program and Plan translated into a language other than English and if the meaning of the translated version differs from the English version, the English version shall control.

X. Electronic Delivery. The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Program and Plan by electronic means. You hereby consent to receive such documents by electronic delivery and agree to participate in the Program and Plan through an online or electronic system established and maintained by the Company or a third party designated by the Company.

XI. Severability. The provisions of this Agreement are severable and if any one or more are determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

XII Plan and Program. This Agreement is subject to all the provisions of the Plan and Program and their provisions are hereby made a part of this Agreement, including without limitation the provisions of Section 9.5 of the Plan relating to Restricted Stock Units, and is further subject to all interpretations, amendments, rules and regulations which may from time to

time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of this Agreement and those of the Plan and the Program, the provisions of the Plan and the Program shall control.

XIII. Governing Law. This Agreement shall be construed and interpreted, and the rights of the parties shall be determined, in accordance with the laws of the State of Delaware, without regard to conflicts of law provisions thereof. For purposes of litigating any dispute that arises hereunder, the parties hereby submit to and consent to the jurisdiction of the State of Delaware, or the federal courts for the United States for the federal district located in the State of Delaware, and no other courts, where this Agreement is made and/or to be performed.

XIV. Appendix. Notwithstanding any provisions in this Agreement, Units shall be subject to any special terms and conditions set forth in any Appendix to this Agreement for your country. Moreover, if you relocate to one of the countries included in the Appendix, the special terms and conditions for such country will apply to you, to the extent the Company determines that the application of such terms and conditions is necessary or advisable in order to comply with local law or facilitate the administration of the Program and Plan. The Appendix constitutes part of this Agreement.

XV. Imposition of Other Requirements. The Company reserves the right to impose other requirements on your participation in the Plan, on the Units and on any Shares acquired under the Program and Plan, to the extent the Company determines it is necessary or advisable in order to comply with local law or facilitate the administration of the Program and Plan, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

Very truly yours,
AMGEN INC.

By: _____
Name:
Title:

Accepted and Agreed,
this ___ day of _____, 201_.

By: _____
Name:

APPENDIX A

ADDITIONAL TERMS AND CONDITIONS OF THE 2009 EQUITY INCENTIVE PLAN AND DIRECTOR EQUITY INCENTIVE PROGRAM

GRANT OF RESTRICTED STOCK UNITS (NON-U.S.)

TERMS AND CONDITIONS

This Appendix includes additional terms and conditions that govern any Units granted under the Program and Plan **if, under applicable law, you are a resident of, or are deemed to be a resident of one of the countries listed below. Furthermore, the additional terms and conditions that govern any Units granted hereunder may apply to you if you relocate to one of the countries listed below**. Certain capitalized terms used but not defined in this Appendix A shall have the meanings set forth in the Program, the Plan and/or the Agreement to which this Appendix is attached.

NOTIFICATIONS

This Appendix also includes notifications relating to exchange control and other issues of which you should be aware with respect to your participation in the Program and Plan. The information is based on the exchange control, securities and other laws in effect in the countries to which this Appendix refers as of February 1, 2009. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the notifications herein as the only source of information relating to the consequences of your participation in the Program and Plan because the information may be outdated when you vest in the Units and acquire Shares under the Program and Plan, or when you subsequently sell Shares acquired under the Program and Plan.

In addition, the notifications are general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of any particular result. Accordingly, you are advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your situation. Finally, if you are a citizen or resident of a country other than the one in which you are currently working, the information contained herein may not be applicable to you or you may be subject to the provisions of one or more jurisdictions.

BELGIUM

NOTIFICATIONS

Tax Reporting Notification. You are required to report any taxable income attributable to the Units granted hereunder on your annual tax return. You are also required to report any bank accounts opened and maintained outside Belgium on your annual tax return.

FRANCE

TERMS AND CONDITIONS

Language Consent. By accepting the grant of Units and this Agreement which provides for the terms and conditions of your Units, you confirm having read and understood the documents relating to this grant (the Plan, the Program and this Agreement), which were provided to you in English. You accept the terms of those documents accordingly.

En acceptant cette attribution gratuite d'actions et ce contrat qui contient les termes et conditions de vos actions gratuites, vous confirmez avoir lu et compris les documents relatifs à cette attribution (le Plan, le Programme et ce contrat), qui vous ont été transmis en langue anglaise. Vous acceptez ainsi les conditions et termes de ces documents.

NOTIFICATIONS

Exchange Control Notification. If you retain Shares outside of France or maintain a foreign bank account, you are required to report such to the French tax authorities when filing your annual tax return.

Exhibit 10.17

FIRST AMENDMENT TO THE
AMGEN INC. EXECUTIVE INCENTIVE PLAN
(AMENDED AND RESTATED EFFECTIVE JANUARY 1, 2009)

The Amgen Inc. Executive Incentive Plan (As Amended and Restated, Effective January 1, 2009) (the "Plan") is hereby amended, effective December 13, 2012, as follows:

The following paragraph shall be inserted immediately following the second paragraph in Section VI:

> If a Participant engaged in misconduct that caused serious financial or reputational damage to the Company during any performance period, including a previous performance period, the Compensation Committee may determine that an award has not been earned or may consider such conduct when determining the amount of any award. This provision is in no way intended to limit any other action that the Company could take against a Participant (including other disciplinary actions (up to termination), ordinary course performance considerations, disclosure of wrongdoing to the government and pursuit of any other legal claims against such Participant).

To record this First Amendment to the Plan as set forth herein, effective December 13, 2012, Amgen Inc. has caused its authorized officer to execute this document this 7th day of January, 2013.

AMGEN INC.

By: /s/ Brian McNamee

Brian McNamee
Senior Vice President
Human Resources

AMENDMENT NO. 1
TO THE
LICENSE AGREEMENT

This **Amendment No. 1 to the License Agreement** (this "***Amendment***"), dated as of June 25, 2010 (the "Amendment Effective Date"), is made by and between **Amgen Inc.**, a Delaware corporation having an address of One Amgen Center Drive, Thousand Oaks, California 91320-1799 ("***Amgen***"), and **Takeda Pharmaceutical company Limited,** a Japanese corporation having an address of 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645 ("***Licensee***").

WHEREAS, Amgen and Licensee entered into that certain License Agreement (multi-product), dated as of February 1, 2008, as amended/supplemented to date (the "***Agreement***"), pursuant to which the Parties entered into a licensing arrangement for the development and commercialization of Licensed Products (as that term is defined in the Agreement); and

WHEREAS, Amgen and Licensee wish to amend the Agreement to, among other things, set forth the terms and conditions for Licensee's participation in Amgen's Global Study (as defined below).

NOW, THEREFORE, in consideration of the mutual promises and covenants hereinafter set forth, the Parties hereto agree to amend the Agreement as follows:

ARTICLE 1 - AMENDMENT

Capitalized terms used in this Amendment and not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

1.1 Amendment of Article 1 (Definitions). The following definitions are added to Article 1, in the appropriate alphabetical order:

"Clinical Supply Schedule" shall mean that certain Clinical Supply Schedule attached as an exhibit to the Agreement.

"Global Study" shall have the meaning set forth in Section 4.6.1.

"Global Study SOPs" shall have the meaning set forth in Section 4.6.1.5.

"Global Support Services Costs" shall have the meaning set forth in Section 8.20.2.

"Japan Enrollment Percentage" shall have the meaning set forth in Section 8.20.2.1

"Licensee External Costs Share" shall have the meaning set forth in Section 8.20.2.1.

"Safety Agreement" shall mean that certain Amended and Restated Safety Agreement (multi-products) by and between Amgen and Licensee, effective as of June 30, 2009 (Amgen Contract # XXXXXXXXX-XXX).

1.2 Amendment of Section 1.7. (Amgen Development Data). Section 1.7 (Amgen Development Data) shall be deleted in its entirety and replaced with the following:

"1.7 "*Amgen Development Data*" shall mean the preclinical and clinical data generated by or on the behalf of Amgen or its Affiliates (both within and outside the Territory) in the course of its preclinical and clinical development of a Licensed Product, both before and after the Effective Date of this Agreement. Amgen Development Data shall also include any such data generated by or on behalf of Amgen or its Affiliates in connection with a Global Study."

1.3 Amendment of Section 1.56 (Licensee Development Data). Section 1.56 (Licensee Development Data) shall be deleted in its entirety and replaced with the following:

"1.56 *"Licensee Development Data"* shall mean the preclinical and clinical data generated by or on behalf of Licensee or its Affiliates in the course of its preclinical (if any) and clinical development of a Licensed Product, on or after the

Effective Date of this Agreement. Licensee Development Data shall also include any such data generated by or on behalf of Licensee or its Affiliates within the Territory, in connection with a Global Study."

1.4 Addition of Section 2.9.5. The following Section 2.9.5 shall be added immediately following Section 2.9.4 of the Agreement.

"Section 2.9.5. *Decision Making Regarding Global Study Matters*. Notwithstanding Section 2.9.4 (Decision Making) of this Agreement, Amgen has final decision-making authority for matters set forth in Sections 4.6.1.1 (Decision Making Regarding Licensee's Participation), 4.6.1.3 (Closing of Global Study) and 4.6.1.4 (Global Study Design). Amgen, in making its decision regarding the matters set forth in Sections 4.6.1.1 (Decision Making Regarding Licensee's Participation), 4.6.1.3 (Closing of Global Study) and 4.6.1.4 (Global Study Design), will take into account whether a particular request of Licensee would adversely affect Amgen's development or commercialization of the relevant Licensed Product outside the Territory as one among other considerations. As an example, in deciding whether to close a Global Study, Amgen will take into account whether Licensee's request to continue the Global Study would have an adverse effect on Amgen's development or commercialization of the Licensed Product outside the Territory. The Parties acknowledge that Amgen, in reaching its decision, has the right to determine, in its sole discretion, that other considerations outweigh any particular request of Licensee. With respect to all other decisions pertaining to a Global Study, each Development Committee shall strive to reach consensus, taking into account the views of each committee member. In the event the committee fails to reach consensus, the committee members appointed by Amgen shall make the final determination."

1.5 Amendment of Section 4.6 The first two (2) sentences of Section 4.6 of the Agreement shall be deleted in their entirety, and the following subsection shall be added to Section 4.6 of the Agreement:

"4.6.1 *Terms and Conditions for Global Study Participation*. The Parties acknowledge that it may be in their mutual interests to integrate Licensee's development of a Licensed Product within the Territory into Amgen's global development plan for such Licensed Product for a particular Licensee Indication. The Parties agree that any participation by Licensee in Amgen's global registration studies for a Licensed Product for a particular Licensee Indication (each such study that Licensee participates in shall be referred to herein as a "Global Study") shall be in accordance with the following terms and conditions, which terms and conditions shall apply to each Global Study.

4.6.1.1 *Decision Making Regarding Licensee's Participation*. Subject to Section 2.9.5 (Decision Making Regarding Global Study Matters), the Development Committee shall discuss whether it would be appropriate and feasible for Licensee to participate in a Global Study; provided however, such determination shall be made by Amgen in its sole discretion, on a Global Study-by-Global Study and Licensed Product-by-Licensed Product basis.

4.6.1.2 *Initiation of Global Study*. Licensee shall complete all necessary clinical trials and non-clinical studies required by the Governmental Authority in the Territory for a particular Licensed Product before participating in any Global Study. Licensee shall meet Amgen's timing requirements for initiation of the Global Study in the Territory; provided, however, that Licensee may elect to commence enrollment of patients in clinical sites in the Territory for a given Global Study, subsequent to Amgen's initiation of the Global Study outside the Territory, so long as Amgen's ability to close the Global Study is not affected. Upon Initiation of a Global Study, Amgen shall provide Licensee with regular (at least quarterly) updates on Global Study enrollment status.

4.6.1.3 *Closing of Global Study*. Subject to Section 2.9.5 (Decision Making Regarding Global Study Matters), Amgen shall have the right to close a given Global Study even if Licensee has not fully enrolled its patients in the Territory for such Global Study, upon fourteen (14) days prior written notice to Licensee (or such shorter time where exigent circumstances make such fourteen (14) day notice impractical).

4.6.1.4 *Global Study Design*. Notwithstanding Section 4.1 (Responsibility for Development in Licensee Indications) of this Agreement, with respect to a given Global Study, Licensee shall follow Amgen's Global Study design for the Global Study. In the course of developing the Global Study design, Amgen shall (A) discuss in good faith with Licensee (via the Development Committee) specifics of the Global Study design; and (B) subject to Section 2.9.5 (Decision Making Regarding Global Study Matters), consider in good faith specific study design requests of Licensee based on Regulatory Approval requirements of the Governmental Authority in the Territory (including without limitation Territory-specific regulatory requirements, standard of care differences, inclusion/exclusion criteria and the availability and sourcing of non-Amgen comparator and/or co-medication products used in the Global Study); provided however, that (i) any request of Licensee cannot

adversely impact the Global Study design outside the Territory or increase the cost of or time to complete the Global Study; and (ii) Amgen shall make the final determination as to the overall study design for the Global Study pursuant to Section 2.9.5 (Decision Making Regarding Global Study Matters).

4.6.1.5 *Standard Operating Procedures***.** Licensee shall utilize Amgen's Standard Operating Procedures for the Global Study ("Global Study SOPs") as well as Amgen's clinical trial and data management systems, to the extent legally permissible under the applicable regulations in the Territory. In addition, any local vendors or contract laboratories engaged by Licensee for the Global Study in the Territory shall be qualified in accordance with the applicable Global Study SOPs. Upon Amgen's request, Licensee shall provide English-translated copies of Licensee's internal standard operating procedures and/or business practices used to supplement the Global Study SOPs in support of the conduct of the Global Study in the Territory. As soon as reasonably practicable, the Parties shall also discuss the management of information flow between Licensee and Amgen for the Global Study, as well as the handling of deviations from Global Study SOPs.

4.6.1.6 *Audit*. Upon reasonable notice (which shall be no less than ten (10) business days prior written notice) and during regular business hours, Amgen shall have the right to audit (i) Licensee's compliance with the Global Study SOPs; (ii) participating Global Study clinical sites in the Territory (which clinical site audits shall be conducted in cooperation with Licensee); and (iii) Functional Service Providers (defined in Section 4.6.1.11 below). External costs incurred by Amgen for such audits shall be reimbursed by Licensee in accordance with Section 8.20.1 (Global Study Costs in the Territory) of the Agreement.

4.6.1.7 *Branding and Publications*. Licensee will not be listed as a co-sponsor of a Global Study in any Global Study protocol, document or publications arising from the conduct of such Global Study outside the Territory; provided, however, that Amgen will provide an acknowledgment in connection with the clinical sites in the Territory (and any data and results arising therefrom), that Licensee is responsible for the development of the applicable Licensed Product in the Territory. Notwithstanding Sections 4.1 (Responsibility for Development in Licensee Indications), 4.12.1 (Communications-Licensee Responsibility) and 10.7 (Publications) of this Agreement, with respect to a given Global Study, Amgen shall control all disclosures of Global Study data and results, including disclosures to any Governmental Authority outside the Territory responsible for Regulatory Approvals of the applicable Licensed Product, clinical trial investigator or key opinion leader, subject to the applicable safety reporting requirements; provided that Licensee and Amgen shall duly coordinate disclosures of any Global Study data and results to any Governmental Authority responsible for Regulatory Approvals of the applicable Licensed Product in the Territory. For the avoidance of doubt, nothing in this Section 4.6.1.7 shall affect Licensee's rights under Section 4.1 (a) of the Agreement to file and seek Regulatory Approval for Licensed Products in the Territory for a particular Licensee Indication, as applicable, in the name of Licensee from the relevant Governmental Authority; provided that Licensee complies with the terms and conditions of Sections 4.7 (Sharing of Regulatory Filings) and 4.12.1 (Communications-Licensee Responsibility) of the Agreement. Licensee shall have the right to publish data and results arising from Global Study clinical sites in the Territory in publications based in the Territory at any time subsequent to Amgen's publication of corresponding Global Study data and results outside the Territory. If Takeda proposes to publish data and results arising from clinical sites in the Territory for the Global Study in publications based in the Territory, simultaneously with Amgen's disclosure of any Global Study data and results outside the Territory, such publications by Takeda shall be made in accordance with Section 10.7 (Publications) of the Agreement.

4.6.1.8 *Global Study Data*. Subject to the limitations set forth in Section 4.6.1.7 (Branding and Publications), the Parties shall, without any additional payment to the other Party (other than payments required to be made under this Agreement), provide and license to each other Licensed Amgen Know-How or Licensed Licensee Know-How generated pursuant to the conduct of a Global Study, as the case may be, and any Licensed Amgen Patents or Licensed Licensee Patents (as the case may be) arising therefrom, in accordance with Article 3 (Grant of License) of this Agreement.

4.6.1.9 *Biomarker and Pharmacogenetics Samples*. Notwithstanding anything to the contrary in this Agreement, Amgen shall own all right, title and interest in and to the biomarker and pharmacogenetics samples collected from patients enrolled in the Global Study (both within and outside the Territory), and all data, inventions and the like, arising out of such samples; provided, however, that any pre-clinical or clinical data related to Licensed Products for the Licensee Indications generated by or on behalf of Amgen or its Affiliates and arising from the use or analysis of such samples, shall be deemed Amgen Development Data. In accordance with Section 8.20.2.1 (External Global Support Services Costs) of this Agreement, Licensee shall pay its Licensee External Costs Share for services pertaining to biomarker and pharmacogenetics samples and analyses related thereto for

a Global Study through receipt of final vendor invoice for such services. After the resulting "true-up" adjustment, Amgen will bear the subsequent long-term storage costs associated with such Global Study biomarker and pharmacogenetics samples.

4.6.1.10 *Establishment of a Joint Work Plan*. As soon as reasonably practicable, Licensee and Amgen shall work together to establish a joint work plan and communication plan for the Global Study, including preparation of CRFs (Case Report Forms), DMPs (Data Management Plans) and applicable procedures for monitoring Global Study clinical sites in the Territory, global safety reporting harmonization, operational issues, audits, statistical analysis, and agreed-upon Territory-specific study requirements. At Licensee's request, Amgen shall promptly provide to Licensee data and information reasonably necessary for Licensee's initiation of the Global Study in the Territory.

4.6.1.11 *Approval of Clinical Sites, Global Study Vendors and Laboratories*. Notwithstanding Section 4.1 (Responsibility for Development in Licensee Indications) of this Agreement, Amgen shall (i) approve all clinical sites in the Territory for the Global Study; and (ii) select, qualify and approve all global vendors and contract laboratories outside the Territory used in connection with each Global Study. Licensee shall be required to use functional service providers for any Global Study's data management and clinical monitoring in the Territory (such providers shall be referred to herein as "Functional Service Providers"). Amgen approves Licensee's use of Quintiles Japan (i.e., Quintiles Transnational Japan KK) as a Functional Service Provider for the AMG 386 Global Study.

4.6.1.12 *Safety Agreement*. Amgen and Licensee shall discuss and agree on any modifications to the Safety Agreement necessary to accommodate additional safety reporting requirements resulting from Licensee's participation in any Global Study.

4.6.1.13 *Clinical Drug and Inventory Management*. Licensee shall follow Amgen's defined processes and systems for distribution of clinical drug and inventory management.

1.6 Addition of Section 8.20 The following Section 8.20 shall be added immediately following Section 8.19 of the Agreement:

"8.20. Global Study Costs.

8.20.1 *Global Study Costs in the Territory*. Licensee shall be solely responsible for all costs (both internal and external) incurred by Licensee, related to a Global Study in the Territory. In the event Amgen incurs any external costs related to the Global Study in the Territory, which costs are incurred by Amgen because of the inclusion of clinical sites in the Territory, Licensee shall reimburse Amgen for such costs on a quarterly basis in accordance with Sections 8.11 (Cost Reimbursement) and 8.12 (Payment Method) of this Agreement. Examples of reimbursable costs incurred by Amgen include the training of Licensee personnel and contractors, audit of participating clinical sites in the Territory and conduct of additional CDM (Clinical Data Management)/biostatistics activities such as sub-population analysis (at Licensee's request). For the avoidance of doubt, such reimbursed external costs related to a Global Study in the Territory shall not be included in Amgen Development Costs. Drug supply costs for a Global Study in the Territory shall be governed by the terms and conditions of the Clinical Supply Schedule (attached as an exhibit to the Agreement).

8.20.2 *Global Support Services Costs***.** Licensee shall pay for support services for a Global Study, including costs related to bio-analysis for the measurement and testing of PK (pharmacokinetics), auto-antibodies and biomarkers by using plasma or serum samples, central patient registration system, data management, biostatistics, clinical chemistry, central laboratory, drug safety monitoring board and KOL (key opinion leader) meetings (collectively referred to as "Global Support Services Costs") as more particularly described below:

8.20.2.1 *External Global Support Services Costs*. Licensee shall pay to Amgen, on a quarterly basis, a pro-rata share (based on the percent of Japanese patient population planned enrollment for a given Global Study (the "Japan Enrollment Percentage")) of accrued external Global Support Services Costs (such pro-rata share, the "Licensee External Costs Share"). For purposes of this Section 8.20.2.1, if the calculated Japan Enrollment Percentage is less than ten percent (10%) for a given Global Study, the Japan Enrollment Percentage is deemed to equal ten percent (10%) for such Global Study. Once the enrollment period for a given Global Study has closed, a one-time "true-up" adjustment shall be made to the Licensee External Costs Share, to the extent that the percentage of Japanese patients actually enrolled in a given Global Study differs from the Japan Enrollment Percentage. After Amgen has received the final invoice from all vendors for Global Support Services Costs for a Global Study, a one-time "true-up" adjustment shall be made to the

Licensee External Costs Share paid by Licensee to reconcile any differences between payments made by Licensee based on the accrual of costs and the actual amounts paid by Amgen with respect to such Global Support Services Costs.

8.20.2.2 *Internal (Amgen FTE) Global Support Services Costs*. To reimburse Amgen for its internal FTE component of the Global Support Services Costs, Licensee shall pay to Amgen, on a quarterly basis, for one and a half (1.5) Amgen FTEs per year at the FTE Rate, for the duration of the Global Study. Such FTE payments shall be made by Licensee commencing upon the date that Amgen provides Licensee with a study concept document for a Global Study (e.g., August 5, 2009 for AMG 386 phase 3 study (ovarian cancer)), and shall continue through submission of Licensee's Regulatory Filing in the Territory for Regulatory Approval of a Licensed Product for the applicable Licensee Indication. After one (1) year from the Initiation of the first Global Study in which Licensee participates, the Parties shall reassess in good faith whether such Amgen FTE number is appropriate. Amgen shall provide Licensee with a written summary of its Global Study support activities, arranged by clinical trial stage (e.g., study initiation, analysis and reporting, filing) and functional area, for the one (1) year period referenced above. Additionally, in the event the scope of activities necessary to support Licensee's participation in a future Global Study materially changes from the scope of activities for the first Global Study in which Licensee participates, then for that particular Global Study only, the Parties shall reassess in good faith the Amgen FTE number for such Global Study. The Parties agree that the number of Amgen FTEs applicable to a Global Study in which Licensee participates (i.e., one and a half (1.5) FTEs) cannot be increased or decreased without the mutual written agreement of the Parties, and such increase or decrease cannot be applied retroactively to any prior Global Study.

8.20.2.3 *Reports; Payment of Global Support Services Costs*. Amgen shall provide Licensee with reports for Licensee External Costs Share and Amgen FTE Global Support Services Costs in accordance with Section 8.9.5 (Reports) of this Agreement. Licensee shall pay the foregoing Licensee External Costs Share and Amgen FTE Global Support Services Costs in addition to any Development Costs Payments made pursuant to Section 8.9 (Development Cost Sharing) of this Agreement and regardless of whether Licensee has satisfied the Annual Maximums and Quarterly Maximums set forth herein; provided that such Licensee External Costs Share and Amgen FTE Global Support Services Costs paid to Amgen by Licensee shall not be included in Amgen Development Costs."

1.7 Not Applicable to AMG 403 Program, etc. The Parties acknowledge and agree that this Amendment, and the terms and conditions set forth herein, shall not apply to, and shall have no force or effect with respect to, the AMG 403 program, as well as any Amgen's global registration study for a Licensed Product for a particular Licensee Indication in which Licensee does not participate.

ARTICLE 2 - REFERENCE TO AND EFFECT ON THE AGREEMENT

2.1 **Reference to Agreement.** Upon and after the effectiveness of this Amendment, each reference in the Agreement to "this Agreement", "hereunder", "hereof" or words of like import referring to the Agreement shall mean and be a reference to the Agreement as modified and amended hereby.

2.2 **Effectiveness of Amendment.** Upon execution and delivery of this Amendment by both Parties, the amendments set forth above shall be effective as of the Amendment Effective Date. Except as specifically amended above, the Agreement is and shall continue to be in full force and effect and is hereby in all respects ratified and confirmed and shall constitute the legal, valid, binding and enforceable obligations of the Parties.

2.3 **No Waiver.** The execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of either Party under the Agreement, nor constitute a waiver of any provision of the Agreement.

ARTICLE 3 - MISCELLANEOUS

3.1 **Governing Law.** This Amendment shall be governed by and construed in accordance with the laws of the State of California, as applied to agreements executed and performed entirely within the State of California, without regard to any applicable principles of conflicts of law. Each of the Parties hereby irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of California and of the United States of America located in the State of California for any matter arising out of or relating to this Amendment and the transactions contemplated hereby.

3.2 **Headings.** The heading for each article and section in this Amendment has been inserted for convenience of reference only and is not intended to limit or expand on the meaning of the language contained in the particular article or section.

3.3 **Counterparts.** This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS THEREOF, duly authorized representatives of the Parties hereto have executed this Amendment as of the date first set forth above.

Takeda Pharmaceutical Company Limited

By: /s/ Masato Iwasaki
Name: Masato Iwasaki
Title: Corporate Officer,
Senior Vice President
Strategic Product Planning Department

Amgen Inc.

By: /s/ George W. Williams
Name: George W. Williams
Title: Vice President,
Global Biomedical Data Sciences

AMENDMENT NO. 2
TO THE
LICENSE AGREEMENT

This **Amendment No. 2 to the License Agreement** (this "***Amendment***"), dated as of June 29, 2012 (the "***Amendment Effective Date***"), is made by and between **Amgen Inc.**, a Delaware corporation having an address of One Amgen Center Drive, Thousand Oaks, California 91320-1799 ("***Amgen***"), and **Takeda Pharmaceutical company Limited,** a Japanese corporation having an address of 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645 ("***Licensee***").

WHEREAS, Amgen and Licensee entered into that certain License Agreement (multi-product), dated as of February 1, 2008, as amended by Amendment No. 1 dated June 25, 2010 (the "***Agreement***"), pursuant to which the Parties entered into a licensing arrangement for the development and commercialization by Licensee in the Territory of Licensed Products (as that term is defined in the Agreement);

WHEREAS, at the beginning of the Collaboration the Steering Committee delegated certain of its responsibilities to a subcommittee referred to as the "Management Committee" which provided oversight and coordination of the Collaboration and functioned as the Joint Project Team under the License Agreement dated as of February 1, 2008 between the Parties relating to AMG706 and terminated as of June 29, 2012; and

WHEREAS, Amgen and Licensee wish to amend the Agreement to, among other things, memorialize the establishment and role of the Management Committee under this Agreement and set forth the terms and conditions for certain audit rights of Licensee.

NOW, THEREFORE, in consideration of the mutual promises and covenants hereinafter set forth, the Parties hereto agree to amend the Agreement as follows:

ARTICLE 1 - AMENDMENT

Capitalized terms used in this Amendment and not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

1.1 Amendment of Section 2.3 (Governance). The first sentence of Section 2.3 (Governance) shall be deleted and replaced with the following: "The Collaboration shall be governed by (i) a Steering Committee, which shall oversee the activities of the Parties hereunder generally, (ii) a Management Committee, which shall oversee and coordinate the activities of the Parties hereunder, and (iii) a Development Committee and a Commercialization Committee for each Licensed Product, which shall manage the development and commercialization, respectively, of Licensed Products in the Territory. The Management Committee shall initially be comprised of the members set forth on the Management Committee Schedule."

1.2 Amendment of Section 2.4 (Membership). The first sentence of Section 2.4 (Membership) shall be deleted and replaced with the following: "Unless otherwise agreed by the Parties, each of the Development Committee and Commercialization Committee shall be comprised of three (3) members appointed by Amgen, and three (3) members appointed by Licensee, and the Management Committee shall be comprised of four (4) members appointed by Amgen, and four (4) members appointed by Licensee."

1.3 Addition of Section 2.11 (Management Committee). The following Section 2.11 (Management Committee) shall be added immediately following Section 2.10 (Commercialization Committee) of the Agreement:

"2.11 Management Committee. The Management Committee shall be responsible for overseeing and coordinating the overall plans of the Parties with respect to the Licensed Products and ensuring an appropriate level of communication between the Parties under this Agreement.

2.11.1 *Meetings.* The Management Committee shall meet quarterly in person, via teleconference or videoconference or otherwise (with at least two (2) meetings per Calendar Year being in person), or as otherwise agreed by the Parties. Any in-person meetings shall be held on an alternating basis between Licensee's and Amgen's facilities, unless otherwise agreed by the Parties. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend Management Committee meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings as reasonably required to resolve particular matters

requested by such Party by at least five (5) business days written notice to the co-chair appointed by the other Party. All Management Committee meetings must have at least one (1) member appointed by each Party in attendance.

2.11.2. *Reporting.* Each Party, through the members appointed by it on the Development Committee and the Commercialization Committee, shall keep the Management Committee fully and promptly informed of progress and results of activities for which each such committee is responsible and with respect to all relevant facts and activities reasonably requested by any member thereof regarding any Licensed Product.

2.11.3 *Decision Making.* The Management Committee shall make decisions by consensus. In the event the Management Committee fails to reach consensus, and the Management Committee determines that it is appropriate to do so, such matter shall be escalated to the Steering Committee for resolution."

1.4 Amendment of Section 8.13 (Audits). Section 8.13 (Audits) shall be deleted in its entirety and replaced with the following:

"8.13 Audits. Licensee shall keep complete and accurate records pertaining to the sale of the Licensed Products in the Territory in sufficient detail to permit Amgen to confirm the accuracy of all payments due hereunder. Amgen shall keep complete and accurate records pertaining to Amgen Development Costs of Licensed Products in sufficient detail to permit Licensee to reasonably confirm the accuracy of all payments due hereunder with respect to Licensee's obligation to reimburse Amgen for Licensee's share of Amgen Development Costs, other than with respect to clinical drug substance and drug product supply of Licensed Products, pursuant to Section 8.9 (Development Cost Sharing). Such records of Licensee and Amgen shall be open (in such form as may be available or reasonably requested by a certified public accountant in accordance with this Section 8.13(Audits)) to inspection for five (5) years following the end of the period to which they pertain; provided, however, such records of Amgen shall only be available with respect to Amgen Development Costs incurred by or on behalf of Amgen on a going forward basis from April 1, 2012. Each Party shall have the right, at its own expense, to have an independent, certified public accountant, selected by it to review the records of the other Party upon reasonable notice and during regular business hours. The final report of such accountant shall be made available to both Parties within two (2) Calendar Quarters of the audit fieldwork having been completed unless otherwise mutually agreed by the Parties; provided, however, that the Party being audited shall have the right to review and comment on the final draft version of the report prior to it being finalized. Such review and comment period shall extend for four (4) weeks after the audited Party's receipt of such draft report. Each Party's audit rights with respect to any Calendar Year shall expire five (5) years after the end of such year and the books and records for any particular Calendar Year shall only be subject to one (1) audit. During any Calendar Year period, each Party's books and records for any particular Calendar Year shall only be subject to audit by the other Party with respect to up to two Licensed Products. Should the inspection lead to the discovery of a discrepancy to the auditing Party's detriment, then the other Party shall pay to the auditing Party the amount of the discrepancy plus interest accrued at the Contract Interest Rate, compounded daily from the day the relevant payment(s) were due. Should the inspection lead to the discovery of a discrepancy to the detriment of the Party being audited, then the auditing Party shall pay to the other Party the amount of the discrepancy without interest. The auditing Party shall pay the full cost of the inspection unless the discrepancy is to the detriment of the auditing Party and is greater than five percent (5%) of the amount actually paid for the audited period, in which case the Party being audited shall pay the cost of such inspection. Notwithstanding the foregoing, Licensee shall have no right to audit Amgen's records under this Section 8.13 (Audits) unless Licensee has timely paid all invoices then due under this Agreement (or timely paid any undisputed portion and escrowed any disputed portion thereof, with a resolution of such dispute within twelve (12) months thereafter)."

1.5 Amendment of Section 14.2.5 (Product Suspension or Product Termination). Section 14.2.5 (Product Suspension or Product Termination) shall be deleted in its entirety and replaced with the following:

"14.2.5 *Product Suspension or Product Termination*. If a Product Suspension or Product Termination occurs for a Licensed Product outside the Territory, Amgen shall promptly notify Licensee and, at either Party's request, the Parties shall discuss such Product Suspension or Product Termination at the Development Committee or Commercialization Committee, as appropriate, and thereafter, at either Party's request, at the Management Committee.

14.2.5.1 *Product Suspension.* In the event a Product Suspension occurs for a Licensed Product outside the Territory, and in light of the cause of such Product Suspension it would not be reasonable for Licensee to continue development and commercialization of such Licensed Product in the Territory, then Licensee shall have the right to (i) suspend its efforts to develop and commercialize that particular Licensed Product in the Territory until such time as Amgen, its Affiliate, and/or a licensee resumes efforts to develop or commercialize such Licensed Product outside the Territory, and all provisions relating to Distracting Programs under this Agreement shall

still apply with respect to such suspended Licensed Product; or (ii) terminate this Agreement with respect to such Licensed Product pursuant to Section 14.2.5.2 (Product Termination) below.

14.2.5.2 *Product Termination.* In the event a Product Termination occurs for a Licensed Product outside the Territory, and in light of the cause of such Product Termination, it would not be reasonable for Licensee to continue development and commercialization of such Licensed Product in the Territory, or if a Product Suspension occurs under Section 14.2.5.1 then, in each case, Licensee shall have the right to terminate this Agreement with respect to such Licensed Product, upon thirty (30) days' prior written notice to Amgen (provided, however, that during such thirty (30) day period and such time as is reasonably necessary thereafter, Licensee shall provide any cooperation reasonably requested by Amgen to transition ongoing activities, and Amgen shall reimburse all reasonable, documented, out-of-pocket expenses incurred by Licensee in connection with the provision of such cooperation).

14.2.5.3 *Certain Product Suspensions and Product Terminations.* Notwithstanding the foregoing, Licensee shall not have the right to suspend its efforts or terminate this Agreement under this Section 14.2.5 (Product Suspension or Product Termination) if the reason for the Product Suspension or Product Termination, as the case may be, is specific to markets or jurisdictions outside the Territory and does not materially apply to the development or commercialization in the Territory. The reason for the Product Suspension or Product Termination will be discussed at the JDC. In the event the JDC fails to reach consensus as to whether the reason for the Product Suspension or Product Termination materially applies to the development or commercialization in the Territory, the committee members appointed by Licensee shall make the final determination."

1.6 Addition of Section 14.3.3 (Terminations by Licensee for Amgen Product Termination). The following Section 14.3.3 (Terminations by Licensee for Amgen Product Termination) shall be added immediately following Section 14.3.2 (Development Cost Share):

"14.3.3 *Terminations by Licensee for Amgen Product Termination.* For clarity, in the event Licensee terminates this Agreement with respect to a Licensed Product pursuant to Section 14.2.5.2 (Product Termination), then the following provisions relating to Distracting Programs shall not survive the Termination Date with respect to such Licensed Product: Sections 3.9 (Right of First Discussion), 6.4 (Activities Outside the Collaboration), 6.5 (Post-Effective Date Affiliates), 6.6 (Termination or Divestiture), 10.3.1 (Ex-Territory Distracting Program), 10.3.2 (Ex-Territory Distracting Transaction), 10.3.3 (Protection of Amgen Information) from the words ", and the Parties shall promptly meet to agree…" through the end of the section, and the penultimate sentence of Section 15.1 (Change of Control)."

1.7 Addition of Management Committee Schedule. Exhibit A hereto shall be attached to the Agreement as a new Management Committee Schedule.

1.8 Licensee's Input into Global Development Strategy.

1.8.1 *Development Committee*. The Parties shall hold an ad hoc Development Committee meeting in Thousand Oaks, California as soon as reasonably practicable following the Amendment Effective Date to discuss and establish processes and procedures to enable Licensee to provide input into Amgen's global development for Licensed Products (including the studies comprising such development) and the annual budget relating thereto, and ensure that Amgen considers such input in good faith (provided, however, that, subject to Section 1.8.2 (Escalation) below, Amgen shall have final decision making authority with respect to such development decisions and further provided, however, where delay is impractical Amgen will have the right to make an interim decision pending such escalation).

1.8.2 *Escalation*. Licensee shall have the right to escalate to the Management Committee any development decision that Licensee (i) determines is reasonably likely to have a material adverse impact on the Development of the relevant Licensed Product in the Territory, or (ii) believes that Licensee's input has not been considered in good faith by the Development Committee in reaching a decision, by providing written notice within five (5) business days of having provided such input at a Development Committee meeting in accordance with the process to be agreed upon as set forth in Section 1.8.1 (Development Committee) above; provided, however, that Amgen shall have final decision making authority with respect to such development decisions after discussion has taken place at the Management Committee.

1.8.3 *Process*. The Parties agree to amend the Agreement to the extent necessary to align the provisions of this Agreement with the processes established by the Development Committee.

1.9 *Supply Terms*. Promptly following the Amendment Effective Date, the Parties shall meet and discuss in good faith whether to amend the rights and obligations of the Parties under this Agreement on a going forward basis with respect to the cost of clinical and commercial supply of Licensed Products in the Territory, which may or may not include audit rights of Licensee with respect to costs charged by Amgen for Licensee's supplies of drug substance and drug product for Licensed Products in the Territory, fixed cost supply obligations, royalty structure modifications or other terms and conditions as may be agreed to by the Parties. Any agreement between the Parties with respect to the foregoing shall be memorialized in writing and this Agreement amended accordingly.

ARTICLE 2 - REFERENCE TO AND EFFECT ON THE AGREEMENT

2.1 **Reference to Agreement.** Upon and after the effectiveness of this Amendment, each reference in the Agreement to "this Agreement", "hereunder", "hereof" or words of like import referring to the Agreement shall mean and be a reference to the Agreement as modified and amended hereby.

2.2 **Effectiveness of Amendment.** Upon execution and delivery of this Amendment by both Parties, the amendments set forth above shall be effective as of the Amendment Effective Date. Except as specifically amended above, the Agreement is and shall continue to be in full force and effect and is hereby in all respects ratified and confirmed and shall constitute the legal, valid, binding and enforceable obligations of the Parties.

2.3 **No Waiver.** The execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of either Party under the Agreement, nor constitute a waiver of any provision of the Agreement.

ARTICLE 3 MISCELLANEOUS

3.1 **Governing Law.** This Amendment shall be governed by and construed in accordance with the laws of the State of California, as applied to agreements executed and performed entirely within the State of California, without regard to any applicable principles of conflicts of law. Each of the Parties hereby irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of California and of the United States of America located in the State of California for any matter arising out of or relating to this Amendment and the transactions contemplated hereby.

3.2 **Headings.** The heading for each article and section in this Amendment has been inserted for convenience of reference only and is not intended to limit or expand on the meaning of the language contained in the particular article or section.

3.3 **Counterparts.** This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Signature page follows]

IN WITNESS THEREOF, duly authorized representatives of the Parties hereto have executed this Amendment as of the date first set forth above.

Amgen Inc.

By: /s/ Sean E. Harper
Name: Sean E. Harper
Title: Executive Vice President,
Research and Development

Takeda Pharmaceutical Company Limited

By: /s/ Masato Iwasaki
Name: Masato Iwasaki
Title: Member of the Board
Senior Vice President
Pharmaceutical Marketing Division
Takeda Pharmaceutical Company Ltd.

Exhibit A

Schedule

Management Committee

Amgen:

XXXX XXXXXXXXX (co-chair), SVP, GRAAS

XXXXXXXX XXXXXXXXXX, VP, Program Management, R&D Compliance and Strategy Operations

XXXX XXXX, VP, Operations (CMC)

XXXXXXX XXX, VP, Business Development

Takeda:

XXXXXXXX XXXXXXXX (co-chair), President, Takeda Bio

XXXXX XXXXXXXX, Chief Medical Officer, Millennium

XXXXXX XXXX, GM CMC Center, Takeda Pharma

XXXXXXXX XXXXXXXX, Director, Oncology Marketing, Takeda Pharma

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

COLLABORATION AND LICENCE AGREEMENT

Between

AMGEN INC.

and

CELLTECH R&D LIMITED

Re

BEER

BEER

COLLABORATION AND LICENCE AGREEMENT

I N DE X

COLLABORATION AND LICENCE AGREEMENT

This Collaboration and Licence Agreement (the "**Agreement**") is made and entered into the 10th day of May, 2002 (the "**Effective Date**") by and between:

AMGEN INC., a corporation organised and existing under the laws of the State of Delaware, USA and having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799 USA ("**Amgen**"), and

CELLTECH R & D LIMITED, a company organised and existing under the laws of England and having its principal office at 208 Bath Road, Slough, Berkshire SL1 3WE, England ("**Celltech**").

RECITALS

WHEREAS,

A. Celltech and Amgen are biopharmaceutical companies with an ongoing interest in the research, development, manufacture and commercialisation of pharmaceutical products for the treatment of human diseases.

B. Celltech and/or its Affiliates have developed certain intellectual property rights, technology, know-how and expertise which relate to BEER, the modulation of which may be useful in the treatment of the Osteoporosis Indication and Other Indications (all terms used in these recitals as defined in Article 1), and which may be useful in Developing and exploiting of BEER technology and know-how and Antibody Products.

C. Amgen has reviewed and evaluated the technology, know-how and intellectual property rights relating to Celltech's BEER programme supplied by Celltech under terms of confidentiality and limited use and Amgen now wishes to collaborate with Celltech regarding using BEER technology, intellectual property rights and know-how in the further Research, Development and Commercialisation of Antibody Products.

D. Amgen and/or its Affiliates have certain technology, know-how and expertise which may be useful in Developing and exploiting of BEER technology and know-how and Antibody Products, and Celltech now wishes to collaborate with Amgen regarding using BEER technology and know-how in the further Research, Development and Commercialisation of Antibody Products.

E. The Parties believe it to be in their mutual interest and in the interest of the public to grant each other such intellectual property licences and other rights as are necessary to continue the research and development begun by Celltech so as to Commercialise Antibody Products resulting from the aforesaid Research and Development.

NOW, **THEREFORE**, Celltech and Amgen, intending to be legally bound, hereby agree as follows:

ARTICLE 1

DEFINITIONS

When used in this Agreement, each of the following terms shall have the meanings set forth in this Article 1:

"Affiliate" means any corporation, company, partnership, joint venture and/or firm which controls, is controlled by, or is under common control with a Party. For purposes of this definition, "control" shall be presumed to exist if one 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 organised 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.

"Amgen Initial Countries" means the United States, Canada, Mexico and Japan.

"[*] **Know-How"** means, other than [*] Know-How and [*] Know-How, all Information and Materials which are [*] for the [*] of Antibody Products to the extent the same are [*] whether [*].

"[*] **Patent Rights"** means, other than [*] Patent Rights and [*] Patent Rights, (i) all Patent Rights to the extent the same are [*] and which claim [*] Know-How and (ii) all Patent Rights of [*] to the extent the same are [*]; and in each case which if not licensed herein would be infringed by [*] Antibody Products.

“[*] **Know-How”** means all Information and Materials characterized, conceived, developed, derived, discovered, generated or identified solely by employees of or consultants to [*] in the course of the [*] of Antibody Products [*] and, in each case, [*] of [*].

“[*] **Patent Rights”** means those Patent Rights of [*] which specifically disclose and claim [*] Know-How.

“[*] **Technology”** means, collectively, [*] Know-How, [*] Know-How, [*] Patent Rights, [*] Patent Rights, and [*]'s interest in [*] Know-How and [*]'s interest in [*] Patent Rights.

“Amgen Territory” means each or all countries (a) in the Amgen Initial Countries and (b) in the Territory in which Amgen is designated the Territorial Commercial Lead pursuant to Article 5.1.

“[*] **Trademarks”** means the Trademarks including house marks and house dress [*] from time to time [*] and used on or in connection with Antibody Products, but excluding the [*] Trademarks.

“Antibody(ies)” means a polyclonal or monoclonal antibody, whether multiple or single chain, recombinant or naturally occurring or a combination of the foregoing, whole or fragment, monospecific or multi-specific, and any analogs, constructs, conjugates, fusions or chemical or other modifications and/or attachments thereof.

“Antibody Product(s)” means any Antibody or Antibodies in whatever form that is (i) delivered by [*] to [*]; (ii) [*] by [*]; or (iii) [*] by [*]; and in each case that binds to BEER. Antibody Product also includes any product incorporating any such Antibody.

“Antibody Raw Material” means the bulk Antibody Product, manufactured and quality control tested in accordance with Article 6 (including, if appropriate, [*] and suitable for use in the manufacture of Antibody Product in Finished Form.

“BEER” means any protein or a portion thereof comprising the polypeptide sequence of [*] and any polypeptide sequence having [*] and any [*].

“Business Day” means a day on which banking institutions in both New York, New York, USA, and London, England are open for business.

“[*] **Patent Rights”** means the patent applications and patents set forth in Part A of Schedule F and all Patent Rights that issue from or claim priority from those Patent Rights and foreign counterparts thereof.

“[*] **Patent Rights”** means the Patent Rights set forth in Part B of Schedule F and all Patent Rights that issue from or claim priority from those Patent Rights and foreign counterparts thereof

“Celltech Initial Countries” means (a) the United Kingdom, France, Germany, Spain, Italy, Norway, Switzerland and any country in addition to those named which, as of the date of first Regulatory Approval for Commercialisation of an Antibody Product is a member state of the European Union; and (b) Australia and New Zealand.

“[*] **Know-How”** means, other than [*] Know-How and [*] Know-How, all Information and Materials relating to Antibodies or BEER which are [*] for the [*] of Antibody Products to the extent the same are [*] whether [*].

“[*] **Patent Rights”** means, other than [*] Patent Rights, [*] Patent Rights and [*] Patent Rights, (i) all Patent Rights to the extent the same are [*] and which claim [*] Know-How and (ii) all Patent Rights of [*] to the extent the same are [*]; and in each case which if not licensed herein would be infringed by [*] Antibody Products. [*] Patent Rights include [*] Patent Rights.

“[*] **Know-How”** means all Information and Materials characterized, conceived, developed, derived, discovered, generated or identified solely by employees of or consultants to [*] in the course of the [*] of Antibody Products [*] and, in each case, any [*] of [*].

“[*] **Patent Rights”** means those Patent Rights of [*] which specifically disclose and claim [*] Know-How.

“[*] **Technology”** means, collectively, [*] Know-How, [*] Know-How, [*] Patent Rights, [*] Patent Rights, [*] Patent Rights, and [*] Know-How and [*] Patent Rights.

“Celltech Territory” means each or all countries (a) in the Celltech Initial Countries and (b) in the Territory in which Celltech is designated the Territorial Commercial Lead pursuant to Article 5.1.

“[*] **Trademarks”** means the Trademarks including house marks and house dress [*] from time to time [*] and used on or in connection with Antibody Products but excluding the [*] Trademarks.

“Collaboration Committee” means the committee formed pursuant to Article 9.1.

“Commercialisation” or **“Commercialise”** means any and all activities (whether before or after Regulatory Approval) directed to the marketing, Detailing and Promotion of an Antibody Product after Regulatory Approval for commercial sale has been obtained and shall include pre-launch and post-launch marketing,

manufacturing for commercial sale, Promoting, Detailing, distributing, offering to sell and selling an Antibody Product, importing an Antibody Product for sale, conducting Marketing Clinical Studies (but not Development clinical studies), and interacting with Regulatory Authorities regarding the foregoing. When used as a verb, **"Commercialising"** means to engage in Commercialisation and **"Commercialised"** shall have a corresponding meaning.

"Commercialisation Expense" shall have the meaning as set forth in Schedule B.

"Commercialisation Plan" means the comprehensive plan and overall strategy, and any updates thereto, and consolidated budget for the Commercialisation of the Antibody Products to be prepared pursuant to Article 5.8.

"Commercially Reasonable Efforts" means efforts and resources commonly associated with good business practice and standards in the research-based pharmaceutical industry to research, develop or commercialise (as appropriate) a product of similar market potential at a similar stage in its product life, taking into account efficacy, the competitiveness of alternative products and product candidates in the marketplace (excluding other products owned or controlled or marketed by a Party or any of its Affiliates), the patent and other proprietary position of the product, the likelihood of regulatory approval given the regulatory structure involved, the profitability of the product including the royalties payable to licensors of patent rights, alternative Third Party products and product candidates and other relevant factors. Commercially Reasonable Efforts where appropriate shall be determined on a market-by-market basis for a particular product, and the level of effort may change over time, reflecting changes in the status of the product and the market involved.

"Confidential Information" means all Information disclosed in good faith for the purposes of this Agreement which is designated as confidential in writing by the disclosing Party, whether by letter or by the use of an appropriate stamp or legend, prior to or at the time any such Information is disclosed by the disclosing Party to the other Party. Notwithstanding anything in the foregoing to the contrary, Information which is disclosed in good faith for the purposes of the Agreement, whether orally, electronically, visually or in writing without an appropriate letter, stamp or legend, shall constitute Confidential Information of a Party (a) if the disclosing Party within thirty (30) days after such disclosure, delivers to the other Party a written document or documents describing the Information and referencing the place and date of such oral, visual, electronic or written disclosure and the names of the persons to whom such disclosure was made or (b) if such Information is of the type that is customarily considered to be confidential information by persons engaged in activities that are substantially similar to the activities being engaged in by the Parties. Any Information of a Party disclosed at a meeting of the Collaboration Committee, Joint Research Committee, Joint Development Committee or the Joint Commercialisation Committee (or any sub-committee or project team of the foregoing) or disclosed

through a report to any such committee shall constitute Confidential Information of such Party unless otherwise specified. The terms of this Agreement shall be considered Confidential Information of each Party.

"Contract Year" means (a) with respect to the first Contract Year, the period beginning on the Effective Date and ending on 31 December 2002 (the "First Contract Year"), and (b) with respect to each subsequent Contract Year, the twelve (12) month period beginning on the day following the end of the First Contract Year and each succeeding twelve (12) month period thereafter.

"Control" or **"Controlled"** means with respect to any (a) Material or Information or (b) intellectual property right, in each case the possession (whether by ownership, licence or other right, other than pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party access and/or a licence (or sublicence) as provided herein under such item or right without violating the terms of any agreement or other arrangement with any Third Party existing before or after the Effective Date and existing as of the date such Party obtains such ownership, licence or other right in such Material, Information or intellectual property.

"Cost of Goods" shall have the meaning set forth in Schedule B.

"Detail" means an interactive face-to-face contact (including a live video presentation) of a Representative with (a) a medical professional with prescribing authority or (b) an office nurse with influence over the pharmaceutical treatment of a patient, *provided that* in the case of (b) such contacts shall not be considered a Detail to the extent they exceed [*] percent ([*]%) of the interactive face-to-face contacts performed by a Party during the Contract Year. To constitute a Detail such interactive face-to-face contact (i) shall be with a medical professional or office nurse designated by the Territorial Commercial Lead as a target call audience in its Lead Territory, (ii) shall occur at the office of such medical professional or office nurse, at hospitals or at other locations (excluding exhibits, displays and other forms of communication not involving face-to-face contact by such sales representative), and (iii) during such contact Regulatory Authority-approved indicated uses, safety, effectiveness, contraindications, side effects, warnings and/or other relevant characteristics of an Antibody Product, shall be described in a fair and balanced manner consistent with the laws and regulations of the relevant part of the Territory, using either or both of the Product Labelling or the Promotional Materials, in an effort to increase physician prescribing preferences of such Antibody Product for its approved indicated uses. A sample drop does not constitute a Detail. When used as a verb, **"Detailing"** means performing Details and **"Detailed"** shall have a corresponding meaning.

"Development" or **"Develop"** means all clinical and other activities undertaken to obtain Regulatory Approval of an Antibody Product after the filing of an IND for an Antibody Product and up to and including the obtaining of Regulatory Approval for commercial sale of such Antibody Product, and including any

supplementary Development forming part of Late Stage Development in the Field in the Territory. For the avoidance of doubt, these activities shall include clinical drug development activities, including, among other things: test method development and stability testing, toxicology, formulation, process development, manufacturing, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, product approval and registration, and regulatory affairs related to the foregoing. When used as a verb, **"Developing"** means to engage in Development and **"Developed"** shall have a corresponding meaning.

"Dollar" means a United States dollar, and **"$"** shall be interpreted accordingly.

"Drug Approval Application" means an application for any Regulatory Approval required before commercial sale or use of an Antibody Product as a drug or to treat a particular indication in a regulatory jurisdiction, including: (a) (i) a Biologics Licence Application ("**BLA**") pursuant to 21 C.F.R. 601.2 (or any successor application or procedure) submitted to the FDA and (ii) any counterpart of a U.S. BLA in any other country in the Territory; and (b) all supplements and amendments that may be filed with respect to the foregoing.

"Early Stage Development" means all post-IND Development up to and including conclusion of Phase II Studies.

"FAMC" shall have the meaning set forth in Schedule E.

"FDA" means the United States Food and Drug Administration or a successor agency thereto.

"Field" means [*].

"Finished Form" means the final finished form of an Antibody Product suitable for use by patients including Antibody Raw Material in combination with excipients, vials or other containers suitable for delivery, delivery devices, packaging and labelling.

"First Commercial Sale" means the first shipment of any Antibody Product sold on arm's-length terms to a non-sublicensee Third Party by a Party, its Affiliates or its sublicensees, in any country in the Territory after the first Regulatory Approval for Commercialisation has been achieved for such Antibody Product in such country in any indication. Sales for test marketing, sampling and promotional uses, clinical trial purposes or compassionate or similar use shall not constitute a First Commercial Sale.

"Force Majeure" means any occurrence beyond the reasonable control of a Party that prevents or substantially interferes with the performance by a Party of any of its obligations hereunder.

"FTE" means a full-time equivalent person year of scientific or technical work, full-time being [*].

"FTE Cost" means, for any quarter, the FTE Rate multiplied by the sum of the number of days (calculated by adding the full and partial percentage of days) actually spent in that quarter by FTEs of a Party working directly on Research and Development of Antibody Products under the terms of this Agreement (as per their time sheets) divided by [*].

"FTE Rate" means the sum of the [*] FTE Rate (as calculated herein below) and the [*] FTE Rate (as calculated herein below). The [*] FTE Rate is [*] Dollars ($[*]) per FTE. This [*] FTE Rate shall be adjusted annually beginning with 1st April 2003 in accordance with [*]. The [*] FTE Rate is [*] Dollars ($[*]) and shall be adjusted annually beginning on April 1, 2003 at the same time as the [*] FTE Rate, by the then-most recently published annual increase in the [*] (as determined by the average annual [*] from the prior year as quoted from the [*])).

"GAAP" means United States generally accepted accounting principles.

"IND" means (a) (i) an Investigational New Drug Application (as defined in the U.S. Federal Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder) that is required to be filed with the FDA before beginning clinical testing of an Antibody Product in human subjects, or any successor application or procedure and (ii) any counterpart of a U.S. Investigational New Drug Application in any other country in the Territory; and (b) all supplements and amendments that may be filed with respect to the foregoing.

"Information" means tangible or intangible know-how, trade secrets, inventions (i.e., conceived or reduced to practice, constructively or actually), methods, knowledge, conclusions, skill, experience, test data and results (including chemical, biological, biochemical, pharmaceutical, pharmacological, toxicological and research, pre-clinical and clinical data, assay, control and manufacturing processes, test data and results), analytical and quality control methods and data, results or descriptions, software and algorithms or other information (whether or not patentable) regarding technology, techniques, practices, products, business information or objectives.

"Joint Commercialisation Committee" means the committee formed pursuant to Article 5.4.

"Joint Development Committee" means the committee formed pursuant to Article 3.7.2.

“[*] **Know-How”** means all Information or Materials that are conceived or developed [*] after [*] and, in each case, [*]of [*].

“[*] **Patent Rights”** means Patent Rights in any country within the Territory which claim [*] Know-How and which identify [*] as inventors.

“Joint Research Committee” means the committee formed pursuant to Article 3.7.1.

“Late Stage Development” means Development following completion of Phase II Studies up to and including filing of a Drug Approval Application for an Antibody Product in any jurisdiction and including any supplementary Development necessary or required by a Regulatory Authority (a) in order to obtain a Regulatory Approval; or (b) as required as a condition or maintenance, as the case may be, of a Regulatory Approval; in each case necessary for the commercial sale and/or use of an Antibody Product in that jurisdiction.

“Lead Territory” means Amgen Territory and/or Celltech Territory as the case may be.

“Licence Agreement” means that certain agreement attached hereto as Schedule G.

“Licence Fees” shall have the meaning set forth in Schedule B.

“Marketing Clinical Studies” means, in any jurisdiction, those clinical studies following Early Stage Development of an Antibody Product, including pharmacoeconomic studies, pharmacoepidemiology studies, investigator-sponsored clinical studies, Phase IIIB, Phase IV and other such studies useful for the Commercialisation of an Antibody Product, including those studies required to expand the label of an Antibody Product in the approved indication, but excluding those studies undertaken as part of Late Stage Development of an Antibody Product.

“Materials” means biological and chemical materials including, Antibodies, Antibody Products, screens, animal models, cell lines, cells, vectors, nucleic acids, receptors and reagents.

“Net Sales” shall have the meaning set forth in Schedule D.

“Osteoporosis Indication” means the [*].

“Other Expense” shall have the meaning set forth in Schedule B.

“Other Indications” means all uses of Antibody Products in the Field other than in the Osteoporosis Indication.

“Party” means Amgen or Celltech; **“Parties”** means Amgen and Celltech.

“Patent Rights” means all (a) existing issued, unexpired patents (with the term “patent” being deemed to encompass an inventor's certificate), including any reissue, re-examination, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent and (b) existing patent applications and patent applications hereafter filed, including any continuations, continuations-in-part, divisionals, provisionals, converted provisional, continued prosecution application, or any substitute applications, any patent issued with respect to any such patent applications, any reissue, re-examination, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent; and all foreign counterparts of any of the foregoing.

“[*] **Antibody”** means an Antibody which is [*] of any [*] and claimed by any of the [*] Patent Rights.

“Phase II Study” means a clinical trial that is designed to establish the safety and preliminary efficacy of a drug for its intended use, and to define warnings, precautions and adverse reactions that are associated with the drug in the dosage range to be prescribed and that satisfy the requirements of 21 CFR 312.21(b) (or its successor regulation), or its equivalent in any other jurisdiction.

“Pivotal Study” means a clinical trial that, if the defined end-points are met, is designed (and agreed to in advance by a Regulatory Authority(ies) having jurisdiction in the country(ies) in which the trial is to be conducted, based upon existing data in the same patient population as of the start of such clinical trial) to definitively establish that an Antibody Product drug is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with the Antibody Product in the dosage range to be prescribed, and provide pivotal data supporting Regulatory Approval of such Antibody Product and that satisfies the requirements of 21 CFR 321.21(c) (or its successor regulation), or its equivalent in any other jurisdiction.

“Position of Detail” means a Primary Detail, a Secondary Detail or a Tertiary Detail as the case may be.

“Primary Detail” means a Detail in which the predominant portion of time or emphasis is devoted to the Detailing of Antibody Product, and the Antibody Product is the first product presentation made.

“Product Contribution” shall have the meaning set forth in Schedule B.

“Product Labelling” means (a) the Regulatory Authority-approved full prescribing information for an Antibody Product, including any required patient information and (b) all labels and other written, printed or

graphic matter upon any container, wrapper or any package insert or outsert utilised with or for an Antibody Product.

"Product Trademark" means any trademarks and trade names (and trademark applications (whether or not registered), and any renewals, extensions or modifications thereto in the Territory) together with all goodwill associated therewith, trade dress and packaging which (a) are Controlled by either Party and (b) are applied to an Antibody Product or any Promotional Materials and (c) distinguishes that Antibody Product; but excluding any house marks or house dress or any reserve trademarks and trade names (and trademark applications and any resulting trademarks) which are Controlled by a Party and are filed with a trademark office for use with an Antibody Product but which shall not have been applied to an Antibody Product.

"Promote" or "Promotion" or "Promoting" or "Promotional" means, with respect to an Antibody Product, those activities and obligations other than Detailing undertaken by a Party to encourage sales of such Antibody Product including, journal advertising, direct mail programs, direct-to-consumer advertising, education, convention exhibits, and other forms of advertising and promotion.

"Promotional Materials" means all sales representative training materials and all written, printed, graphic, electronic, audio or video matter including, journal advertisements, sales visual aids, direct mail, direct-to-consumer advertising, Internet postings, product inserts, broadcast advertisements, and sales reminder aids (e.g., scratch pads, pens and other such items) intended for use or used by a Party in connection with any Promotion or Detailing of an Antibody Product, except Product Labelling.

"Regulatory Approval" means any and all approvals (including any applicable supplements, amendments, pre- and post-approvals, governmental price and reimbursement approvals and approvals of applications for regulatory exclusivity), licences, registrations, or authorisations of any federal, national, multinational, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity necessary for the manufacture, distribution, use, storage, import, export, transport, Promotion, marketing and sale of an Antibody Product in a country or jurisdiction.

"Regulatory Authority" means any governmental or regulatory authority involved in granting Regulatory Approvals of any Antibody Product including, in the United States, the FDA.

"Regulatory Filings" means, collectively, INDs, Drug Approval Applications, establishment licence applications (**"ELAs"**) and drug master files (**"DMFs"**) or any other similar filings (including any equivalents in other jurisdictions and further including any related correspondence and discussions) and applications for

regulatory exclusivity, and all data contained therein, as may be required by the FDA or equivalent Regulatory Authorities in other jurisdictions, for the Development or Commercialisation of an Antibody Product.

"Representative" shall have the meaning set forth in Schedule B.

"Research" means all research and pre-clinical activities up to and including the filing of any IND for an Antibody Product. When used as a verb **"Research"** means to engage in Research, and **"Researched"** and **"Researching"** shall have a corresponding meaning.

"Research and Development Cost" means for all activities performed following the Effective Date for the Research and Development of Antibody Products (a) all out-of-pocket costs and expenses incurred on an arm's-length basis (calculated in accordance with GAAP) and paid to Third Party subcontractors (or accrued therefor) by Amgen or Celltech or their Affiliates, (b) the FTE Cost of such activities, and (c) the cost of Materials used in such activities. For the avoidance of doubt, Research and Development Costs excludes [*] made by [*] to [*] pursuant to [*].

"Research Plan" means the plan of Research activities to be performed by the Parties and attached hereto as Schedule A, and as may be modified from time to time pursuant to Article 3.7.1(c).

"Secondary Detail" means a Detail in which the second-most predominant portion of time or emphasis is devoted to the Detailing of Antibody Product, it being understood that, in most but not all Secondary Details, Antibody Product shall be the second product presentation made.

"Term" means the term of this Agreement as set forth in Article 14.1.

"Territorial Commercial Lead" means, with respect to a particular country, the Party designated pursuant to Article 5.1 to lead Commercialisation of Antibody Products in such country.

"Territory" means all the countries of the world.

"Tertiary Detail" means a Detail in which Antibody Product is included in the Detail, with lesser prominence than a Secondary Detail but more prominence than mere inclusion in a product list.

"Third Party" means any person, partnership, joint venture, corporation, trust, estate, unincorporated organisation, government or any department or agency thereof, or any entity other than a Party or any of its Affiliates.

“Trademark” means any and all corporate names, service marks, logos or trademarks and trademark applications (whether or not registered) together with all good will associated therewith, and any renewals, extensions or modifications thereto either filed or used.

“Wind Down Costs” means all reasonable out-of-pocket costs incurred by either Party in terminating or transferring to the other Party (or its nominee) Research, Development or Commercialisation activities (including the termination or assignment of relevant related contracts and Materials) as set forth in Article 14.9, following the service of a notice of termination of this Agreement to the extent such activities, contracts and Materials have been approved by the Collaboration Committee and are not accounted for in Commercialisation Expense or Research or Development Cost.

Each of the following definitions are found in the body of this Agreement as indicated:

Defined Terms	**Page/Article**
“Acquiring Party”	Article 17.1
“Amgen Indemnitees”	Article 18.2
“Amgen Loss(es)”	Article 18.2
“Amgen”	Pg. 1, paragraph 2
“Auditing Party”	Article 8.5
“Balance Payment”	Article 8.3(b)
“BLA”	Article 1, def. “Drug Approval Application”
“Celltech Indemnitees”	Article 18.1
“Celltech Loss(es)”	Article 18.1
“Celltech”	Pg. 1, paragraph 3
“[*]”	Article 5.7(i)
“Co-Detailer”	Article 5.2(a)
“Consultation Rights”	Article 11.2.2(b)
“Continuing Party”	Article 14.8(a)
“Country Plan”	Article 5.9
“Defaulting Party”	Article 14.4(a)
“DMFs”	Article 1, def. “Regulatory Filings”
“Effective Date”	Pg. 1, paragraph 1
“ELAs”	Article 1, def. “Regulatory Filings”
“Excepted Matters”	Article 3.7.1(e)
“[*]”	Article 15.1
“Filing Notice”	Article 5.2(b)
“First Contract Year”	Article 1, def. “Contract Year”
“include” or “includes” or “including”	Article 19.12
"intellectual property"	Article 14.5
“Indemnify”	Article 18.1
“Insolvency Event”	Article 14.5(b)
“Joint Activities”	Article 5.5(a)(iii)
“Joint Loss(es)”	Article 18.3
“Late Stage Development Plan”	Article 3.4(a)
“Manufacturing Lead”	Article 6.1(a)
“[*] Patent Rights”	Article 11.2.2(a)
“[*] Patent Rights”	Article 11.2.2(a)
“Milestone Event”	Article 7.2
“Milestone Payment(s)”	Article 7.2
“non-Acquired Party”	Article 17.1
“Non-Defaulting Party”	Article 14.4(a)
“Notice of Default”	Article 14.4(a)
“[*]”	Article 15.1
“opt-out right”	Article 3.4(a)
“Performance Default”	Article 14.4(a)
“Quality Responsibilities”	Article 6.8
“Recall”	Article 4.8(a)
“Representation Default”	Article 14.4(a)
“SOPs”	Article 4.8(a)
“Subsequent Products”	Article 3.4(a)

“Supply Agreements”	Article 6.1(a)(ii)
“Termination Date”	Article 14.8(b)
“Third Party Licence Agreement”	Article 11.9
“Transition Date”	Article 11.2.9
“Transition Plan”	Article 14.9(b)(iii)

ARTICLE 2

SCOPE OF RELATIONSHIP

2.1 **Exclusive Collaboration.** The Parties agree to collaborate exclusively in the Research, Development and Commercialisation of Antibody Products in the Field in accordance with the terms of this Agreement and, other than as explicitly permitted under this Agreement, not to undertake or enable any Third Party to undertake any activities for Antibody Products without the other Party's prior written consent (which may be withheld for any reason), including to undertake or enable any Third Party to undertake any activities for Antibody Products for any use outside of the Field (including [*]).

2.2 **Provision of Assistance.** Each Party shall co-operate reasonably with the other Party to facilitate the Research, Development and Commercialisation of Antibody Products in the Field. In addition to other assistance explicitly set forth in this Agreement, during the Term Amgen shall provide Celltech with reasonable technical assistance relating to the use of [*] Know-How, [*] Know-How and [*] Know-How and Celltech shall provide Amgen with reasonable technical assistance relating to the use of [*] Know-How, [*] Know-How and [*] Know-How, each solely to the extent licensed to the other Party in this Agreement. In addition, during the Term each Party shall make its employees, consultants and agents reasonably available upon reasonable notice during normal business hours at their respective places of employment to consult with the other Party on issues relating to this Agreement or any request from any Regulatory Authority concerning an Antibody Product, including requests relating to regulatory, scientific and technical issues. Each Party shall also keep the Joint Research Committee, Joint Development Committee, Joint Commercialisation Committee and Collaboration Committee, as appropriate, informed as to its progress in the Research, Development and Commercialisation of Antibody Products. A Party shall not be in breach of any obligation under this Agreement to the extent its inability to perform such obligation is caused by the other Party's failure to perform any of its obligations under this Agreement.

2.3 **Decision Making and Obligations.** Control of a final decision-making authority for any aspect of the Research, Development and/or Commercialisation as set forth in this Agreement shall not relieve the Party with such control from any of its obligations under this Agreement .

2.4 **Transfer of Materials.** The Parties anticipate that each Party may transfer certain of its Materials to the other Party. Each Party agrees that it will use such Materials of the other Party only in accordance

with the terms and conditions of, and solely for the purposes of the activities conducted pursuant to, this Agreement, and will not transfer such Materials of the other Party to any Third Party without the consent of the other Party, except as expressly permitted under this Agreement.

2.5 **Third Party Research Agreements.** The Parties shall, through the Collaboration Committee or its designees, agree upon and co-ordinate Material transfer agreements and collaboration agreements with Third Parties (excluding Third Party subcontractors) to the extent such agreements relate to the Research or Development of Antibody Products or BEER or involve the use of Antibody Products or BEER, in a manner so as to conserve the available quantities of the Parties' Materials and to avoid compromise of the Parties' abilities to fulfil their obligations and responsibilities under this Agreement, and with a view toward maintaining access to relevant intellectual property rights. Notwithstanding the above, other than with respect to Antibody Products, neither Party may transfer the other Party's Materials to any such Third Parties, without the express written consent of the other Party.

2.6 **Employee Obligations.** Prior to beginning work relating to any aspect of the subject matter of this Agreement and/or being given access to the [*] Technology or [*] Technology, each employee, consultant or agent of Celltech and Amgen shall be bound by an employment agreement or other agreement pursuant to which (a) each such person (other than administrative and/or non-technical personnel) shall (but in the case of a Party's own Technology, only to the extent such Party's employees consultants or agents are conducting activities pursuant to this Agreement) be obliged to comply with all of the obligations of Celltech or Amgen under this Agreement, as appropriate, including: (i) following Celltech's or Amgen's (as appropriate) policies and procedures regarding reporting any invention, discovery, process, software program or other intellectual property right created by such person in the course of his or her employment or retainer with Celltech or Amgen, as appropriate, within [*] Technology or [*] Technology; (ii) assigning to Celltech or Amgen, as appropriate, all of his or her right, title and interest in and to any such invention, discovery, process, software program or other intellectual property right; (iii) co-operating in the preparation, filing, prosecution, maintenance and enforcement of any Patent Rights covering the same; and (iv) performing all acts and signing, executing, acknowledging and delivering any and all papers, documents and instruments required for effecting the obligations and purposes of this Agreement and (b) each person shall be bound by obligations of confidentiality and non-use consistent with the terms of this Agreement. It is understood and agreed that any such agreement need not be specific to this Agreement.

2.7 **No Parking.** Each Party acknowledges that using Commercially Reasonable Efforts requires it to take ongoing actions that are consistent with a good faith intention to achieve the objective of

Developing an Antibody Product and obtaining Regulatory Approvals to Commercialise such Antibody Product for the [*] (or if the [*] is dropped in accordance with the terms of this Agreement an [*] chosen in accordance with the terms of this Agreement) in the Field, and to Commercialise such Antibody Product, throughout the Amgen Territory and Celltech Territory. For the avoidance of doubt, Development and Commercialisation in each instance includes the manufacture and the supply of Antibody Product. If a Party decides that deployment of Commercially Reasonable Efforts does not justify it making continued, ongoing efforts towards this objective it shall promptly notify the other Party in writing.

ARTICLE 3

RESEARCH AND DEVELOPMENT OF

ANTIBODY PRODUCTS

3.1 **Collaboration Regarding Research and Development.**

3.1.1 From and after the Effective Date:

(a) the Parties shall use diligent and timely efforts to satisfactorily complete Research of the Antibody Products and obtain in one of the [*] for an Antibody Product an IND in the [*] or, if agreed by the Joint Research Committee pursuant to Article 3.7.1(e), an [*];

(b) In addition to its Development supply obligations as set out in Article 6, Celltech shall use Commercially Reasonable Efforts:

(i) to satisfactorily complete, in respect of an Antibody Product, those Development activities assigned to it pursuant to Article 3.2.2(b) and Article 3.2.2(c); and

(ii) following delivery by Amgen to Celltech of a filed data package pursuant to Article 4.1(d), to obtain Regulatory Approval to Commercialise an Antibody Product supported by, in the indication supported by, such data package, in the Field throughout the Celltech Territory.

(c) Amgen shall:

(i) use Commercially Reasonable Efforts to satisfactorily complete all Development activities with respect to an Antibody Product (other than those Development activities assigned to Celltech pursuant to Article 3.2.2(b) and Article 3.2.2(c)); and

(ii) use Commercially Reasonable Efforts to obtain Regulatory Approval to Commercialise an Antibody Product;

in each case for the [*] (or if the [*] is dropped in accordance with the terms of this Agreement an [*] chosen in accordance with the terms of this Agreement) in the Field throughout the Amgen Territory.

(d) Each Party acknowledges that the obligations it undertakes pursuant to this Article 3.1.1 are material obligations.

3.1.2 Each Party agrees to conduct its Research activities and Development activities in compliance with all laws, regulations and guidelines that are applicable to the particular stage of Research or Development for the Antibody Product, including, GLP, GCP and GMP, of the relevant jurisdiction as the same may be amended from time to time.

3.1.3 Neither Party will approve, oppose or take any action under this Agreement which is contrary to its preliminary or final conclusions that the safety or toxicity of an Antibody Product then being considered for Development or being Developed pursuant to this Agreement would pose a [*] that is [*] to patients.

3.1.4 Notwithstanding any other term of this Agreement, [*] shall not, except with the written consent of [*], have an Antibody Product in Late Stage Development in more than one [*] unless (i) Regulatory Approval for the Commercialisation of an Antibody Product has been obtained in any of the [*] or (ii) such additional [*] was included in the first [*] for such Antibody Product presented to [*] pursuant to Article [*].

3.2 **Activities.** Without limiting the obligations of Article 3.1 the Parties shall undertake the Research and Development activities as follows:

3.2.1 *Research*

(a) The Parties shall conduct all activities for the Research of Antibody Products in accordance with the Research Plan, a copy of which is attached as Schedule A, as may be amended from

time to time by the Joint Research Committee, with the Research objective of filing an IND and initiating clinical studies for at least one Antibody Product.

(b) As part of the Research, Celltech shall use diligent and timely efforts to:

(i) supply Amgen with [*] Antibody in amounts in line with the Research Plan as of the Effective Date and such additional amounts as may be reasonably requested by Amgen (which request will recognize timing constraints for supply imposed by Celltech's existing capacity to provide), and in each case to specifications and timing agreed by the Joint Research Committee, for use by Amgen in [*] studies;

(ii) supply Amgen with such quantities of [*] as requested by Amgen and as Celltech shall have the existing capacity to provide, and to specifications and timing agreed by the Joint Research Committee, for use by Amgen in [*] studies; and

(iii) provide Amgen with any Information [*] which [*] reasonably considers to be [*] to the [*] safety and/or toxicity of Antibody Products (being considered for Development or being Developed).

(c) As part of the Research, Amgen shall use diligent and timely efforts to:

(i) conduct [*] studies required to select an Antibody Product clinical candidate and file an IND therefor in one of the [*]. For the avoidance of doubt, nothing in this Agreement shall preclude Amgen from filing INDs in such other countries as it sees fit;

(ii) conduct studies to identify, test and select [*] and, if applicable, [*] for use in the Development of Antibody Products; and

(iii) provide [*] with any [*] arising from the studies referred to in (i) and (ii), and with any [*] which [*] reasonably considers to be [*] to the [*] safety and/or toxicity of Antibody Products (being considered for Development or being Developed).

(d) If (i) Celltech has not achieved Milestone 1 as set out in Schedule A by the [*] of the [*]; or (ii) if Celltech achieves [*] but subsequently fails to achieve Milestone 3 as set out in Schedule A within [*] of Amgen notifying Celltech in writing (pursuant to Article 3.2.1(g) below) of [*] Antibody as determined by the [*] study results; the Parties (upon the written request of

[*]) shall for a period of [*] of [*] with respect to unachieved Milestone 1 or unachieved Milestone 3 (as applicable) discuss the possibility of extending such time period for an additional, mutually agreed period. Each Party acknowledges that it shall be [*] as to whether or not to agree to such an extension of any such time period.

(e) Within [*] of expiry of each date referred to in Article 3.2.1(d) or any extension to such dates agreed to by the Parties, Amgen shall notify Celltech in writing that Amgen will either:

(i) assume the right and obligation to Research, Develop, and supply either itself or through agreement with a Third Party the [*] referred to in Milestone 1 and/or (as appropriate) the [*] referred to above in Article 3.2.1(d); or

(ii) terminate this Agreement.

If Amgen does not serve such a notice it will be deemed to have exercised the option set out in Article 3.2.1(e)(i).

(f) Where Amgen has exercised the option set out in Article 3.2.1(e)(i) the following shall apply and this Agreement shall be deemed to be amended as follows:

(i) all Research and Development Costs incurred by either Party after the exercise of such option shall be shared equally by the Parties;

(ii) Amgen shall have no obligation to pay any Milestone Payments pursuant to Article 7.2 not already paid or due to be paid at the time that Amgen exercises such option;

(iii) Amgen shall cease to have any rights to use or exploit any of the [*] Patent Rights and any other [*] Technology that [*] to any invention claimed by any of the [*] Patent Rights, and Celltech shall cease to have any obligation to provide Amgen with any Information concerning the [*] Patent Rights, or to provide Amgen with assistance or guidance in using or understanding the [*] Technology covered by the same, but without prejudice to the rights [*] has to other [*] Technology as granted hereunder;

(iv) Celltech's obligations to conduct Research activities shall terminate save for those under Articles 3.2.1(b)(ii) and (iii) and its obligations with respect to the manufacture and supply of Antibody Raw Material (including those pursuant to Articles 3.2.2(c) and Article 6) shall terminate and Amgen shall assume all such responsibilities; and

(v) Amgen's Research obligations shall, for a period not to exceed [*] from the date Amgen exercised the option pursuant to Article 3.2.1(e), be amended by the substitution of "Commercially Reasonable Efforts" for "diligent and timely efforts" wherever it appears. Celltech shall provide Amgen with reasonable co-operation in connection with its Research activities. If Amgen has not commenced [*] on an Antibody Product clinical candidate within [*] of exercise of the option referred to in Article 3.2.1(e)(i), this Agreement shall terminate automatically and without notice. If Amgen has commenced such [*] before such date, from the commencement of such [*] Amgen shall again be obliged to use diligent and timely efforts where it was previously obliged to use diligent and timely efforts. Save for the change in the level of effort required by Amgen during such period, Amgen's Research and Development obligations as set out in this Agreement shall continue to apply;

provided however if at that time the Parties mutually agree in writing to develop an Antibody Product claimed by any of [*] Patent Rights the provisions of Articles 3.2.1(f)(i) through (v) shall not apply and this Agreement shall remain in force unamended.

(g) Amgen shall provide the Joint Research Committee with the results of the [*] studies conducted as set out in the Research Plan, within [*] of completion of those studies. The Joint Research Committee shall determine the characteristics required of the [*] for Milestone 3 within [*] of its receipt of the results of the [*] studies and Amgen shall promptly notify Celltech in writing of such characteristics. Should the Joint Research Committee subsequently decide to change such characteristics, Amgen shall notify Celltech of such change within [*] of the Joint Research Committee decision and the [*] referred to in Article 3.2.1(d) (with respect to the achievement of Milestone 3) shall commence on the date of Celltech's receipt of such subsequent notice.

3.2.2 *Development*

(a) Other than as specifically set forth in this Article 3.2.2 and Article 6, Amgen shall be responsible for all activities of Development of Antibody Products, and shall have the right to make all strategic and tactical decisions with respect to the Development of Antibody Products subject always to its obligations under this Agreement. Amgen shall be responsible for all Development tasks (other than those which Celltech undertakes pursuant to Article

3.2.2(b) or Celltech is responsible for pursuant to Article 3.2.2(c) and Article 6, below), including:

(i) determining in which [*] to conduct clinical studies *provided that* Amgen may not select an [*] in substitution of the [*] except in accordance with Article 3.2.2(e);

(ii) submitting all necessary Regulatory Filings for initiation of clinical studies;

(iii) identifying key Development objectives, expected associated resources, risk factors, timelines, Go/No Go decision points and relevant decision criteria;

(iv) forecasting clinical manufacturing production requirements;

(v) carrying out all aspects of (e.g., designing studies and protocols for and conducting) clinical studies (but excluding [*]), as well as establishing new dosage forms, new formulations or other enhancements of approved Antibody Products including (1) establishing/contracting with clinical sites, investigators and CROs; (2) enrolling clinical study patients; (3) organising investigator meetings, scientific meetings, advisory panel workshops and regulatory meetings; and (4) analysing, summarising clinical study results;

(vi) performing any other additional pre-clinical research in support of the clinical development of Antibody Products;

(vii) subject to Article 4, reporting to Regulatory Authorities on study design, study outcome, other regulatory communications and filings; and

(viii) maintaining a database of clinical trial data accumulated from clinical studies of all Antibody Products, all safety data, and any adverse reaction information acquired for all Antibody Products during Development or Commercialisation.

(b) With respect to any Antibody Product and indication which is in [*], Celltech may undertake supplemental [*] activities for that indication in the Celltech Territory where it reasonably considers that such studies are [*] in order to obtain any Regulatory Approvals within the Celltech Territory. Such studies shall be carried out in a manner consistent with the objectives of [*] for that indication as determined by the Joint Development Committee (which objectives shall recognise Celltech's right to conduct such studies).

(c) Celltech shall be responsible for providing Amgen with guidance and Information Controlled by Celltech and obtained from Celltech's experience in the development of [*], including pre-clinical and clinical safety data and other information Controlled by Celltech, in each case to the extent Celltech in good faith considers the same to be [*] to the Development of Antibody Products.

(d) Each Party shall conduct its Development responsibilities regarding Antibody Product(s) pursuant to this Article 3.2.2 in a manner consistent with its obligations under Article 3.1.

(e) Should Amgen reasonably determine that it no longer wishes to continue to pursue Research or Development activities of an Antibody Product for the [*] and that it wishes instead to Develop Antibody Product for an [*] it shall promptly notify the Joint Research Committee (if the Antibody Product is still the subject of Research activities); or the Joint Development Committee if the Antibody Product has ceased to be in Research and is the subject of Development activities. Such notice shall set out Amgen's reasons in detail, and include reasonable supporting evidence. If Celltech disputes that the [*] should be dropped, or disputes the choice of an [*] and suggests a different [*] it shall notify the relevant Committee in writing setting out its reasons in detail, and including reasonable supporting evidence. If the Joint Research Committee or Joint Development Committee (as appropriate) cannot agree (and [*] has [*]) the decision as to whether the [*] should be dropped and an [*] substituted in its place shall be escalated for consideration by the Collaboration Committee. Within the Collaboration Committee, in the case of a dispute arising out of the Research Committee, [*] shall have [*] and, in the case of a dispute arising out of the Development Committee, [*] shall have [*] on this issue. If, following such consideration the relevant Committee determines that the [*] shall be dropped and an [*] substituted in its place then such [*] shall be substituted for the [*] for the purposes of this Agreement. Neither Party shall unreasonably withhold or delay its consent to any [*] proposed by a Party pursuant to this Article. Each Party shall, if requested to do so, provide written reasons to the relevant Committee supporting its choice of an [*], or its rejection of the same.

3.3 **Sharing of Information.**

3.3.1 Without prejudice to its other obligations, each Party shall disclose to the other Party all Information Controlled by it and which it reasonably considers to be [*] to any Antibody Product as soon as

practicable after it is [*] or its [*] is [*]. The Parties shall [*] in the data dossiers used to support applications for Regulatory Approvals and in the database referred to in Article 3.2.2(a)(viii).

3.3.2 In addition to being informed of the progress of the Research and Development via the Joint Research Committee (pursuant to Article 3.7.1) and the Joint Development Committee (pursuant to Article 3.7.2), each Party shall have the right to obtain through the Joint Research Committee or Joint Development Committee (as appropriate), copies of final reports and a reasonable number of interim reports (in existence) of any studies carried out pursuant to Research and Development conducted under this Agreement and the Joint Research Committee and Joint Development Committee shall have no right to refuse any such request. If, after receiving any such report (or in the event no such report exists), a Party reasonably requires additional Information generated during Research and Development by either Party from pre-clinical studies and clinical trials of each Antibody Product, to exercise its rights or fulfil its obligations under this Agreement the other Party shall in response to a request, use Commercially Reasonable Efforts to provide such additional Information but only to the extent such additional Information is Controlled by it. The Party requesting such Information shall, if the Information provided by the other Party is incomplete, have the right to access such Information during regular business hours and on reasonable notice.

3.3.3 Each Party shall provide reasonable assistance to the other Party in understanding the data dossiers, database and reports referred to in this Article 3.3, *provided that* such Party shall use such data, dossiers, databases and reports only for the purpose of exercising its rights or fulfilling its obligations under this Agreement.

3.3.4 Notwithstanding the obligations in this Agreement to provide Information, co-operation and assistance, [*] shall not be obliged to provide to [*] any of the same in relation to the [*] Patent Rights or any invention claimed by any of the [*] Patent Rights or any [*] Technology specific to any such inventions, except in compliance with its obligations under Article 6.7.

3.4 **Celltech Opt-Out Right.**

(a) Celltech shall have the option (the "**opt out right**") to terminate this Agreement with respect to any Antibody Product which proceeds to Late Stage Development (as well as all other Antibody Products ("**Subsequent Products**") excluding any Antibody Product which has previously been subject to the procedure under this Article 3.4 and for which Celltech shall have previously elected in accordance with this Article 3.4 to remain subject to the terms of this Agreement), as set out in this Article 3.4. Celltech may exercise such opt-out right by

providing written notice to Amgen at any time within [*] of Celltech's receipt from Amgen of (i) a detailed report of the results of the Phase II Studies of such Antibody Product; (ii) Amgen's proposed plan for Late Stage Development ("**Late Stage Development Plan**") for such Antibody Product together with Amgen's confirmation of its intention to proceed with such plan if Celltech were not to exercise its opt-out right; (iii) Amgen's good-faith estimate of the Research and Development Costs of such Late Stage Development Plan and (iv) if the [*] has been dropped in accordance with Article 3.2.2(e) the Late Stage Development Plan will identify any intention Amgen has to develop the [*]. For the avoidance of doubt, with respect to any such intention set forth in such Late Stage Development Plan, other than as set forth in a revised Late Stage Development Plan provided pursuant to Article 3.4(b) below, Amgen shall not be obliged to inform Celltech of any change to Amgen's intention after providing such Late Stage Development Plan pursuant to this Article 3.4(a). The report, plan and estimate provided to Celltech pursuant to this Article shall be the same standard, quality and completeness as those utilised by Amgen in its internal deliberations and decision making concerning whether to proceed with Development of such Antibody Product.

(b) If at any stage during the conduct of activities pursuant to a Late Stage Development Plan, but prior to obtaining the first Regulatory Approvals to Commercialise such Antibody Product in the Amgen Territory,

(i) the Joint Development Committee has decided (in accordance with the terms of this Agreement) to drop the indication set out in the Late Stage Development Plan and has selected a new indication (subject to Article 3.2.2(e) where the initial indication is the [*]); and

(ii) Amgen decides to advance such Antibody Product into Late Stage Development for such new indication; and

(iii) the cost of Late Stage Development of such Antibody Product is expected to exceed the good-faith estimate of Research and Development Costs received by Celltech pursuant to Article 3.4(a) by [*] ([*]%) or more; then

Amgen shall provide Celltech with written notice that it wishes to perform Late Stage Development activities pursuant to a revised Late Stage Development Plan. With such notice Amgen shall provide Celltech with:

(iv) a detailed report of the results of the studies undertaken in Late Stage Development completed at the time of such notice together with preliminary results of any other such studies that are still in progress and for which interim or final results are available;

(v) Amgen's proposed revised Late Stage Development Plan for such Antibody Product;

(vi) Amgen's good faith estimate of the Research and Development Costs of such revised Late Stage Development Plan; and

(vii) the revised Late Stage Development Plan will identify any intention Amgen has to develop the [*] (For the avoidance of doubt, with respect to any such intention set forth in such revised Late Stage Development Plan Amgen shall not be obliged to inform Celltech of any change to Amgen's intention after providing such revised Late Stage Development Plan pursuant to this Article 3.4(b)).

The report, plan and estimate provided to Celltech pursuant to this Article shall be the same standard, quality and completeness as those utilised by Amgen in its internal deliberations and decision making concerning whether to proceed with the Development of such Antibody Product in the new indication. Within [*] of receiving such notice, Celltech may again exercise its opt out right with respect to such Antibody Product by written notice to Amgen.

(c) At the date Celltech provides its written notice to Amgen that it is exercising its opt-out right pursuant to Articles 3.4(a) or 3.4(b), as appropriate, Celltech shall provide Amgen with a document signed by an authorized officer of Celltech on its behalf either indicating in such document that (i) the written representations and warranties of Celltech set out in Articles 16.1, 16.2 and 16.3 are true and correct as if made as of the date of such document and as if referring to the Licence Agreement and not this Agreement or (ii) such written representations and warranties of Celltech are not true and correct and the reasons why such representations and warranties are not true and correct; *provided that* failure to provide Information that is subject to a Third Party confidentiality obligation shall not make the representation and warranty under Article 16.2(c) or 16.3(c) untrue or incorrect.

(d) Within [*] after receipt of Celltech's written notice to Amgen under Article 3.4(c), Amgen shall provide Celltech with a document signed by an authorized officer of Amgen on its behalf either indicating in such document that (i) the written representations and warranties of Amgen set out in Articles 16.1 and 16.2 are true and correct as if made as of the date of such document

and as if referring to the Licence Agreement and not this Agreement or (ii) such written representations and warranties of Amgen are not true and correct and the reasons why such representation and warranties are not true and correct; *provided that* failure to provide Information that is subject to a Third Party confidentiality obligation shall not make the representation and warranty under Article 16.2(c) untrue or incorrect.

(e) If Celltech shall not have exercised its opt-out right under Articles 3.4(a) or 3.4(b) with respect to an Antibody Product, this Agreement shall remain in full force and effect with respect to all Antibody Products. However, Celltech's opt out right shall apply to any other Antibody Product that Amgen proposes to advance or advances to Late Stage Development, and Articles 3.4(a) and (b) shall apply mutatis mutandis to all such Antibody Products.

(f) In the event Celltech shall exercise its opt-out right pursuant to Article 3.4(a) or (b) for any Antibody Product, the Licence Agreement shall immediately come into full force and effect for such Antibody Product (as well as all Subsequent Products). This Agreement shall terminate in relation to such Antibody Product (as well as all Subsequent Products), but remain in full force and effect with respect to any Antibody Product which has previously been subject to the procedures set out in Article 3.4(a) and which Celltech shall not have previously exercised its opt-out right. If Celltech exercises its opt-out right, Celltech shall have no liability for any Research and Development Costs of Late Stage Development, whether or not incurred prior to expiry of the opt-out period.

3.5 **Budgets.** The budgets for each Contract Year during Research and Development shall be specified by each Party and submitted to the other Party (via the Joint Research Committee or Joint Development Committee, respectively) in a format to be agreed by the Parties but which must include line item estimates of Research and Development Costs by function. The budgets shall be updated by the Joint Research Committee or Joint Development Committee (as appropriate) at least once annually on a timeline that meets the budget planning requirements of both Parties, but in no event less than [*] before the end of the preceding Contract Year; *provided however*, it is acknowledged and agreed that such budgets may need to be modified from time-to-time between annual updates, based upon the results of clinical studies and other unanticipated events. In any Contract Year, each Party shall promptly inform the other Party upon such Party determining that it is likely to exceed or underspend by more than [*] ([*]%) its respective total budget in that Contract Year. In addition, if in any Contract Year a Party exceeds its budget by more than [*]%, the Party who has so exceeded its budget shall, at the request of the other Party, provide to the Joint Research Committee or Joint Development

Committee (as appropriate) and to the Collaboration Committee (if the matter is escalated to the Collaboration Committee) a full explanation for exceeding its budget (as requested). Each Committee may, [*], reduce the amount of any overspend to be included in the Research and Development Costs as it considers equitable in the circumstances. If either the Joint Research Committee or Joint Development Committee do not [*] on how to deal with such overspend, the matter shall be escalated to the Collaboration Committee for consideration. The members of any such Committee (as appropriate) may elect to reduce or not reduce such overspend [*], and unless the relevant Committee [*] to reduce the overspend, [*].

3.6 **Costs.** Amgen and Celltech shall share all costs for the Research and Development of Antibody Products on the following basis:

3.6.1 *Research Costs*

Other than as provided below with respect to amounts paid to Third Parties, Celltech and Amgen shall each bear its own Research and Development Costs in carrying out its Research activities. The cost of supplying Amgen with Antibodies for Research shall be considered as Research and Development Costs to be borne by Celltech. All out-of-pocket Research and Development Costs paid to Third Parties shall be paid to any such Third Parties by the Party engaging the services of such Third Parties and, as between Amgen and Celltech, shall be shared on the basis of [*]:[*] Amgen: Celltech. Such Third Party costs shall include the cost of supply of GMP Antibody for Research by a Third Party on behalf of Celltech as required by Amgen for the purposes of pre-clinical or formulation studies.

3.6.2 *Early Stage Development Costs*

All Research and Development Costs cumulatively incurred (whether FTE Cost incurred directly by Amgen or Celltech or amounts payable to Third Parties engaged by Celltech or Amgen) for Early Stage Development of Antibody Products shall be shared, as follows:

(a) up to [*] Dollars ($[*]) of such cumulative Research and Development Costs, on the basis of [*]:[*] Amgen:Celltech;

(b) over [*] Dollars ($[*]) of such cumulative Research and Development Costs on the basis of [*]:[*] Amgen:Celltech.

For the avoidance of doubt, (i) any cost incurred for an Early Stage Development activity shall be a Research and Development Cost of Early Stage Development, even if such activity occurs before the filing of an IND or after any Late Stage Development activity has commenced; and (ii) (without limiting the foregoing) the cost of manufacture of Antibody Product required for the purposes of Early Stage Development shall be deemed Research and Development Costs of Early Stage Development even if such Antibody Product is manufactured before the filing of an IND.

3.6.3 *Late Stage Development Costs*

All Research and Development Costs cumulatively incurred (whether FTE Cost incurred directly by Amgen or Celltech or amounts payable to Third Parties engaged by Celltech or Amgen) for Late Stage Development of Antibody Products shall be shared as follows:

(a) up to [*] Dollars ($[*]) of such cumulative Research and Development Costs, on the basis of [*]:[*] Amgen:Celltech; and

(b) over [*] Dollars ($[*]) of such cumulative Research and Development Costs, on the basis of [*]:[*] Amgen:Celltech.

The costs of manufacture, including scale-up and validation of Antibody Raw Material and Antibody Product in Finished Form, shall be deemed Research and Development Costs of Late Stage Development to the extent only that Antibody Raw Material and Antibody Product in Finished Form so produced is not used for Commercialisation and otherwise shall be a Cost of Goods.

3.6.4 *Quarterly Reconciliation of Research and Development Costs*

(a) At least [*] prior to the end of each Calendar Quarter, each Party shall submit to the other Party: (i) a report of the actual Research and Development Costs incurred by such Party in the first [*] of such quarter; and (ii) an estimate of Research and Development Costs to be incurred in the [*] of such quarter.

(b) Within [*] following the end of each Calendar Quarter, Amgen shall submit to Celltech a written report setting forth in reasonable detail (to the extent made or incurred by Amgen) its Research and Development Costs for such quarter showing, on a line item basis, variances from the budget for that quarter, together with an estimate of Research and Development Costs for the remainder of that Contract Year.

(c) Within [*] following the end of each Calendar Quarter, Celltech shall submit to Amgen a written report setting forth in reasonable detail (to the extent made or incurred by Celltech) its Research and Development Costs for such quarter showing, on a line item basis, variances from the budget for that quarter, together with an estimate of Research and Development Costs for the remainder of that Contract Year.

(d) Within [*] following the end of each Calendar Quarter, Amgen shall submit to Celltech a written consolidated report setting forth in reasonable detail the calculation of all Research and Development Costs and the calculation of any net amount owed by Celltech to Amgen or by Amgen to Celltech, as the case may be, in order to ensure the appropriate sharing of Research and Development Costs in accordance with the provisions of Article 3.6.1 or 3.6.2 or 3.6.3 as appropriate. The net amount payable shall be paid by Amgen or Celltech, as the case may be, within [*] after receipt of such written report. If the invoiced amount exceeds the initial budget forecast for such quarter (as provided in Article 3.5) by more than [*] ([*]%), the paying Party may elect to carry the difference between the budgeted amount and the invoiced amount over to the next Calendar Quarter. The election to carry the difference over must be provided within [*] after the date such above-referenced written report is provided by Amgen to Celltech. If, as a result of carrying over such difference to a subsequent quarter, the total amount payable in that subsequent quarter exceeds the initial budget forecast for that quarter by more than [*] ([*]%), the difference between the budgeted amount and the invoiced amount (including the carryover from the previous quarter) may be carried over to the next quarter. Such carry over may be continued quarter-by-quarter to the end of the Contract Year when it shall be paid in full within ten (10) Business Days of the receipt of the above-referenced report by Celltech from Amgen at the end of the Contract Year.

3.6.5 *Pre-Launch Commercialisation Cost*. Each Party shall provide the Joint Development Committee with a good faith preliminary estimate of its pre-launch Commercialisation Costs of an Antibody Product on or about the date Amgen provides written notice to Celltech that it intends to proceed with Late Stage Development activities with respect to such Antibody Product.

3.7 **Governance of Research and Development.**

3.7.1 *Research*

(a) Promptly after the Effective Date the Parties shall form a Joint Research Committee to co-ordinate the Research activities of the Parties. The Joint Research Committee shall consist

of equal numbers (not more than three) from each Party. Either Party may (with the consent of the other Party not to be unreasonably withheld or delayed) invite additional participants from either Party to provide expert opinions for some or all of the meetings.

(b) Meetings of the Joint Research Committee shall be held at least every three (3) months and shall be held more frequently if reasonably requested by either Party. Meetings which are held in person shall be held alternately at Amgen and Celltech locations (with the first meeting to be held at a Celltech location). Meetings may take place by videoconference or similar means if agreed by both Parties. Promptly following the Effective Date the Joint Research Committee shall hold an organisational meeting to establish its operational requirements. At each scheduled Joint Research Committee meeting each Party shall present a detailed report showing any progress on its Research activities since the previous scheduled meeting of the Committee.

(c) The Joint Research Committee generally shall have the responsibility of managing, directing and overseeing Research including the following responsibilities:

(i) modifying the Research Plan, as appropriate;

(ii) co-ordinating the Research activities of both Parties in accordance with the Research Plan, so as to identify Antibody Products suitable for Development;

(iii) agreeing Antibody Product candidates (including whether to select a [*] Antibody and/or [*] Antibody) for filing of an IND; and

(iv) agreeing key decisions required in order to progress the Research and the appropriate criteria to be met in reaching such decisions.

(d) [*] shall appoint from amongst its representatives a chairperson of the Joint Research Committee with the responsibility to arrange meetings in accordance with this Agreement and to prepare and distribute the minutes of all key decisions made by the Joint Research Committee. Such minutes shall be distributed by the chairperson within ten (10) Business Days of each Joint Research Committee meeting. Minutes shall be approved or disapproved and revised if necessary at the next meeting.

(e) A primary objective of the Joint Research Committee is to reach unanimous decisions, with the representatives of each Party who are members of the Joint Research Committee

collectively having one (1) vote, arrived at through open discussions amongst the representatives of each of the Parties. In the event of a tied vote, the [*] shall, after giving due consideration to the views expressed by both Parties, have [*] in all matters, except the following ("**Excepted Matters**"):

(i) changes in the direction of Research and Development from the [*] to an [*] as the initial indication for which to file an IND;

(ii) [*]. [*] will not, having regard to the potential impact of any proposed change on [*], unreasonably withhold or delay its consent to any reasonable change proposed by [*];

(iii) changes in the Research Plan that represent a major change in the scope or direction of the Research Plan. [*] will not, having regard to the potential impact of any proposed change on [*], unreasonably withhold or delay its consent to any reasonable change proposed by [*]; or

(iv) any changes to the then-approved [*] as set out in [*].

In the event of a tied vote on an Excepted Matter, the Joint Research Committee shall promptly submit such issue to the Collaboration Committee for resolution. If the Collaboration Committee is unable to resolve such dispute within [*] of submission (in writing) to the Collaboration Committee, such Excepted Matters shall be resolved using the disputes procedure outlined in Article 15.

3.7.2 *Development*

(a) Upon the decision of the Joint Research Committee to file the first IND application for an Antibody Product, the Parties shall form a Joint Development Committee. The Joint Development Committee shall consist of equal numbers (not more than three) from each Party. Either Party may (with the consent of the other Party, not to be unreasonably withheld or delayed) invite additional participants from either Party to provide expert opinions for some or all of the meetings. Meetings of the Joint Development Committee shall be held at least every six (6) months and shall be held more frequently if reasonably requested by either Party. If agreed between the Parties at any time, the Joint Development Committee may assume any residual responsibilities of the Joint Research Committee, and the latter may then be disbanded.

(b) Meetings of the Joint Development Committee which are held in person shall be held alternately at Amgen and Celltech locations (with the first meeting to be held at an Amgen location). Meetings may take place by videoconference or similar means if agreed by both Parties. At each scheduled Joint Development Committee meeting each Party shall present a detailed report showing any progress on its Development activities since the previous scheduled meeting of the Committee.

(c) The responsibilities of the Joint Development Committee shall be to (i) co-ordinate the Development activities of both Parties; (ii) share information about Development activities and the results thereof; and (iii) establish procedures for the collection, sharing and reporting of adverse event information pursuant to Article 4.6 and relating to the Antibody Products obtained after Regulatory Approval thereof.

(d) [*] shall appoint from amongst its representatives a chairperson of the Joint Development Committee with the responsibility to arrange meetings in accordance with this Agreement and to prepare and distribute the minutes of all key decisions made by the Joint Development Committee. Such minutes shall be distributed by the chairperson within fifteen (15) Business Days of each Joint Development Committee meeting. Minutes shall be approved or disapproved and revised if necessary at the next meeting.

(e) A primary objective of the Joint Development Committee is to reach unanimous decisions, with the representatives of each Party who are members of the Joint Development Committee collectively having one (1) vote, arrived at through open discussions amongst the representatives of each of the Parties. In the event of a tied vote, [*] shall, after giving due consideration to the views expressed by both Parties, have [*] in all matters *provided that* to the extent the matter concerns a Research activity [*] shall not have [*] in respect of the Excepted Matters set out in Article 3.7.1(e).

ARTICLE 4

REGULATORY

4.1 **Rights and Responsibilities through** [*]**.**

(a) The Parties shall fully consult and co-operate with each other on all matters relating to and in communications with Regulatory Authorities and shall use Commercially Reasonable

Efforts to obtain Regulatory Approval for Commercialisation of each Antibody Product and indication in [*] at the earliest possible opportunity. In particular, until Celltech assumes exclusive control for regulatory matters in any country in the Celltech Territory the Parties will co-ordinate all communications with Regulatory Authorities in countries in the Celltech Territory to ensure consistent and clear communication with the Regulatory Authorities in those countries. In addition, each Party will discuss in advance with the other Party any planned communication with any Regulatory Authority in the Celltech Territory, where such communication may affect the activities of the other Party.

(b) When designing and implementing [*] studies Amgen will consult with Celltech and accommodate the requirements of the Celltech Territory within Amgen's [*] studies, to the extent that is practicable. To the extent any such requirements are not accommodated within such Amgen studies, Celltech may conduct such studies as supplemental [*] studies in accordance with Article 3.2.2(b).

(c) Subject to Article 4.1(a) and (b), in each jurisdiction Amgen shall be primarily responsible for all regulatory matters (including communications with Regulatory Authorities) concerning each Antibody Product and each indication with such Antibody Product up to delivery to Celltech of the filed data package in accordance with Article 4.1(d). Notwithstanding the previous sentence, during Development prior to completion of a said data package Celltech shall have the right to communicate with Regulatory Authorities in the Celltech Territory solely for the purposes of Article 4.1(c) (i)-(iv) below:

(i) determining appropriate filing strategies for Drug Approval Applications within the Celltech Territory and matters concerning such Drug Approval Applications;

(ii) planning, designing and conducting supplemental [*] activities as permitted by Article 3.2.2(b)

(iii) planning, designing and conducting Marketing Clinical Studies; and

(iv) with respect to process Development, manufacture and supply of Antibody Raw Material, unless Amgen is the only Manufacturing Lead.

(d) Amgen shall provide Celltech with a copy of and reasonable opportunity to comment on the data package suitable for a Drug Approval Application for each Antibody Product in each

indication intended to be submitted by Amgen to the FDA. Amgen shall provide Celltech with a copy of such data package when filed and with any subsequent data packages filed in such indication.

4.2 **Rights and Responsibilities of Territorial Commercial Leads.** On an indication-by-indication basis, as reasonably required, each Territorial Commercial Lead shall have the right to monitor, review and direct all aspects of all regulatory matters to the extent the same concern the activities and studies for which it is responsible pursuant to Article 4.1 with respect to each such Antibody Product, including making all strategic and tactical decisions with respect thereto. Each Territorial Commercial Lead shall have the right and responsibility for the filing of a Drug Approval Application in its own name, including the conformation of the data package provided by Amgen to the requirements of each jurisdiction within its Lead Territory and for seeking Regulatory Approvals for such Antibody Products in its Lead Territory. Notwithstanding the above, pursuant to Article 4.1, Amgen shall remain responsible for all regulatory matters for all Antibody Products for any indication which is not yet the subject of [*].

4.3 **Additional Rights and Responsibilities of Manufacturing Lead.** The Manufacturing Lead in the case of Antibody Raw Material and Amgen in the case of Antibody Products in Finished Form (as appropriate) shall be responsible for obtaining all necessary Regulatory Approvals to enable it to supply the same as specified in Article 6.

4.4 **Co-operation.** Notwithstanding anything to the contrary in this Agreement, each Party shall have the right to receive from the other Party, and each Party shall provide to the other Party, all regulatory data or information which Amgen or the Territorial Commercial Lead is required to submit to a Regulatory Authority (as it is required by law, rule, regulation or a Regulatory Authority having jurisdiction in any part of the Territory to have access) in sufficient time to comment on and consult with each other with respect to the same.

4.5 **Access to INDs.** At the request of Celltech and for the purposes set out in Article 4.1(c), Amgen shall grant Celltech a right of access and reference to (and name it a party of record on) all INDs in such country in the Celltech Territory and shall promptly notify Regulatory Authorities in such country of (and as soon as is reasonably practicable thereafter take all actions reasonably necessary to effect or evidence) the right of access and reference to (and naming Celltech as a party of record on) such INDs.

4.6 **Adverse Event Reporting; Customer Complaints.**

(a) Each Party shall maintain a record of all non-medical and medical product-related complaints and reports of adverse events that it receives with respect to any Antibody Product. Each Party shall notify the other Party of any complaint received by it and, within three (3) days of the initial receipt, shall provide the other Party with a copy of such complaint(s) and adverse event reports. Amgen shall maintain such adverse reaction information in the database described in Article 3.2.2(a).

(b) Except as set forth in Article 4.6(c) below, each Party shall be responsible for reporting to Regulatory Authorities any adverse experience and safety issues for such Antibody Product arising out of its activities and studies, in compliance with the requirements of the laws, rules and regulations in its Territory, and shall promptly thereafter provide the other Party with a copy of such report. If possible, with respect to the Celltech Territory, the other Party shall have an opportunity to review and the Parties shall consult with each other, prior to submission of any such report.

(c) Following the delivery of the filed data package for an Antibody Product to Celltech pursuant to Article 4.1(d), each Territorial Commercial Lead shall be responsible for reporting to Regulatory Authorities, in each country within its Lead Territory, any adverse experience and safety issues for such Antibody Product in the relevant jurisdiction in compliance with the requirements of all applicable laws and regulations in such country and shall promptly thereafter provide the other Party with a copy of such report. Notwithstanding anything to the contrary in this Agreement, the Territorial Commercial Lead shall have the right to receive from the other Party (and the other Party shall provide to the Territorial Commercial Lead) any regulatory data or information Controlled by the other Party which the Territorial Commercial Lead, as the holder of any Drug Approval Application or Regulatory Approval in its Lead Territory, requires by law, rule, regulation or a Regulatory Authority having jurisdiction in its Lead Territory to have access, or which the Territorial Commercial Lead reasonably requires in order to carry out its responsibilities pursuant to this Agreement.

4.7 **Communications.**

(a) In addition to the responsibilities in Article 4.6(c), each Party shall have primary responsibility for all correspondence and for any official communications with Regulatory Authorities in the Territory in respect of the activities and studies for which it is responsible. Each Party shall reasonably co-operate with the other Party regarding any direct communications with the Regulatory Authorities.

(b) Both Parties shall have the right to [*] with Regulatory Authorities having jurisdiction in any part of the Celltech Territory where any matter which may affect the activities or studies of the other Party is to be discussed.

(c) Without prejudice to the other provisions of this Article 4, following delivery of the filed data package to Celltech pursuant to Article 4.1(d), the Territorial Commercial Lead for such country shall have exclusive responsibility for all correspondence in respect of the Antibody Product covered by such data package and for any official communications with Regulatory Authorities in such country regarding its rights and responsibilities under this Article 4 (including submitting Regulatory Filings, seeking Regulatory Approvals, filing annual reports, and filing of Promotional Materials) consistent with all applicable laws and regulations of any such country. Except as may be required by applicable laws and regulations, or requested by the Territorial Commercial Lead or any Regulatory Authority having jurisdiction in such country, the other Party shall not communicate regarding any Antibody Product with any Regulatory Authority having jurisdiction in such country. The other Party shall keep the Territorial Commercial Lead informed of any such required communications.

(d) Regarding the manufacture of any Antibody Raw Material and/or Antibody Product, both Parties shall have the right to [*] with Regulatory Authorities having jurisdiction in the Territory wherein issues regarding the manufacturing of such Antibody Raw Material and/or Antibody Product in Finished Form contained in any Regulatory Filings is to be discussed, where the Party responsible for communications is different from the Party responsible for said manufacturing issues or where required by law or regulation. Notwithstanding the above, and unless Amgen is the Manufacturing Lead, Celltech shall have exclusive responsibility for all correspondence and for any official communications with Regulatory Authorities in the Territory in connection with the supply of Antibody Raw Material and as reasonably required to meet its obligations with respect to any such supply under this Agreement. The Manufacturing Lead with respect to Antibody Raw Material, and Amgen with respect to Antibody Product in Finished Form, shall have the right, to the extent permitted by Regulatory Authorities, to file a drug master file with a Regulatory Authority to make their respective proprietary manufacturing information (e.g., the CMC section contained in any Regulatory Filings) and formulation information available directly to the Regulatory Authority, in order to help preserve the proprietary nature thereof; *provided however*, that the other Party shall have the right of access and reference to the extent required, as a result of its responsibilities

hereunder, by law, rule, regulation or a Regulatory Authority having jurisdiction in the Territory.

(e) Each Party shall promptly notify and provide the other Party with a copy of any correspondence or other reports or complaints submitted to or received by the first Party from any Regulatory Authority or other Third Party claiming that any Promotional Materials are inconsistent with the Product Labelling or are otherwise in violation of any applicable laws and regulations of any country in the Territory.

4.8 **Recalls.**

(a) The Parties shall exchange their internal standard operating procedures as to product recalls ("**SOPs**") reasonably promptly after the first filing of a Drug Approval Application for an Antibody Product and reasonably promptly after such SOPs are approved or modified thereafter. In the event that, in a country, the Territorial Commercial Lead for such country determines that an event, incident or circumstance has occurred which may result in the need for a "recall" or "market withdrawal" or "stock recovery" (as such terms are defined in U.S. regulations in 21 CFR 7.3 or another similar national, state or local law or regulation), hereinafter collectively referred to as a "**Recall**", of Antibody Product or any lot(s) thereof, such Party shall promptly notify the other Party in writing.

(b) The Territorial Commercial Lead shall have the right to determine whether and upon what terms and conditions to Recall the Antibody Product within its Lead Territory; *provided however*, if the Territorial Commercial Lead shall elect not to conduct a Recall of the Antibody Product, and solely if the other Party is responsible for the manufacture of Antibody Raw Material or Antibody Product in Finished Form, and the manufacture of Antibody Raw Material or Antibody Product in Finished Form is the basis of such proposed Recall, the other Party shall have the right to conduct such Recall if, in its good faith opinion, regulatory requirements or public safety considerations so require. Prior to making any Recall decision in any part of its Territory, each Party shall consult with the other Party. The Territorial Commercial Lead shall be responsible for discussions with Regulatory Authorities within the applicable country regarding all aspects of the Recall decision and the execution thereof. Any costs or expenses of any Recall in any part of the Territory shall be a Commercialisation Expense. Celltech and Amgen shall each maintain complete and accurate records of any

Recall it has the right to control pursuant to this Article 4.8 for such periods as may be required by legal requirements, but in any event for no less than [*].

4.9 **Applications for Regulatory Exclusivity.** The Parties recognise that exclusivity rights granted or provided for under regulatory laws of the countries of the Territory may be commercially significant to Antibody Products. To the extent permitted by law, as between the Parties, the Territorial Commercial Lead for a country shall have the exclusive right to file for, request and maintain any regulatory exclusivity rights for Antibody Products in such country (including regulatory exclusivity rights based upon an orphan drug designation of an Antibody Product) and to conduct and prosecute any proceedings or actions to enforce such regulatory exclusivity rights.

ARTICLE 5

COMMERCIALISATION OF ANTIBODY PRODUCTS

5.1 **Territorial Commercial Lead.** The Parties shall Commercialise each Antibody Product in the Territory, with one Party (on a country-by-country basis) being the Territorial Commercial Lead for all Antibody Products in each such country as follows:

(a) Amgen shall be the Territorial Commercial Lead in the Amgen Initial Countries;

(b) Celltech shall be the Territorial Commercial Lead in the Celltech Initial Countries;

(c) With respect to additional countries in the Territory outside the Amgen Initial Countries and the Celltech Initial Countries, at a time [*] prior to the planned filing date for the first Drug Approval Application of an Antibody Product, the Joint Commercialisation Committee shall designate (such designation [*]), between the Parties, the Territorial Commercial Lead in such additional countries (and such countries shall be included within the Lead Territory of the Territorial Commercial Lead), in accordance with the following principles. If at the time the Joint Commercialisation Committee considers the issue:

(i) only one Party wishes to be the Territorial Commercial Lead, that Party shall be designated the Territorial Commercial Lead; if neither Party wishes to be the Territorial Commercial Lead, neither Party shall be designated the Territorial Commercial Lead; if both Parties wish to be the Territorial Commercial Lead, then;

(ii) if only one Party has a [*] that is [*] of the Antibody Product in that country, the Party with such [*] shall be designated the Territorial Commercial Lead in that country;

(iii) if both Parties have a [*] the Antibody Product in that country, the Party best able to exploit the Antibody Product to best advantage in that country (having regard to [*]of the [*]) shall be designated the Territorial Commercial Lead;

(iv) if neither Party has a [*] the Antibody Product the Joint Commercialisation Committee shall consider whether either Party has immediate and funded plans to establish a [*] for that country and any other relevant factors that indicate one Party may be better suited to exploit Antibody Products to best advantage in that country, including management of a Third Party subcontractor pursuant to Article 5.3;

provided that, the Joint Commercialisation Committee shall designate the Territorial Commercial Lead for countries outside the Amgen Initial Countries and Celltech Initial Countries such that the [*] of all Antibody Products from such countries used in the [*] for which such [*], is [*].

(d) If the Joint Commercialisation Committee shall fail, for any reason, to designate the Territorial Commercial Lead in any country where both Parties wish to be the Territorial Commercial Lead, the matter shall be referred to the Collaboration Committee who shall make such designation in accordance with the terms of Article 5.1(c).

(e) In the event a Territorial Commercial Lead is not designated in a country at the time specified in Article 5.1(c) because, at that time, neither Party wished to be the Territorial Commercial Lead in such country, the Joint Commercialisation Committee shall upon receipt of a notice from a Party expressing the wish to be the Territorial Commercial Lead in such country designate such Party as the Territorial Commercial Lead in such country, *provided that* the Joint Commercialisation Committee shall give the other Party a reasonable period (not to [*]) to also serve such a notice. If both Parties serve such a notice, the Joint Commercialisation Committee shall designate the Territorial Commercial Lead in accordance with Article 5.1(c).

(f) The Territorial Commercial Lead shall use Commercially Reasonable Efforts to maximise the Product Contribution of each Antibody Product in its Lead Territory.

5.2 **Co-Detailer.**

(a) In the event a Party is not the Territorial Commercial Lead in a country, such Party shall have the right to deploy a supportive co-Detailing sales force in such country. If such Party exercises that right, in accordance with Article 5.2(c) below, such Party shall be termed the "**Co-Detailer**" in such country.

(b) The Territorial Commercial Lead shall notify the other Party in writing of the date on which it expects to file the first Drug Approval Application for each Antibody Product in each country in its Lead Territory at least [*] prior to each such filing ("**Filing Notice**").

(c) If a Party is not the Territorial Commercial Lead in such country, it shall have the right to notify the Territorial Commercial Lead within [*] of the Filing Notice for such country and such Antibody Product. The notice shall identify the country or countries identified in such Filing Notice where the Party that is not the Territorial Commercial Lead exercises its right to deploy a supportive co-Detailing sales force in such country. The Territorial Commercial Lead shall have the sole right and responsibility to Commercialise in accordance with Article 5 such Antibody Product in any country not identified in the notice (or if no notice is served, in all countries in its Lead Territory) and the Party that is not the Territorial Commercial Lead shall have no further right to co-Detail in such country.

5.3 **Third Parties.** The Territorial Commercial Lead may determine that the services of a Third Party are required or desirable to Commercialise an Antibody Product in any country in its Lead Territory. The Territorial Commercial Lead shall be free to enter into an agreement with such Third Party on arm's-length terms; *provided that* such terms shall be consistent with the terms of this Agreement so as to preserve the rights of the other Party in such country including the right (if any) of such Party to co-Detail pursuant to Article 5.2, and *provided that* in the reasonable estimation of the Territorial Commercial Lead, in such country, [*] in the absence of such agreement. The Territorial Commercial Lead shall, in entering into such agreement, be entitled to grant such Third Party any licences or sublicences to [*] Technology or [*] Technology required by the Third Party solely to Commercialise an Antibody Product in such country. The Net Sales from and the costs incurred by a Party in such Third Party arrangement shall be included in calculating the Product Contribution for such Antibody Product in such country.

5.4 **Joint Commercialisation Committee Formation.** Immediately following [*], the Parties shall establish a Joint Commercialisation Committee to facilitate the Commercialisation of Antibody

Products on a global basis. The Joint Commercialisation Committee shall be comprised of an equal number of Celltech and Amgen representatives (not to exceed three (3) from each Party), with each Party having one vote. The Joint Commercialisation Committee shall meet at times to be agreed and, commencing no later than [*] before the expected date for the first filing of the first Drug Approval Application, at least quarterly. In addition, the Joint Commercialisation Committee shall appoint a chairperson and otherwise follow the organisational and meeting procedures set forth in Article 9 with respect to the Collaboration Committee.

5.5 **Joint Commercialisation Committee and Territorial Commercial Lead Responsibilities.**

(a) Each Territorial Lead has the right and responsibility to Commercialise Antibody Product in the manner it deems appropriate, but subject always to its obligations under this Agreement including those set out in this Article. If the Joint Commercialisation Committee determines that any Commercialisation activities should be conducted jointly or on a co-ordinated basis, such activities shall be co-ordinated through the Joint Commercialisation Committee. The Parties now agree that it is likely they will wish to co-ordinate the following matters, and that unless and until one Party objects to the Joint Commercialisation Committee determining any or all such matters, and subject always to Article 5.7, the Joint Commercialisation Committee shall be responsible for:

(i) co-ordination of the Commercialisation of Antibody Products throughout the Territory in accordance with the Commercialisation Plan;

(ii) addressing strategic issues with relevance throughout the Territory (e.g., branding, regulatory issues, product positioning);

(iii) deciding any activities that the Parties shall undertake jointly in order to Commercialise Antibody Products on a worldwide basis (e.g. pre-launch activities, market research, launch, and post-launch marketing and promotion) ("**Joint Activities**");

(iv) co-ordinating Marketing Clinical Studies;

(v) co-ordinating the packaging, labelling and language to be included in the package insert;

(vi) co-ordinating commercial manufacturing production requirements;

(vii) selecting, obtaining and maintaining generic names and Product Trademarks and domain names incorporating any of the same or otherwise referencing Antibody Products;

(viii) developing and updating a Commercialisation Plan pursuant to Article 5.8; and

(ix) resolving any complaint by a Party that the activities of the other Party are adversely affecting the Commercialisation of Antibody Product in the Lead Territory of the Party making the complaint;

provided however, and subject to Article 5.7, in the event that the Joint Commercialisation Committee is unable to agree on any such matters within its authority, that particular matter shall at the written request of either Party, be removed from the responsibility of the Joint Commercialisation Committee and the Territorial Commercial Lead shall (to the extent such matters concern its Lead Territory only) determine such matters for its Lead Territory.

(b) The Territorial Commercial Lead shall be responsible in each country in its Lead Territory for determining the Commercialisation of Antibody Product in a manner consistent with the Commercialisation Plan (if any), including:

(i) tactical issues, for example, sales force allocation and disposition;

(ii) determining Promotional Materials suitable for each such country; and

(iii) preparing and implementing a Country Plan (as defined in Article 5.9 below) and monitoring budgets and forecasts for each such country; and

(iv) booking sales of Antibody Products, taking orders, distributing Antibody Product, handling returns, and contracting and administering accounts.

5.6 **Decision Making.** A primary objective of the Joint Commercialisation Committee shall be to reach unanimous decisions (with each Party having one (1) vote), arrived at through open discussions amongst the representatives of each of the Parties. All decisions of the Joint Commercialisation Committee shall be made by the unanimous decision of Celltech and Amgen (subject to Article 5.7), with the representatives of each Party who are members of the Joint Commercialisation Committee collectively having one vote in any matter. The Parties agree that all decisions regarding the Commercialisation of an Antibody Product will be made in the interests of securing the best value from the Antibody Product on a global basis.

5.7 **Dispute Resolution.** If the Joint Commercialisation Committee shall have a disagreement with respect to any issue (including those set forth in Article 5.1(c) and 5.5(a), or should a Party wish to remove any matter set out in Article 5.5(a) from the responsibility of the Joint Commercialisation Committee, such issue shall be promptly submitted in writing to the Collaboration Committee for resolution. If the Collaboration Committee is unable to agree on the resolution of such dispute within [*] of such written submission to the Collaboration Committee:

(i) the matter, if an issue set forth in [*], shall be promptly submitted in writing to [*]. If following discussion between them, the [*] are unable to agree a resolution of the matter within [*] after the matter has been submitted to them, the Territorial Commercial Lead for any country shall determine such issue with respect to any [*]; or

(ii) the matter, if relating to any other issue, shall be determined by [*].

5.8 **Commercialisation Plan.**

Pursuant to Article 5.5(a), the Joint Commercialisation Committee shall develop a Commercialisation Plan for each Antibody Product which shall:

(i) outline the overall strategy for the Commercialisation of each Antibody Product throughout the Territory;

(ii) adopt a budget for any Joint Activities;

(iii) consolidate the budgets of each Territorial Commercial Lead; and

(iv) address any other issue where the Parties wish to adopt a co-ordinated approach throughout the Territory.

The Commercialisation Plan shall be first developed and approved by the Joint Commercialisation Committee no later than [*] before it is expected to file the first Drug Approval Application for an Antibody Product and shall be updated and approved as deemed necessary but at least annually, in time for the annual budget cycle of each of the Parties.

5.9 **Country Plans.** In each country, the Territorial Commercial Lead for such country, in consultation with the Co-Detailer (if any) of that country, shall develop a commercialisation plan and budget ("**Country Plan**") for such country setting out the work activities, including the number of Details and the Position of Detail to be carried out in such country in the following year, in a manner consistent

with the Commercialisation Plan, but taking into account the specific circumstances appropriate to the Commercialisation of such Antibody Product in such country. The Country Plan shall be developed to a standard and timing consistent with other products marketed by the Territorial Commercial Lead in that country. In the event of any dispute between the Territorial Commercial Lead and the Co-Detailer on any matter relating to the Commercialisation of an Antibody Product in that country, the Territorial Commercial Lead shall, after taking due consideration of the views expressed by the other Party, determine the resolution of such matter. Any dispute regarding whether or not a Country Plan is consistent with the Commercialisation Plan shall, at the request of either Party, be determined by the Joint Commercialisation Committee, subject to Article 5.7.

5.10 **Implementation of Commercialisation Plan and Country Plan.** Once the Commercialisation Plan has been approved by the Joint Commercialisation Committee, or if the Joint Commercialisation Committee fails to approve a Commercialisation Plan, the Territorial Commercial Lead with respect to its Lead Territory shall be free to Commercialise an Antibody Product in each country in such Lead Territory, in such manner that they reasonably deem appropriate in accordance with the Country Plan for such country; *provided however*, that neither Party shall undertake any activity that is inconsistent with such Commercialisation Plan (if any) or with its obligation to use Commercially Reasonable Efforts to maximise the value of the Antibody Product on a global basis.

5.11 **Co-Detailing.** The Co-Detailer's right to support the Territorial Commercial Lead in a country shall include the following terms and conditions.

(a) The Co-Detailer's sales force shall be deployed as determined by the Territorial Commercial Lead (e.g., whether or not such supportive sales force representatives shall double call on customers already called on by sales force representatives of the Territorial Commercial Lead).

(b) The Co-Detailer's sales force shall jointly Detail with the sales force of the Territorial Commercial Lead under a single Product Trademark in accordance with the Country Plan including being trained by and using the field sales force materials (including Promotional Materials) of the Territorial Commercial Lead and systems compatible with the systems of the Territorial Commercial Lead.

(c) On an Antibody Product-by-Antibody Product and indication-by-indication basis, the planned level of Detailing effort conducted by the Co-Detailer's sales force for an Antibody Product in an indication shall be [*] ([*]%) (or such lesser percentage as the Co-Detailer may agree) of the planned level of Detailing effort of the [*] for that Antibody Product and indication in

any Contract Year.

(d) Subject to (c) above the Territorial Commercial Lead shall determine the minimum level of effort and resources the Co-Detailer is directed to commit to individual field activities under this Article 5.11, provided the Co-Detailer shall not be required to provide overall effort and resources that exceed the generally proportional level of effort and resources of the Territorial Commercial Lead, having regard to the relative number of sales representatives deployed by the Co-Detailer in relation to the total number of sales representatives deployed by both Parties in such country, pursuant to the Country Plan for such country.

(e) Except with the prior written consent of the Territorial Commercial Lead, all sales representatives of the Co-Detailer Detailing an Antibody Product shall be [*]. Notwithstanding Article 5.11(g) below, if any sales representative of the Co-Detailer is not competent or qualified to carry out the Co-Detailer's responsibilities pursuant to this Article 5.11, the Territorial Commercial Lead (at its discretion, after consultation with the Co-Detailer) may require the Co-Detailer to remove such sales representative from the Detailing of all Antibody Products.

(f) If an Antibody Product is returned to the Co-Detailer, it shall promptly be shipped to the facility responsible for shipment of Antibody Products in the country in question, to the attention of a department or another location as may be designated by the Territorial Commercial Lead.

(g) Neither Party shall have any responsibility for the hiring, firing or compensation of the other Party's employees or for any employee benefits. No employee or representative of a Party shall have any authority to bind or obligate the other Party to a Third Party for any sum or in any manner whatsoever, without said first Party's written approval.

(h) Upon the other Party's request and to the extent permitted by law, regulation or Regulatory Authorities in such a country, the other Party's corporate name and logo shall be included on Promotional Materials and Product Labelling in positions of equivalent prominence and frequency with the corporate name and logo of the Territorial Commercial Lead. In order to maintain the value of the other Party's corporate name and logo, when using the other Party's corporate name and logo, the Territorial Commercial Lead shall maintain such reasonable quality standards as it maintains for its own corporate name and logo and shall comply with the other Party's then-current policies regarding use of its corporate name and logo (as applied to products marketed by the other Party in that country); *provided however*, that such policies

are consistent with the first sentence of this Article 5.11(h). Prior to the use thereof, the Territorial Commercial Lead shall provide to the other Party a prototype of any Promotional Materials or Product Labelling which contains the other Party's corporate name and logo, so that the other Party may review the manner in which its corporate name and logo are used therein. The other Party shall notify the Territorial Commercial Lead within thirty (30) days after delivery of such prototype as to whether the other Party approves or disapproves of the manner of such use and, in the case of disapproval, the specific reasons therefor and an acceptable alternative. In the event the other Party fails to so notify the Territorial Commercial Lead within such thirty (30) day period, the other Party shall be deemed to have approved the manner of such use.

5.12 **Commercialisation Budget.**

(a) Prior to the First Commercial Sale and before the end of each Contract Year following the First Commercial Sale, at a time to be agreed by the Joint Commercialisation Committee, but consistent with the annual budget cycles of each Party, each Party shall provide the Joint Commercialisation Committee with a budget of expected Commercialisation Expenses and forecasted revenue (calculated as set forth in Schedule B) for the ensuing Contract Year for that Party's Lead Territory. Such budget shall be in a form to be agreed by the Joint Commercialisation Committee and shall, unless agreed otherwise by the Joint Commercialisation Committee, be prepared by each Party as a consolidation of the individual budgets for each country in such Party's Lead Territory. For the avoidance of doubt, each budget prepared by a Territorial Commercial Lead will be provided to the Joint Commercialisation Committee for its information but not for its approval. The Joint Commercialisation Committee shall also agree a budget for and agree on an allocation of responsibilities between the Parties for any Joint Activities on which the Parties agree for the ensuing year.

(b) The Joint Commercialisation Committee shall review on a quarterly basis the Commercialisation Expenses actually incurred against the budget for such expenses in the applicable calendar year and will consider for approval any appropriate changes to such budget. If in the course of the quarterly review, the Joint Commercialisation Committee should determine for any Antibody Product that the actual amounts incurred are, in the aggregate, likely to be greater than [*] ([*]%) of the amount budgeted, the Joint Commercialisation Committee shall review the reasons for such potential overrun and

determine whether such overrun is appropriate. If the Joint Commercialisation Committee determines that such overrun is appropriate, the Joint Commercialisation Committee shall approve a revised Commercialisation budget. If the Joint Commercialisation Committee determines that such overrun is not appropriate, the Joint Commercialisation Committee shall initiate (within [*]) such actions as required to remedy the situation. If the Joint Commercialisation Committee is unable to agree on any matter relating to said overrun, [*].

5.13 **Public Statements Regarding Antibody Products.** Each Party shall be responsible for disseminating accurate information regarding any Antibody Product to its sales representatives based on Product Labelling and Promotional Materials. In exercising their rights pursuant to this Article 5, Celltech and Amgen shall ensure that no claims or representations in respect of the Antibody Products or the characteristics thereof (e.g., safety or efficacy) are made by or on behalf of it (by members of its sales force or otherwise) which do not represent an accurate summary or explanation of the Product Labelling of the Antibody Product in the country in question.

5.14 **Medical and Other Inquiries.** The Territorial Commercial Lead shall be responsible for responding to all medical questions or inquiries relating to the Antibody Products sold in countries in its respective Lead Territory, except that the Co-Detailer, in the course of carrying out its activities under Article 5.11(c), may respond to any such question or inquiry which can be answered by reference to the Product Labelling and package insert in the applicable country. The Territorial Commercial Lead shall designate a medical liaison to whom the Co-Detailer shall instruct its medical affairs group, as well as its sales forces engaged in the Detailing of Antibody Products, to direct medical questions or inquiries relating to the Antibody Products. The Territorial Commercial Lead shall keep such records and make such reports as are reasonably necessary to document such communications in compliance with all applicable regulatory requirements.

5.15 **Compliance with Laws.**

(a) Each Party agrees to comply with all applicable laws, regulations and rules with respect to the Commercialisation of Antibody Products and in all material respects to conform its practices and procedures with the recommended industry practices and procedures applicable to the relevant part of the Territory, as the same may be amended from time to time. Each Party shall use Commercially Reasonable Efforts to conduct its business operations and shall use Commercially Reasonable Efforts to cause each of its employees, representatives and

agents to do nothing which such Party knows or reasonably should know would jeopardise the good will or reputation of the other Party or the Antibody Products.

(b) Neither Party shall be required to undertake any activity relating to the Commercialisation of Antibody Products that it believes, in good faith, may violate any law.

(c) To the extent that a Party's sales force engages in the distribution of samples of Antibody Products pursuant to any activities conducted pursuant to this Agreement, that Party shall ensure that all such activities are conducted in a manner which conforms to this Agreement, the Country Plan and all applicable laws.

(d) In addition to its responsibilities under Article 4.7(e), the other Party shall promptly notify the Territorial Commercial Lead of and provide the Territorial Commercial Lead with a copy of any correspondence or other reports with respect to the Detailing or Promotion of Antibody Products submitted to or received from any Regulatory Authority or industry association in the relevant part of the Territory. Each Party shall in all material respects conform its practices and procedures relating to educating the medical community in the relevant part of the Territory with respect to Antibody Products to any applicable Regulatory Authority or industry association regulations, policies and guidelines, as the same may be amended from time to time, and the other Party shall promptly notify the Territorial Commercial Lead of and provide the Territorial Commercial Lead with a copy of any correspondence or other reports submitted to or received from any such Regulatory Authority or industry association with respect to Antibody Products.

5.16 **Detailing Reports.**

(a) For information purposes, each Party shall, at country level, provide the other Party with current reports giving detailed information on [*]. Such Detailing reports and any other relevant sales force information related to such Antibody Product shall be provided to the other Party [*].

(b) No later than forty-five (45) days after the conclusion of each Calendar Quarter after First Commercial Sale of an Antibody Product in each country, each Party shall submit to the other Party a report, based upon such Party's internal Detailing report data, setting forth the [*] or otherwise as required by the Country Plan. Except as set forth in Article 5.16(c) below, for purposes of this Agreement the number of Details and Position of Detail for an Antibody

Product performed by the first Party for a given Calendar Quarter shall be based on such first Party's internal Detailing report data.

(c) Each Party agrees, if requested by the other Party, to make available to independent accountants nominated by the other Party (subject to the approval of the Party receiving the request, such approval not to be unreasonably withheld or delayed), upon reasonable advance notice, such books and records necessary to verify the accuracy of such report in respect of any Calendar Quarter ending not more than [*] prior to the date of such request. Upon expiration of [*] following the end of any Contract Year, the report reflecting such Party's Details for such Antibody Product for such Contract Year shall be binding on the other Party, and such Party shall be released from any liability or accountability to the other Party with respect to the number of Details given during such Contract Year unless prior to such expiration the other Party has notified the first Party of an issue regarding such audit report (arising from such inspection) pursuant to this Article 5.16(c).

(i) If, after an audit, the other Party has a good faith concern with the accuracy of the [*] of Details reflected by the first Party's internal Detailing report data, based on the other Party's assessment of such data when compared to available Third Party audit data, sampling data (if applicable) or other relevant data relating to the first Party's Detailing of such Antibody Product, then the other Party shall so advise the first Party of such concern, and promptly thereafter the other Party and the first Party's representatives shall consider in good faith whether the [*] of Details reflected by the first Party's internal Detailing report data are accurate and, if not, whether an adjustment to the [*] of Details of such Antibody Product performed by the first Party for such Calendar Quarter is appropriate.

(ii) If such representatives referred to in Article 5.16(c)(i) are unable to resolve the matter, either Party may (by notice to the other Party) have the dispute referred to the [*] of each Party, or their designees, for attempted resolution by good faith negotiations for a period of not more than [*] after such notice is received or such other period of time as may be mutually agreed upon by the Parties to determine whether an adjustment to the [*] of the first Party's Details for Antibody Product in such Calendar Quarter is appropriate.

(iii) If the Parties are unable to resolve the matter after such negotiation as provided in Article 5.16(c)(ii), then such dispute regarding the [*] of the first Party's Details for Antibody Product in such Calendar Quarter shall be referred for final resolution to an independent market research firm or another expert, mutually acceptable to the Parties. The fees that such market research firm or other expert, shall be paid in connection with such resolution shall be charged to the Product Contribution account as a Commercialisation Expense. The settlement of such dispute by such market research firm or other expert shall, after each Party has been given the reasonable opportunity to present written evidence, be binding upon the Parties, and shall be to the exclusion of any court of law with respect to proceedings based solely on such dispute (it being understood that such matter is not within the Collaboration Committee's authority).

5.17 **Post-Regulatory Approval Activities.** The Territorial Commercial Lead shall have the right to conduct all activities for Marketing Clinical Studies in its Lead Territory.

ARTICLE 6

MANUFACTURE AND SUPPLY

6.1 **Manufacturing.**

(a) Celltech shall use Commercially Reasonable Efforts to procure the supply of Antibody Raw Material for Development and Commercialisation and, in so doing, shall be responsible for using Commercially Reasonable Efforts to:

(i) identify one or more suitable Third Party suppliers of Antibody Raw Material;

(ii) negotiate the terms of and enter into agreements ("**Supply Agreements"**) with one or more of such Third Party suppliers for the supply of Antibody Raw Material to meet the Development and Commercialisation requirements of the Parties as set forth in Article 6.4; and

(iii) manage the relationship with and require any such Third Party supplier(s) to fulfill the responsibilities of the Manufacturing Lead as set forth in this Agreement.

Such Third Party supplier or suppliers is herein referred to as the "**Manufacturing Lead**" for Antibody Raw Material, unless a Party assumes manufacture of Antibody Raw Material

pursuant to Article 6.7 below, in which case such Party shall be responsible for the supply of Antibody Raw Material and shall be designated the "Manufacturing Lead".

(b) Amgen shall use Commercially Reasonable Efforts to procure the supply (itself and/or through a Third Party subcontractor) of Antibody Product in Finished Form. To the extent Amgen uses a Third Party subcontractor to supply Antibody Product in Finished Form the terms of Articles 6.1(a)(i)-(iv) and 6.2(b), as they relate to agreement with any such Third Party subcontractor, shall apply mutatis mutandis to the supply of Antibody Product in Finished Form.

6.2 **Manufacture of Antibody Products for Development.**

(a) With respect to each Antibody Product selected to be advanced to [*], the Manufacturing Lead shall be responsible for [*] and for [*], Antibody Raw Material for use in all pre-clinical studies, formulation, development studies and clinical studies in the Territory, in quantities (as forecast by Amgen) and with the specifications agreed between the Parties.

(b) Development Supply Agreements shall have terms and conditions as are customary in transactions of this type and reasonable under all of the circumstances. The terms and conditions of such Development Supply Agreements shall include the cost and specification of the Antibody Raw Material, the quality standards and the method of forecasting demand to be used during Development.

(c) Amgen shall be responsible for [*] Antibody Product in Finished Form, including [*], for all pre-clinical studies, formulation, development studies and clinical studies in the Territory, in quantities (as forecast by the Parties) and with the specifications agreed between the Parties.

6.3 **Manufacture of Antibody Product(s) for Commercialisation.**

(a) With respect to each Antibody Product receiving Regulatory Approval for Commercialisation, the Manufacturing Lead shall be responsible for [*] Antibody Raw Material for commercial use in the Territory (in quantities as forecast in the Commercialisation Plan and with specifications set forth in the Regulatory Approval of such Antibody Raw Material). Commercialisation Supply Agreements shall have terms and conditions as are customary in transactions of this type and reasonable under all circumstances. The terms and conditions of such Commercialisation Supply Agreements shall include the cost and specification of the

Antibody Raw Material, commercial quality standards and the method of forecasting demand to be used during Commercialisation.

(b) Amgen shall be responsible for [*] Antibody Product in Finished Form and [*] Antibody Product in Finished Form in quantities (as forecast in the Commercialisation Plan) and with specifications set forth in the Regulatory Approval of such Antibody Product.

(c) The Parties shall agree procedures and terms for the transfer of title in Antibody Products to the Territorial Commercial Lead prior to the sale thereof in its Lead Territory.

6.4 **Third Party Manufacturers.** Celltech shall not enter into any Supply Agreement with a Third Party for Antibody Raw Material as specified in this Article 6 without first obtaining the consent of Amgen to such agreement (such consent not to be unreasonably withheld or delayed). Celltech shall use Commercially Reasonable Efforts to ensure that, in addition to the terms set forth in Articles 6.2 and 6.3 (as appropriate), such Supply Agreement shall contain terms that, in the event that either Celltech or Amgen assumes exclusive responsibility for manufacture and supply of Antibody Raw Material pursuant to Article 6.7, will grant Celltech the right to (a) terminate such agreement on reasonable notice with respect to Antibody Raw Materials, (b) have transferred to Amgen or Celltech (as appropriate) and to receive assistance reasonably required by Amgen or Celltech (as appropriate) to effect transfer of the Third Party's Information relating to the manufacture and analysis of Antibody Raw Material in sufficient detail for Amgen or Celltech (as appropriate) to implement the [*] of such[*], including Information contained in the [*] of any applicable Regulatory Filings and the results of any stability studies performed on Antibody Raw Material, (c) have provided Amgen or Celltech (as appropriate) such Information pertaining to the manufacture and analysis of Antibody Raw Material as Amgen or Celltech (as appropriate) shall reasonably request; (d) if requested by Amgen or Celltech (as appropriate), obtain reasonable assistance in the manufacture of trial batches of Antibody Raw Material to enable Amgen or Celltech (as appropriate) to determine its ability to manufacture Antibody Raw Material; (e) audit in accordance with Article 6.6; (f) obtain copies of any direct communications by or to the Manufacturing Lead from Regulatory Authorities having jurisdiction in the Territory regarding and concerning the manufacture of any Antibody Product and (g) name Amgen as a permitted assignee or sublicensee.

Once Amgen has given such consent, Amgen shall be deemed to have accepted the terms of such Third Party Supply Agreement. Both Parties shall comply and operate in accordance with the terms of any such Supply Agreement accepted by Amgen and entered into by Celltech. To the extent the

same relates to Antibody Product, all (i) out-of-pocket costs, expenses and liabilities (calculated on an arm's-length basis in accordance with GAAP), (ii) FTE Cost and (iii) cost of Materials used, which are incurred by Celltech in discharging its obligations pursuant to this Article 6 shall be Research and Development Costs if incurred for Development and a Commercialisation Expense if incurred for Commercialisation, and all amounts recovered from any Third Party supplier shall be credited to Product Contribution revenues, *provided however*, that if the costs, liabilities and/or amounts recovered are also applicable to products other than Antibody Products, then only an equitable portion of such costs, liabilities and/or amounts recovered shall be so allocated. The sharing of liabilities under any Third Party Supply Agreement is without prejudice to Article 18. In the event that Amgen obtains supply of Antibody Product in Finished Form from a Third Party, costs, liabilities and/or amounts recovered shall also be allocated to Research and Development Costs or Commercialisation Expenses mutatis mutandis.

6.5 **Standards of Supply.** Antibody Raw Material, in the case of the Manufacturing Lead, and Antibody Products in Finished Form, in the case of Amgen, shall be manufactured in accordance with current GMP in manufacturing processes and facilities as described in the applicable Regulatory Filings submitted to and approved by the Regulatory Authority.

6.6 **Audit.** Each Party, to the extent it is not the Manufacturing Lead, shall have the right to conduct reasonable quality assurance audits with respect to all facilities, operations and laboratories (and any records related thereto) of the other Party or its subcontractors (*provided that*, where the Manufacturing Lead is a Third Party, only to the extent permitted by the relevant Supply Agreement), where applicable manufacturing activities are conducted, as is reasonably necessary to verify the Manufacturing Lead's conformance (or Amgen's conformance with respect to Antibody Product in Finished Form) with cGMP, cGLP, cGCP and other regulatory requirements. Such audits shall be conducted upon reasonable notice during reasonable business hours.

6.7 **Manufacturing Option.**

(a) At any time during Development or Commercialisation and subject to any commitments already made to any Third Party supplier either Party may seek to manufacture and supply Antibody Raw Material by providing written notice to the other Party and the Collaboration Committee that it wishes to assume manufacture and supply of the Antibody Raw Material for the Territory or its Lead Territory. Within [*] after receipt of such request, the other Party

shall have the right to provide reciprocal notice of its desire to manufacture and supply Antibody Raw Material.

Thereafter, the Collaboration Committee shall promptly meet to consider any and all requests and determine ([*]) whether one or both of the Parties should have the right and obligation to manufacture and supply Antibody Raw Material, applying the following criteria:

(i) the FAMC resulting from the requesting Party's manufacturing is likely to be less than the actual or probable FAMC as invoiced by the Third Party manufacturer or, if both Parties desire to assume such responsibility, the probable FAMC as between the Parties;

(ii) other benefits, such as stability of supply or quality of product, are like to accrue to both Parties as a result of manufacture of Antibody Raw Material by the requesting Party or Parties;

(iii) a Third Party manufacturer for Development or Commercialisation supplies has not been identified or such Third Party manufacturer is unable or unwilling to enter into a Supply Agreement on terms reasonably satisfactory to both Parties;

(iv) the desirability of a second (or further) source of supply of Antibody Raw Material;

(v) that the Third Party manufacturer is in material breach of its supplier obligations and that as a result of such breach, the requesting Party or Parties should assume manufacture and supply of Antibody Raw Material; or

(vi) the cost and difficulty of enforcing the relevant Supply Agreement to enable one or both Parties to manufacture and supply Antibody Product.

(b) If the Collaboration Committee determines that, after applying the foregoing criteria, in total it would be beneficial to the interests of both Parties that the requesting Party or Parties manufacture and supply Antibody Raw Material, the selected Party or Parties shall have the right and obligation to manufacture and supply Antibody Raw Material for either the Territory or its Lead Territory as determined by the Collaboration Committee. Upon selection of a Party, then

(i) If Amgen is the selected Party, Celltech shall itself transfer any Information Controlled by Celltech, and Celltech shall use the level of effort determined by the Collaboration Committee to enforce (or, at the request of Amgen and to the extent permitted by the

terms of the Supply Agreement assign to Amgen the right to enforce) the terms and conditions of the Third Party Supply Agreement entered into by Celltech pursuant to Article 6.4 including (but only to the extent permitted by the Supply Agreement with such Third Party) the provision to Amgen of any Information and assistance reasonably required by Amgen from such Third Party pertaining to the manufacture and analysis of Antibody Raw Material with the objective of Amgen being enabled to implement the [*] of [*], including Information contained in the [*] of any applicable Regulatory Filings and the results of any stability studies performed by or on behalf of Celltech; and

(ii) If Amgen is the selected Party, Celltech shall, at the request of Amgen, use the level of effort determined by the Collaboration Committee to enforce (or, to the extent permitted by the Supply Agreement with such Third Party assign to Amgen the right to enforce) the terms and conditions of the Third Party Supply Agreement entered into by Celltech pursuant to Article 6.4 (but only to the extent such terms are included in any such Supply Agreement, and only to the extent such Supply Agreement relates to Antibody Raw Material) including termination of the Third Party Supply Agreement on reasonable notice (but only if the Collaboration Committee has determined Amgen shall have the exclusive right and obligation to manufacture and supply Antibody Raw Material); and

(iii) The Parties (as appropriate) shall continue to work with the Third Party supplier in order to achieve the manufacturing transition or second sourcing with minimal disruption, and to ensure adequate supplies of Antibody Raw Material during the transitional process; and

(iv) The Party or Parties assuming the obligation to manufacture and supply Antibody Raw Material Party shall use Commercially Reasonable Efforts to put all necessary manufacturing processes in place so as to be able to meet Development or Commercialisation requirements (as appropriate) of Antibody Raw Material (of a quality and quantity required of the Manufacturing Lead); and

(v) The Party assuming the obligation to manufacture and supply Antibody Raw Material shall have the right to include the cost of [*] as Research and Development Costs if such transfer takes place during Development or as a Commercialisation Expense if

such transfer takes place during Commercialisation (but only to the extent any such costs relate to Antibody Raw Material).

(c) All amounts paid to the Third Party in connection with the supply of Antibody Raw Material and any Third Party Supply Agreement (including all amounts paid in connection with the provision of Information and assistance), and all costs incurred by the Parties in enforcing the terms of any Supply Agreement, shall be a Research and Development Cost if incurred for Development and a Commercialisation Expense if incurred for Commercialisation. All amounts recovered from the Third Party by way of damages as a result of any breach by the Third Party supplier in the supply of Antibody Raw Material shall be revenues included in the calculation of the Product Contribution.

6.8 **Quality Responsibility.** The Parties acknowledge that, in order to meet regulatory requirements prior to the commencement of any supply of Antibody Raw Material or Antibody Product in Finished Form, appropriate quality assurance agreements relating to such supply must be entered into between the Parties and between each Party and its Third Party manufacturers. The Parties will negotiate such quality assurance agreements in good faith having regard to the document entitled "**Quality Responsibilities**" and dated March 12, 2002. If the Parties are unable to conclude any such agreement then the matter shall be referred at the request of either Party to the Collaboration Committee.

ARTICLE 7

CONSIDERATION

7.1 **Up-front Fees.** In consideration of the rights granted hereunder by Celltech, Amgen shall pay Celltech a non-refundable, non-creditable licence fee of [*] ($[*]) within [*] after the Effective Date.

7.2 **Milestone Payments.** As further consideration for the rights granted hereunder by Celltech, Amgen shall make non-creditable, non-refundable payments ("**Milestone Payment(s)**") to Celltech within [*] after the first occurrence of each of the corresponding events listed below (each, a "**Milestone Event**"), in the amount provided:

	Milestone Event	Milestone Payment Amount
(a)	[*].	[*] ($[*])
(b)	[*].	[*] ($[*])
(c)	[*].	[*] ($[*])
(d)	[*].	[*] ($[*])
(e)	[*].	[*] ($[*])

Each Milestone Payment shall be payable only once, no matter how many times the corresponding Milestone Event is achieved by one or more Antibody Product(s).

ARTICLE 8

COMPENSATION

8.1 **Product Contribution.** The Parties shall split 50:50 the Product Contribution from Commercialisation of Antibody Products throughout the Territory whether such Product Contribution is a profit or a loss. For the avoidance of doubt, any Commercialisation Expenses incurred prior to Regulatory Approval of an Antibody Product shall be charged to the Product Contribution and be borne by the Parties on a 50:50 basis.

8.2 **Calculation and Duration of Product Contribution.** The Product Contribution shall be payable in respect of sales in the Territory, on an Antibody Product-by-Antibody Product basis, for so long as there are sales by either Party or their sublicensees or distributors of that Antibody Product in the Territory. The Product Contribution shall be calculated on a quarterly basis for each Antibody Product in accordance with Schedule B.

8.3 **Quarterly Reconciliation of Product Contribution.**

(a) Within [*] following the end of each Calendar Quarter, each Party shall submit to the other Party a written report (in reasonable detail specified by the categories set out in Schedule B and with supporting documentation) which shall show separately with respect to each Antibody Product and each country in the Territory, to the extent made or incurred by each Party the following: (i) a calculation of the Product Contribution showing all Net Sales achieved and recoveries from legal actions and any other relevant revenues, Cost of Goods, Commercialisation Expenses (per category), Other Expenses and Licence Fees incurred; (ii)

the variation from the budgeted Product Contribution for that quarter (identifying in the same any variance which is attributable to fluctuations in currency exchange rates); and (iii) an estimate for the Product Contribution for the remainder of the Contract Year.

(b) Within [*] following the end of each Calendar Quarter, Amgen shall submit to Celltech a written consolidated report setting forth in reasonable detail the calculation of total Product Contribution for each Antibody Product in each country in the Territory for that Calendar Quarter and the calculation of any net amount owed by Celltech to Amgen or by Amgen to Celltech, as the case may be in order to ensure the appropriate sharing of Product Contribution in accordance with Article 8.1, and the net amount payable (the "**Balance Payment**") shall be paid by Amgen or Celltech (as the case may be) within [*] after receipt of such written report. If the Product Contribution is a negative number and the Balance Payment is [*] ([*]%) or greater in excess of the budgeted Balance Payment for that quarter (after taking into account any change in applicable exchange rates used in calculating the Balance Payment for that quarter and the budgeted Balance Payment), the paying Party may elect to carry over to the next quarter the difference between the budgeted Balance Payment and the invoiced Balance Payment, and such carried sum shall be included in the calculation of the amount of the Balance Payment for the next quarter. The election to roll over must be provided within [*] after receipt of the above-referenced written report.

(c) In the event of a dispute with respect to any amounts under this Article 8.3, the disputing Party shall provide written notice to the Joint Commercialisation Committee within [*] after receipt of the written report in question, specifying such dispute and explaining the basis of the dispute. The Joint Commercialisation Committee shall promptly thereafter meet and negotiate in good faith a resolution to such dispute. The resolution of such dispute shall [*]. In the event that the Parties are unable to resolve such dispute within [*] after written notice by the disputing Party, the matter shall be resolved in the manner set forth in Article 15. Notwithstanding the above, such dispute shall not affect a Party's obligation to pay all undisputed amounts (and all undisputed amounts shall be paid in accordance with Article 8.3(b)) or a Party's right to audit the records of the other Party in accordance with Article 8.5.

(d) Interest shall accrue from the due date for payment as set out in Article 8.3(b) on all amounts due and payable but unpaid, including any amounts withheld which are subsequently agreed

or determined to be payable. All withheld amounts, together with interest, shall be paid within [*] of any such agreement or determination.

8.4 **Payments; Tax Matters.**

(a) All payments to be made under this Agreement shall be made in U.S. Dollars by bank wire transfer in immediately available funds to a bank account designated from time to time in writing by the Party receiving the funds.

(b) Net Sales or other revenues received or payments due in currencies other than Dollars shall first be calculated in the relevant foreign currency and then converted to Dollars against the currency in question on the rate of exchange applicable on the last Business Day of the Calendar Quarter in respect of which the funds are payable using the currency exchange rates quoted by *Bloomberg Professional*, a service of Bloomberg L.P., during the period of such Net Sales, or in the event *Bloomberg Professional* is not available then *The Wall Street Journal*. Budgets and intra-budget forecasts of future Net Sales and expenses in currencies other than Dollars shall be converted into Dollars at budget rates to be agreed between the Parties at the Joint Commercialisation Committee.

(c) All amounts due under this Agreement shall be paid exclusive of any Value Added Tax (which, if applicable shall be payable by a Party in addition upon receipt of a valid Value Added Tax invoice). Each Party agrees to inform the other Party forthwith if it concludes that there is a Value Added Tax law or practice, or a change in such law or practice, which requires it to account for Value Added Tax on any payments due pursuant to this Agreement at any time after the Effective Date, with a view to the Parties using their best endeavours to agree on the manner in which subsequent payments shall be made to reduce or eliminate the liability of the Parties to pay Value Added Tax.

(d) All amounts due under this Agreement shall be paid in full without deduction for any applicable taxes, levies, imposts, duties and fees of whatever nature imposed by or under the authority of any government or public authority, except for tax legally required to be deducted or withheld. Where any sum due to be paid to a Party under this Agreement is subject to any withholding or similar or other tax, the Parties shall take all reasonable steps to do all such acts and things and to sign all such deeds and documents as will enable them to take advantage of any applicable double taxation agreements to reduce the rate of withholding or similar taxes with the object of paying the sums due under deduction of a reduced rate of withholding

tax or on a gross basis. In the event there is no double taxation agreement or the reduced rate of withholding tax under the relevant double taxation agreement is greater than [*] ([*]%), the Party making payment shall pay such withholding or similar tax, deduct the relevant amount from the payment due to the other Party, and secure and send to the other Party proof of such withholding or similar tax in a form in accordance with the relevant taxation authority as evidence of such payments. Each Party agrees to inform the other Party forthwith if it concludes that there is any law or practice or any change in such law or practice which requires it to deduct or withhold tax in respect of any payments due pursuant to this Agreement at any time after the Effective Date with a view to the Parties using their best endeavours to agree on the manner in which subsequent payments shall be made to reduce or eliminate the liability of both Parties to deduct or withhold any amount on account of tax.

(e) Any payment of any amount under this Agreement not received by the due date specified herein shall accrue interest thereafter on the sum due and owing from the date payment is due until the date payment is received at the rate equal to [*].

8.5 **Records; Audits.** Each of Celltech and Amgen and their respective Affiliates shall keep and maintain complete and accurate records and books of account documenting in detail sufficient to track and determine, in a manner consistent with GAAP, all revenues, expenses and all other data necessary for the Product Contributions and other sums payable pursuant to this Agreement and in compliance with the terms of the Agreement. Such records shall be retained for a period of the later of (a) a [*] period following the year in which any payments were made hereunder; (b) the expiration of the applicable tax statute of limitations (or any extensions thereof); or (c) such longer period as may be required by law. Each Party and their respective Affiliates shall permit independent accountants of internationally recognised standing retained by the other Party (the "**Auditing Party**") and reasonably acceptable to the other Party, upon reasonable prior written notice, to have access to its and its Affiliates' records and books and premises for the sole purpose of determining the appropriateness of costs charged by or accrued to the Party being audited and the correctness of amounts due and payable under this Agreement for any year ending no more than [*] prior to the date of such request; *provided however*, that the books and records for any particular Contract Year shall only be subject to one audit. Such examination shall be conducted during regular business hours and no more than once in each calendar year. The report of such accountant shall be limited to a certificate verifying, or not verifying, as the case may be, any report made or payment submitted by the audited Party during such period. In the event the accountant shall be unable to verify the correctness of any such

payment, the accountant's report shall specify why such payment is unverifiable and the amount of any discrepancy. The audited Party shall receive a copy of each such report concurrently with receipt by the Auditing Party and the Parties shall use good faith efforts to resolve any discrepancies. All information contained in any such report shall be deemed Confidential Information hereunder. If such examination reveals that such costs or payments have been misstated, any adjustment shall be promptly refunded or paid, as appropriate. The Auditing Party shall pay the fees and expenses of the accountant engaged to perform the audit, unless such audit reveals a net discrepancy of [*] ([*]%) or more for the period examined which is to the disadvantage of the Auditing Party, in which case the Party who misreported shall pay all reasonable costs and expenses incurred by the Auditing Party in the course of making such determination. Upon the expiration of [*] following the end of any Contract Year, the calculation of any such amounts payable with respect to such year shall be binding and conclusive upon a Party entitled to such audit and the other Party or its Affiliates shall be released from any liability or accountability with respect to such amounts for such year.

ARTICLE 9

COLLABORATION

9.1 **Collaboration Committee Formation.** As soon as practicable following the Effective Date, the Parties shall establish a Collaboration Committee to oversee the Research, Development and Commercialisation of all Antibody Products. The Collaboration Committee shall be comprised of an equal number (not more than four) of Celltech and Amgen representatives and shall include senior officers or managers from each Party. The Collaboration Committee shall follow the organisational and meeting procedures set forth in Article 9.3.

9.2 **Collaboration Committee Responsibilities.**

The Collaboration Committee shall be responsible for:

(a) managing the relationship between the Parties;

(b) resolving issues in the Joint Research, Joint Development and Joint Commercialisation Committees that are [*], or that are expressed to be matters to be considered or determined by the Collaboration Committee; and

(c) performing such other functions as are expressly set out in this Agreement as matters for the Collaboration Committee or are consistent with the terms of this Agreement to further the purposes of the collaboration as set forth in Article 2, as determined by the Parties.

9.3 **Decision Making**; **Administrative Matters.**

(a) All decisions of the Collaboration Committee shall be made by the unanimous decision of Celltech and Amgen, with the representatives of each Party who are members of the Collaboration Committee collectively having one vote in any matter requiring the approval of the Collaboration Committee. The Parties agree that all decisions regarding the Research, Development or Commercialisation of an Antibody Product will be made in the interests of maximising the value of the Antibody Product on a global basis.

(b) If the Collaboration Committee is unable to reach unanimous agreement on any issue within its authority pursuant to Article 9.2, the Parties shall attempt to resolve such dispute in accordance with the provisions of Article 15.

(c) The Collaboration Committee shall establish its own procedural rules for its operation, consistent with the terms of this Article 9.3(c). A chairperson for the Collaboration Committee shall be appointed from among its members. The chairperson shall be appointed on an annual basis and shall alternate each year between a Celltech representative and an Amgen representative, with Celltech being responsible for designating the chairperson for the First Contract Year after the Effective Date. The chairperson shall be responsible for calling meetings of the Collaboration Committee and for leading the meetings. A Collaboration Committee member of the Party hosting a meeting of the Collaboration Committee shall serve as secretary of that meeting. The secretary of the meeting shall prepare and distribute (within ten (10) Business Days following each meeting) to all members of the Collaboration Committee the minutes of the meeting. Such minutes shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the Collaboration Committee. The minutes of each Collaboration Committee meeting shall be approved or disapproved, and revised as necessary, at the next meeting. Final minutes of each meeting shall be distributed to the members of the Collaboration Committee by the chairperson.

(d) The Collaboration Committee shall meet at least every six (6) months and in addition within [*] of a request by either Party to have such a meeting . Such meetings shall be held at such

times as are mutually agreed upon by the Collaboration Committee. Meetings may take place by video conference or telephone conference or such other means as the Collaboration Committee shall decide, *provided that* all members of the Collaboration Committee shall meet in person at least [*]. Meetings held in person shall alternate between Amgen and Celltech locations. The first meeting shall be held at Celltech's facilities.

(e) If a Party's representative is unable to attend a meeting, such Party may designate an appropriate alternate representative to attend such meeting in place of the absent representative. In addition, each Party may (at its discretion and with the consent of the other Party) invite additional employees, consultants or scientific advisors to attend the Collaboration Committee meetings.

ARTICLE 10

GRANT OF RIGHTS

10.1 **Patent Licences.**

(a) Amgen hereby grants to Celltech (i) a sole royalty-free licence (co-exclusive with Amgen), under the [*] Patent Rights, [*] Patent Rights, [*] Know-How, [*] Know-How [*] and [*] Know-How; and (ii) a non-exclusive royalty-free licence under the [*] Patent Rights and other [*] Know-How to Research, Develop, Commercialise, make, have made, use, sell, have sold, offer to sell or resell, import, export, distribute or otherwise transfer physical possession of or otherwise transfer title in Antibody Products in the Field in the Territory, solely in compliance with the terms and conditions of this Agreement. For the avoidance of doubt, the grant of a licence under [*] Patent Rights and [*] Know-How is not intended to require the transfer by Amgen to Celltech of Materials and Information beyond that explicitly set forth in this Agreement.

(b) Celltech hereby grants to Amgen (i) a sole royalty-free licence (co-exclusive with Celltech), under the [*] Patent Rights, [*] Patent Rights, [*]Patent Rights, [*] Know-How, [*] Know-How [*] and [*] Know-How; and (ii) a non-exclusive royalty-free licence under [*] Patent Rights and other [*] Know-How to Research, Develop, Commercialise, make, have made, use, sell, have sold, offer to sell or resell, import, export, distribute or otherwise transfer physical possession of or otherwise transfer title in Antibody Products in the Field in the

Territory, solely in compliance with the terms and conditions of this Agreement. For the avoidance of doubt, the grant of a licence under [*]Patent Rights and [*] Know-How is not intended to require the transfer by Celltech to Amgen of Materials and Information beyond that explicitly set forth in this Agreement.

(c) Certain licence rights granted to a Party under this Article 10.1 may include a sublicence of Patent Rights and/or know-how of Third Parties under Third Party licences. Notwithstanding anything to the contrary in this Agreement, the Party receiving a sublicence of such Third Party licences shall, in exercising such sublicence rights, subject to and so far as the terms are applicable to its activities, comply with the provisions of such Third Party licences relating to Antibody Products to the extent the granting Party has notified in writing the terms of such Third Party licence to the Party receiving a sublicence of such Third Party licences. Each Party shall promptly provide to the other Party a copy of any notice of breach received by it under any such Third Party licence.

10.2 **Trademark; Copyright Licences.**

(a) Amgen hereby grants to Celltech a non-exclusive, royalty-free licence to use and display the Amgen Trademarks (subject to the provisions of Article 5.11(h)) and a sole royalty-free licence (co-exclusive with Amgen), to use and display the Product Trademarks, in connection with Antibody Products in the Territory. Celltech hereby grants to Amgen a non-exclusive, royalty-free licence to use and display (subject to the provisions of Article 5.11(h)) the Celltech Trademarks and a sole royalty-free licence (co-exclusive with Amgen) to use and display Product Trademarks in connection with Antibody Products in the Territory. All licences granted under this Article 10.2(a) are sublicensable pursuant to the terms of Article 19.10.

(b) Each Party hereby grants to the other Party a sole royalty-free licence (co-exclusive with the Party), with the right to sublicence solely pursuant to the terms of Article 19.10, under the Party's entire right, title and interest in any intellectual property rights in Promotional Materials and additional Antibody Product-specific materials to reproduce, distribute copies of, prepare derivative works of and publicly perform and display such Promotional Materials or additional Antibody Product-specific materials solely in connection with Antibody Products in the Field in the Territory and in accordance with this Agreement.

(c) The Joint Commercialisation Committee shall determine a Product Trademark that shall be applied to each Antibody Product in the Territory. In the event that the Joint Commercialisation

Committee is unable to agree on such a Product Trademark, and if the matter is not determined in accordance with Article 5.7, the Territorial Commercial Lead shall be free to choose and in any event the Territorial Commercial Lead shall own, the Product Trademark in its respective Lead Territory.

ARTICLE 11

INTELLECTUAL PROPERTY RIGHTS

11.1 **Ownership.**

11.1.1 As between the Parties, Amgen shall own all right, title and interest in and to all [*] Technology (other than [*] Know-How and all [*] Patent Rights), subject to the rights and licences granted to Celltech hereunder.

11.1.2 As between the Parties, Celltech shall own all right, title and interest in and to all [*] Technology (other than [*] Know-How and all [*] Patent Rights), subject to the rights and licences granted to Amgen hereunder.

11.1.3 As between the Parties, all right, title and interest in and to all [*] Know-How and all [*] Patent Rights shall be [*] by [*]. Subject to the rights and licences granted hereunder, each Party shall have [*].

11.1.4 Other than as expressly set forth in this Agreement, neither Party shall have any right in and to any intellectual property owned or controlled by the other Party and neither Party shall have an obligation to grant the other Party any rights therein.

11.1.5 Other than as expressly set forth in Articles 11.2, 11.4 and 11.6, neither Party shall have the right to prepare, file, prosecute, maintain, defend, settle and/or enforce Patent Rights or Product Trademarks Controlled by the other Party, such activity being the exclusive right (but not the obligation) of the Party Controlling the same.

11.2 **Prosecution and Defence.**

11.2.1 Promptly after the Effective Date, Celltech shall provide Amgen with copies of all material documents in Celltech's possession pertaining to [*] Patent Rights [*]. During the term of this Agreement, each Party shall as soon as practicable provide the other Party (as appropriate) with all material documents

and any other document Controlled by a Party reasonably requested by the other Party (such request to identify the specific documents required), pertaining to [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and [*] Patent Rights.

11.2.2 (a) Amgen shall have the first right (but not the obligation) to have mutually acceptable outside counsel (i) at any time prepare, file, prosecute, maintain and defend the Product Trademarks in the Amgen Territory and [*] Patent Rights outside the Celltech Territory; (ii) prior to, on and following the Transition Date (as defined in Article 11.2.9 below) prepare, file, prosecute and maintain any [*] Patent Rights and the [*] Patent Rights that are [*] to any Antibody Products ("[*] **Patent Rights**") in the Amgen Territory; (iii) on and following the Transition Date, defend any [*] Patent Rights and [*] Patent Rights in the Amgen Territory; and (iv) for the avoidance of doubt only, prior to the Transition Date defend any [*] Patent Rights that are [*]to any Antibody Products ("[*] **Patent Rights**") in the Celltech Territory.

(b) Celltech shall have the right to review and comment on any papers pertaining to proposed applications, responses, interferences and oppositions before the filing thereof by such counsel with any patent or trademark office (e.g., national, regional or international) ("**Consultation Rights**"), regarding [*] Patent Rights, [*] Patent Rights and Product Trademarks in the Amgen Territory. Celltech shall also have Consultation Rights regarding [*] Patent Rights and [*] Patent Rights outside the Amgen Territory. If such outside counsel concludes that taking, or failing to take, any specific action(s) would be inconsistent with its instructions under Article 11.2.4, then Amgen shall not take, or shall take (as the case may be), such specific action(s) unless the prior express written consent of Celltech shall have been obtained. Amgen shall have the right to propose an alternative strategy for Celltech's consideration. To that end, Amgen shall instruct such outside counsel to furnish Celltech with a reasonably complete draft of each submission to a patent or trademark authority regarding any such [*] Patent Rights, [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and Product Trademarks no later than [*] prior to the date such submission is proposed to be made, or if given less than [*] to respond as soon as practicable, and will consider any of Celltech's reasonably timely comments thereon. Additionally, Amgen shall instruct such outside counsel to provide Celltech with a copy of each submission made to and document received from a patent or trademark authority regarding any such [*] Patent Rights, [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and Product Trademarks reasonably promptly after making such filing.

(c) Amgen shall have the right, at any time and at its sole option, to elect not to proceed with and/or to abandon the preparation, filing, prosecution, maintenance and/or defence of any Patent Right or any Product Trademark it is permitted to pursue under Article 11.2.2(a), *provided that* it shall give Celltech notice of such intention at least [*] before a final due date which would result in the abandonment, cancellation or lapse of an issued patent or pending patent application or abandonment, cancellation or lapse of such granted trademark or pending trademark application. In such case, Celltech, at its option, may assume the right to prepare, file prosecute, maintain and/or defend any such Patent Right or Product Trademark. Amgen shall have Consultation Rights in respect of any such Patent Right and Product Trademark and if such outside counsel concludes that taking, or failing to take, (as the case may be) any specific action(s) would be inconsistent with its instructions under Article 11.2.4, then Celltech shall not take, or shall take (as the case may be), such specific action(s) unless the prior express written consent of Amgen has been obtained. Celltech shall have the right to propose an alternative strategy for Amgen's consideration. To that end, Celltech shall instruct such outside counsel to furnish Amgen with a reasonably complete draft of each submission to a patent or trademark authority regarding any such Patent Rights and Product Trademark no later than [*] prior to the date such submission is proposed to be made, or if given less than [*] to respond as soon as practicable, and will consider any of Amgen's reasonably timely comments thereon. Additionally, Celltech shall instruct such outside counsel to provide Amgen with a copy of each submission made to and document received from a patent or trademark authority regarding any such Patent Rights and Product Trademark reasonably promptly after making such filing.

(d) A decision by Amgen not to exercise its right pursuant to Article 11.2.2(a) to prepare, file, prosecute, maintain and/or defend any Patent Right or any Product Trademark as permitted by the terms of that Article shall not affect any of Amgen's licence or other rights under this Agreement.

11.2.3 (a) Celltech shall have the first right (but not the obligation) to have mutually acceptable outside counsel (i) at any time prepare, file, prosecute, maintain and defend the Product Trademarks in the Celltech Territory and [*] Patent Rights in the Celltech Territory; (ii) prior to, on and following the Transition Date prepare, file, prosecute and maintain any [*] Patent Rights in the Celltech Territory; (iii) on and following the Transition Date, defend any [*] Patent Rights

in the Celltech Territory; and (iv) for the avoidance of doubt only, prior to the Transition Date defend any [*] Patent Rights and [*] Patent Rights in the Amgen Territory.

(b) Amgen shall have Consultation Rights regarding [*] Patent Rights and [*] Patent Rights outside the Amgen Territory. Amgen shall also have Consultation Rights regarding [*] Patent Rights, [*] Patent Rights and Product Trademarks in the Celltech Territory. If such outside counsel concludes that taking, or failing to take, any specific action(s) would be inconsistent with its instructions under Article 11.2.4, then Celltech shall not take, or shall take, (as the case may be) such specific action(s) unless the prior express written consent of Amgen shall have been obtained. Celltech shall have the right to propose an alternative strategy for Amgen's consideration. To that end, Celltech shall instruct such outside counsel to furnish Amgen with a reasonably complete draft of each submission to a patent or trademark authority regarding any such [*] Patent Rights, [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and Product Trademarks no later than [*] prior to the date such submission is proposed to be made, or if given less than [*] to respond as soon as practicable, and will consider any of Amgen's reasonably timely comments thereon. Additionally, Celltech shall instruct such outside counsel to provide Amgen with a copy of each submission made to and document received from a patent or trademark authority regarding any such [*] Patent Rights, [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and Product Trademarks reasonably promptly after making such filing.

(c) Celltech shall have the right, at any time and at its sole option, to elect not to proceed with and/or to abandon the preparation, filing, prosecution, maintenance and/or defence of any Patent Right or Product Trademark it is permitted to pursue under Article 11.2.3(a), *provided that* it shall give Amgen notice of such intention at least [*] before a final due date which would result in the abandonment, cancellation or lapse of an issued patent or pending patent application or abandonment, cancellation or lapse of such granted trademark or pending trademark application. In such case Amgen, at its option, may assume the right to prepare, file, prosecute, maintain and/or defend any such Patent Right or Product Trademark. Celltech shall have Consultation Rights in respect of any such Patent Right and Product Trademark and if such outside counsel concludes that taking, or failing to take, any specific action(s) would be inconsistent with its instructions under Article 11.2.4, then Amgen shall not take, or shall take (as the case may be), such specific action(s) unless the prior express written consent of Celltech has been obtained. Amgen shall have the right to propose an alternative

strategy for Celltech's consideration. To that end, Amgen shall instruct such outside counsel to furnish Celltech with a reasonably complete draft of each submission to a patent or trademark authority regarding any such Patent Rights and Product Trademark no later than [*] prior to the date such submission is proposed to be made, or if given less than [*] to respond as soon as practicable, and will consider any of Celltech's reasonably timely comments thereon. Additionally, Amgen shall instruct such outside counsel to provide Celltech with a copy of each submission made to and document received from a patent or trademark authority regarding any such Patent Rights and Product Trademark reasonably promptly after making such filing.

(d) A decision by Celltech not to exercise its right pursuant to Article 11.2.3(a) to prepare, file, prosecute, maintain and/or defend any Patent Right or any Product Trademark as permitted by the terms of that Article shall not affect any of Celltech's licence or other rights under this Agreement.

11.2.4 Outside counsel retained under this Article 11 shall be instructed to act in the best interests of both Parties under this Agreement and such counsel shall also be instructed to secure claims of the broadest possible scope without jeopardising validity.

11.2.5 The Parties shall closely co-ordinate the defence of any attack on the validity and/or any enforcement (against a Third Party developing or commercialising an Antibody that binds to BEER) of the [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and/or the [*] Patent Rights through the Collaboration Committee (including the right of the Party not responsible for such defence or enforcement to review and comment on any papers relating thereto which are material to the conduct of such defence or enforcement). Notwithstanding anything to the contrary in this Article 11, prior to the Transition Date, neither Party shall have any right to enforce or defend the validity of Patent Rights Controlled by the other Party, which right shall be exclusively that of the Party Controlling the Patent Rights. The Party responsible for such defence or enforcement shall not take (nor fail to take) any action with respect to any such defence and/or enforcement which would, in the opinion of the retained outside counsel, be inconsistent with the instructions given to outside counsel under Article 11.2.4.

11.2.6 Celltech agrees to use reasonable efforts to ensure that with respect to any patent application forming part of the [*] Patent Rights and [*] Patent Rights which it shall initially file in the Celltech Initial Countries in accordance with Article 11 will be filed in a form sufficient to establish the date of

original filing as a priority date for the purposes of a subsequent filing in the Amgen Initial Countries. Amgen agrees to use reasonable efforts to ensure that with respect to any patent application forming part of the [*] Patent Rights and [*] Patent Rights which it shall initially file in the Amgen Initial Countries in accordance with Article 11 will be filed in a form sufficient to establish the date of original filing as a priority date for the purposes of a subsequent filing in the Celltech Initial Countries.

11.2.7 Each Party agrees to co-operate with the other Party in the preparation, filing, prosecution, maintenance and defence of intellectual property rights as set forth in this Article 11.2, including the signing of any necessary legal papers, and to provide the other Party with data or other information in support thereof, and to use best efforts to ensure the co-operation of any of their respective personnel as might reasonably be requested in any such matters.

11.2.8 Notwithstanding any other provision of this Article 11, neither Party shall have an obligation, which is in violation of, or not permitted by, the terms of a Third Party agreement, to prosecute or maintain, or take or defend any action in respect of, nor shall either Party have any right, in violation of the terms of a Third Party agreement, to take or defend any action in respect of, any Patent Right which is owned by a Third Party and licensed to such Party under such Third Party agreement.

11.2.9 For the purposes of this Article 11, "**Transition Date**" means the date of [*].

11.3 **Patent and Trademark Expenses.**

11.3.1 Amgen shall have the right to charge (i) up to the date of Regulatory Approval to Commercialise the first Antibody Product, as a Research and Development Cost; and (ii) thereafter, to the Product Contribution account as a Commercialisation Expense; all of Amgen's external costs, expenses and fees (as documented by written invoices for legal and expert services and receipts for filing and maintenance fees paid) to have outside counsel prepare, file, prosecute and maintain and/or defend [*] Patent Rights, [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and Product Trademarks in accordance with Article 11 during the Term.

11.3.2 Celltech shall have the right to charge (i) up to the date of Regulatory Approval to Commercialise the first Antibody Product, as a Research and Development Cost; and (ii) thereafter, to the Product Contribution account as a Commercialisation Expense; all of Celltech's external costs, expenses and fees (as documented by written invoices for legal and expert services and receipts for filing and maintenance fees paid) to have outside counsel prepare, file, prosecute and maintain, and/or defend [*] Patent Rights, [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and Product Trademarks in

accordance with Article 11 during the Term.

11.4 **Enforcement.**

11.4.1 Amgen shall have the sole right but not the obligation to bring any suit or action (or to otherwise seek payment and/or claim) against a Third Party developing or commercialising an Antibody product which binds BEER, and Celltech agrees to be joined as a plaintiff to any such suit or action if Amgen so requests: (i) for infringement of a claim within the [*] Patent Rights outside of the Celltech Territory; (ii) on or following the Transition Date, for infringement of a claim within the [*] Patent Rights and/or [*] Patent Rights in the Amgen Territory; and/or (iii) regarding any Product Trademark in the Amgen Territory. Amgen shall, subject to prior consultation with Celltech, have the right to determine the strategy and to exclusively control the conduct and all aspects of any such proceedings including the right to settle or compromise such proceedings (by, for example, granting any such Third Party a sublicence, covenant not to sue or other rights to the Patent Rights or Product Trademark being enforced); *provided however*, that in any such settlement or compromise Amgen will not admit the invalidity of any claim within [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and/or [*] Patent Rights without the prior written approval of Celltech.

11.4.2 Celltech shall have the sole right but not the obligation to bring any suit or action (or to otherwise seek payment and/or claim) against a Third Party developing or commercialising an Antibody product which binds BEER, and Amgen agrees to be joined as a plaintiff to any such suit or action if Celltech so requests: (i) on or following the Transition Date, for infringement of a claim within the [*] Patent Rights in the Celltech Territory; (ii) for infringement of a claim within the [*] Patent Rights in the Celltech Territory; and/or (iii) regarding any Product Trademark in the Celltech Territory. Celltech shall, subject to prior consultation with Amgen, have the right to determine the strategy and to exclusively control the conduct and all aspects of any such proceedings including the right to settle or compromise such proceedings (by, for example, granting any such Third Party a sublicence, covenant not to sue or other rights to the Patent Rights or Product Trademark being enforced); *provided however*, that in any such settlement or compromise Celltech will not admit the invalidity of any claim within [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and/or such [*] Patent Rights without the prior written approval of Amgen.

11.4.3 Neither Party shall bring any action in the Lead Territory of the other Party to enforce any Patent Rights Controlled by the non-lead Party against a Third Party in respect of such Third Party developing

or commercialising an Antibody product which binds BEER, without the lead Party's prior written consent.

11.4.4 Both Parties shall be entitled to charge to the Product Contribution account as a Commercialisation Expense all out-of-pocket costs and expenses (including outside attorneys' fees) incurred by such Party in preparing for and/or enforcing Patent Rights or Product Trademarks Controlled by it against a Third Party in respect of the Development or Commercialisation of an Antibody product that binds BEER, and/or in bringing any suit under this Article 11.4. Recoveries in any actions under this Article 11.4 shall be credited to the Product Contribution account.

11.5 **Infringement Defence.**

(a) The Territorial Commercial Lead shall have the first right to defend any actual, alleged or threatened claim or action in its Lead Territory which names the Territorial Commercial Lead and/or the Territorial Commercial Lead and the other Party and which claims (i) the infringement of Third Party Patent Rights or know-how through Researching, Developing, Commercialising, making, having made, using, selling, having sold, offering to sell or resell, importing, exporting, distributing or otherwise transferring physical possession of or otherwise transferring title in or to an Antibody Product or (ii) that any Product Trademark infringes any Third Party Trademark or its use constitutes any unfair trade practice, trade dress imitation, passing off of counterfeit goods or like offence. If the Territorial Commercial Lead shall decide not to defend such an action, the other Party, to the extent it is named, may defend any such claim or action. The Party defending such claim or action shall have the right to determine the strategy and to exclusively control the conduct and all aspects of any such proceedings; *provided however* that the Party defending such claim or action shall not settle or compromise such proceedings that affect the other Party's rights or interests, without the prior written consent of the other Party (which consent shall not be unreasonably withheld or delayed). When named, the Party not defending such claim or action shall be entitled to participate in and to have counsel selected by it participate in any action in which the other Party is a named party.

(b) If either Party defends such claim or action, both Parties shall be entitled to charge if and to the extent the costs of such defence are incurred during Research or Development as a Research and Development Cost and if and to the extent the costs of such defence are incurred during Commercialisation to the Product Contribution account (as a Commercialisation Expense) all external costs and expenses (including outside attorneys' fees) incurred in preparing for

and/or carrying out the activities described in this Article 11.5. In addition, any payment that either or both Parties are obliged to make on past and/or future sales of Antibody Product(s) as a result of a settlement or judgment in such a suit shall also be treated as a Commercialisation Expense.

11.6 **Trademarks.** Each Territorial Commercial Lead may, but shall not be obligated to, elect to defend the Product Trademarks against any challenges in its applicable Lead Territory and to enforce the Product Trademarks against any actual, alleged or threatened infringement by Third Parties or against any unfair trade practices, trade dress imitation, passing off of counterfeit goods or like offences in the applicable Lead Territory. In the event the Territorial Commercial Lead shall so elect, the Territorial Commercial Lead shall determine the strategy and the other Party shall reasonably assist and co-operate in any such enforcement or defence. All out-of-pocket costs and expenses incurred by either Party in defending or taking any such action shall be charged to the Product Contribution account as a Commercialisation Expense.

11.7 **Patent Markings.** To the extent practical, each Territorial Commercial Lead shall mark the Antibody Product(s) sold in its Territory with all applicable patent numbers of Patent Rights of the Parties to the extent permitted by law in those countries of its Lead Territory in which such markings have notice value as against infringers of patents.

11.8 **Co-operation.**

(a) Each Party shall promptly notify the other upon becoming aware of (i) any actual, alleged or threatened Third Party claim or action against Celltech and/or Amgen for infringement of any Third Party Trademark through the Development or Commercialisation of an Antibody Product; or of any Third Party Patent Rights through Researching, Developing, Commercialising, making, having made, using, selling, having sold, offering to sell or resell, importing, exporting, distributing or otherwise transferring physical possession of or otherwise transferring title in or to Antibody Products in the Field in the Territory; or (ii) any Third Party infringement of the Product Trademarks, or any Patent Rights of either Party relating to an Antibody that binds to BEER, or (iii) in respect of any Antibody Product, any unfair trade practices, trade dress imitation, passing off of counterfeit goods or like offences.

(b) With respect to a Party bringing or defending a suit as permitted under this Article 11 the other Party shall assist and co-operate with the Party bringing or defending such suit, and if the Party bringing or defending such suit finds it necessary or desirable to join the other Party as

a party in such suit, the other Party shall execute all papers or perform such other acts as may reasonably be required by the Party bringing or defending such suit.

(c) A Party bringing or defending suit as permitted under this Article 11 shall notify the other Party of all substantive developments with respect to such enforcement or defensive actions including, all material filings, court papers and other related documents, substantive settlement negotiations and offer of settlement.

(d) Without prejudice to the other terms of this Article 11, all actual, alleged or threatened claims, actions and defences referred to in this Article 11 (including any settlement and conduct of same) shall be co-ordinated through the Collaboration Committee.

11.9 **Third Party Licences.** The Parties acknowledge that they have entered into licence agreements with Third Party owners of potentially blocking intellectual property and that it may be necessary or desirable to enter into such further licences (individually herein called a "**Third Party Licence Agreement**"). The Parties agree to treat such Third Party Licence Agreements as follows:

(a) Following the Effective Date, if a Party desires to enter into a new Third Party Licence Agreement, it shall inform the Collaboration Committee and, prior to determining whether to enter into such Third Party Licence Agreement, shall give due consideration to any reasonable comments by the other Party relating thereto, including, comments that entering into such Third Party Licence Agreement [*] of the other Party. If the Collaboration Committee cannot unanimously agree whether or not such a Third Party Licence Agreement should be entered into, the matter shall be promptly submitted in writing to the [*] of both Parties. If following discussion between them, the [*] are unable to agree a resolution of the matter within [*] after the matter has been submitted to them the Territorial Commercial Lead may determine the matter for the countries within its Lead Territory.

(b) Any fees or other payments due Third Parties under Third Party Licence Agreements prior to the first Regulatory Approval for Commercialisation of an Antibody Product shall be Research and Development Costs, *provided however*, that if the rights under such Third Party Licence Agreement are also applicable to products other than Antibody Products, then only an equitable portion of such fees or other payments shall be allocated to the Antibody Product as Research and Development Costs.

(c) Any fees or other payments due to a Third Party under a Third Party Licence Agreement after the first Regulatory Approval of an Antibody Product shall be Licence Fees, *provided however*, that if the rights under such Third Party Licence Agreement are also applicable to products other than Antibody Products, then only an equitable portion of such fees or other payments shall be allocated to the Antibody Product as Licence Fees.

ARTICLE 12

CONFIDENTIALITY AND NON-USE

12.1 **Confidential Information.** Except as otherwise provided in this Article 12, (a) the Parties shall maintain in confidence and use only for purposes specifically authorised under this Agreement any Confidential Information of the other Party pursuant to this Agreement; (b) Celltech shall keep confidential all [*] Know-How which is [*] to [*], and/or which is [*] to [*] to [*]and all [*] Know-How and [*] Know-How which is [*] to Antibody Products and/or [*] (whether generated prior to or during the term of this Agreement) and, *provided however*, where such [*] Know-How may have [*] outside [*], or where such [*] Know-How or [*] Know-How may have [*] outside Antibody Products and/or [*], Celltech shall be free to use and exploit the same and to disclose the same to Third Parties subject always to obligations of confidentiality; and (c) Amgen shall keep confidential all [*] Know-How which is [*] to [*] and/or which is [*] to Antibodies to [*], and all [*] Know-How and [*] Know-How which is [*] to Antibody Products and/or [*] (whether generated prior to or during the term of this Agreement) and, *provided however*, where such [*] Know-How may have [*] outside [*], or where such [*] Know-How or [*] Know-How may have [*] outside Antibody Products and/or [*], Amgen shall be free to use and exploit the same and to disclose the same to Third Parties subject always to obligations of confidentiality.

12.2 **Disclosure.**

12.2.1 To the extent it is reasonably necessary or appropriate to fulfil its obligations or exercise its rights under this Agreement, a Party may disclose such Confidential Information of the other Party as it is otherwise obliged under Article 12.1 not to disclose:

(a) to its Affiliates and to its (whether actual or potential) sublicensees, consultants, outside contractors and clinical investigators, on a need-to-know basis and on the condition that such entities or persons agree to keep the Confidential Information confidential for the same time

periods and to the same extent as such Party is required to keep such Confidential Information confidential;

(b) to Regulatory Authorities to the extent that such disclosure is reasonably necessary to obtain authorisations to conduct clinical studies or to file, obtain and maintain Regulatory Approvals and to Commercialise the Antibody Products;

(c) to the extent that such disclosure is reasonably necessary in connection with preparing, filing, prosecuting, defending and/or maintaining the other Party's Patent Rights in accordance with Article 11; or

(d) in prosecuting or defending litigation as explicitly authorised under this Agreement; and in establishing rights or enforcing obligations under this Agreement; *provided that* it shall (i) give reasonable advance notice to the other Party of such disclosure requirement; (ii) provide a copy of the proposed disclosure to the other Party; and (iii) at the request of the other Party, use Commercially Reasonable Efforts in assisting the other Party to secure confidential treatment of such Confidential Information required to be disclosed, including co-operating with the other Party to obtain a protective order of the other Party's Confidential Information.

12.2.2 Notwithstanding Article 12.1, Amgen may disclose [*] Know-How and [*] Know-How and Celltech may disclose [*] Know-How and [*] Know-How and each Party may disclose the [*] Know-How which is subject to an obligation of confidentiality under Article 12.1 in any of the following circumstances:

(a) where such disclosure would [*];

(b) to its Affiliates, and to its (whether actual or potential) sublicensees, consultants, outside contractors and clinical investigators, on a need-to-know basis and on the condition that such entities or persons agree to keep the Confidential Information confidential for the same time periods and to the same extent as such Party is required to keep such Confidential Information confidential;

(c) to Regulatory Authorities to the extent that such disclosure is reasonably necessary to obtain authorisations to conduct clinical studies or to file, obtain and maintain regulatory approvals and to commercialise products other than Antibody Products;

(d) without prejudice to Article 11, to the extent that such disclosure is reasonably necessary in connection with preparing, filing, prosecuting, maintaining and/or defending Patent Rights; or

(e) in prosecuting or defending litigation and in establishing rights or enforcing obligations under this Agreement or in complying with applicable laws, regulations, court or administrative orders, the rules of any relevant stock exchange or the U.S. Securities and Exchange; *provided however*, in the case of [*] Know-How which is [*] to [*] and/or which is [*] to Antibodies to [*],[*] Know-How which is [*] to [*] and/or which is [*] to Antibodies to [*],[*] Know-How and [*] Know-How only, to the extent practicable it shall (i) give reasonable advance notice to the other Party of such disclosure requirement; (ii) provide a copy of the proposed disclosure to the other Party; and (iii) at the request of the other Party, use Commercially Reasonable Efforts to secure confidential treatment of such [*] Know-How which is [*] to [*] and/or which is [*] to Antibodies to [*],[*] Know-How which is [*] to BEER and/or which is [*] to Antibodies to [*],[*] Know-How and [*] Know-How required to be disclosed, including seeking a protective order of such [*] Know-How which is [*] to [*] and/or which is [*] to Antibodies to [*],[*] Know-How which is [*] to [*] and/or which is [*] to Antibodies to [*],[*] Know-How and [*] Know-How.

12.3 **Exceptions.** The obligation not to disclose Confidential Information under this Article 12 shall not apply to any part of such Confidential Information that:

(a) is or becomes published or otherwise becomes publicly known other than by acts of the Party obligated not to disclose such Confidential Information or its Affiliates or permitted Third Parties pursuant to Article 12.2.1(a) or 12.2.2(b) in breach of this Agreement;

(b) was disclosed to the receiving Party or its Affiliates or sublicensees by a Third Party, *provided that* such Confidential Information was not obtained by such Third Party from the disclosing Party under an obligation of confidentiality;

(c) prior to disclosure under this Agreement, was already in the possession of the receiving Party or its Affiliates or sublicensees, *provided that* such Confidential Information was not obtained from the disclosing Party under an obligation of confidentiality;

(d) can be shown by written documents to have been independently developed by the receiving Party or its Affiliates without breach of any of the provisions of this Agreement or access to any Confidential Information provided by the disclosing Party; or

(e) is required to be disclosed by the receiving Party to comply with applicable laws, or with a court or administrative order or the rules of any relevant stock exchange, or the U.S. Securities and Exchange Commission *provided however*, that this Article 12.3(e) shall not permit a Party to disclose the other Party's Confidential Information for the purpose of obtaining Patent Rights and, *further provided however*, the receiving Party shall, if practicable, notify the disclosing Party in writing (and if practicable provide a copy of the proposed disclosure) prior to any such disclosure and shall use reasonable efforts to secure confidential treatment thereof prior to its disclosure (whether by protective order or otherwise).

12.4 **Terms of Agreement.**

Except as permitted by the foregoing provisions or as otherwise required by law or the rules of any relevant stock exchange or the U.S. Securities and Exchange Commission, the Parties shall not disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party; *provided however*, that each Party shall be entitled to disclose the terms of this Agreement without such consent on a need-to-know basis to its financial and legal advisors and potential investors or other financing sources on the condition that such entities or persons agree to keep such terms confidential for the same time periods and to the same extent as such Party is required to keep such terms confidential. Each Party shall give the other Party a reasonable opportunity to review all filings with the United States Securities and Exchange Commission or any stock exchange describing the terms of this Agreement prior to submission of such filings, and shall give due consideration to any reasonable comments by the non-filing Party relating to such filing, including the provisions of this Agreement for which confidential treatment should be sought.

12.5 **Public Announcements.** Following the Effective Date, the Parties shall issue one or more press releases regarding this Agreement, the timing and content of which shall be mutually agreed. Except to the extent required by law or the rules of a relevant stock exchange or as otherwise permitted in accordance with this Article 12, neither Party shall make any further public announcements concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of any press releases prior to the issuance thereof.

12.6 **Residual Information.** Each Party acknowledges that personnel of the Parties and their Affiliates who participate in the collaboration set forth in this Agreement also participate in the research, development and commercialisation of other pharmaceutical products unrelated to this Agreement and that each Party's personnel shall have access to Confidential Information of the other Party. Each Party further acknowledges that such personnel will retain and use residual information derived from the collaboration and that use of such residual information by such personnel shall not constitute a breach of this Article 12 to the extent such personnel did not know (and could not reasonably be expected to know) it was the confidential Information of the other Party or otherwise subject to a confidentiality or restricted use obligation; *provided however*, that notwithstanding the above, no rights are granted to practice under the other Party's Patent Rights and such personnel shall not use the written Confidential Information of the other Party. Each Party shall implement appropriate procedures to identify to its personnel Information which is the subject of confidentiality or restricted use obligations.

12.7 **Third Party Obligations.** Other than with respect to Article 16.4(e), neither Party is obliged to disclose to the other any Information if to do so would put the disclosing Party in breach of an existing or future obligation owed to a Third Party. Without limitation to the foregoing, Amgen acknowledges that Celltech is not obliged to disclose to Amgen, and will not disclose to Amgen, any Information, data or know-how concerning Celltech's products [*] whether arising out of Celltech's [*] or otherwise.

ARTICLE 13

PUBLICATIONS

13.1 **Procedure.** The Collaboration Committee (or its appropriate designees) shall determine the strategy for and co-ordinate the publication and presentation of results of studies of Antibody Products or which incorporates data generated under this Agreement. Each Party to this Agreement recognises that the publication of papers regarding results of and other information regarding activities under this Agreement, including oral presentations and abstracts, may be beneficial to both Parties *provided* such publications are subject to reasonable controls to protect Confidential Information. In particular, it is the intent of the Parties to maintain the confidentiality of any Confidential Information included in any patent application until such patent application has been published. Accordingly, each Party will have the right to review and approve any paper proposed for publication by the other Party, including oral presentations and abstracts, which incorporates data generated under this Agreement

and/or includes Confidential Information of the other Party. Before any such paper is submitted for publication or an oral presentation is made, the publishing or presenting Party will deliver a complete copy of the paper or materials for oral presentation to the other Party at least [*] prior to submitting the paper to a publisher or making the presentation. The other Party will review any such paper and give its comments to the publishing Party within [*] of the delivery of such paper to the other Party. With respect to oral presentation materials and abstracts, the other Party will make reasonable efforts to expedite review of such materials and abstracts, and will return such items as soon as practicable to the publishing or presenting Party with appropriate comments, if any, but in no event later than [*] from the date of delivery to the other Party. Failure to respond within such [*] shall be deemed approval to publish or present. If approval is not given or deemed given, for publications or presentations of other than Marketing Clinical Studies, the matter shall be referred to the Collaboration Committee together with the reasons for withholding approval. Publications or presentations to the extent relating to Marketing Clinical Studies shall be determined by the Territorial Commercial Lead that conducted such Marketing Clinical Studies, having considered the comments of the other Party. Notwithstanding the foregoing, the publishing or presenting Party will comply with the other Party's request to delete references to the other Party's Confidential Information in any such paper and, with respect to Marketing Clinical Studies, will withhold publication of any such paper or any presentation of same for an additional [*] in order to permit the Parties to obtain patent protection, if either of the Parties deems it necessary, in accordance with the terms of this Agreement.

13.2 **Credit.** Any such publication will include recognition of the contributions of the other Party according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate.

ARTICLE 14

TERM AND TERMINATION

14.1 **Term.** This Agreement shall become effective on the Effective Date and shall remain in full force and effect, unless earlier terminated pursuant to Article 3.4 or this Article 14, for such time as the Antibody Products are being Researched, Developed or Commercialised by the Parties.

14.2 **Termination for Convenience.**

14.2.1 Amgen may terminate this Agreement at any time following presentation of the [*] demonstrating an [*] in the [*] referred to in [*] of [*] but prior to the expiry of Celltech's opt out right as set out

in Article 3.4 by providing [*] prior written notice of termination to Celltech. Termination shall be effective upon the expiry of the [*] notice period. Should Amgen exercise (or be deemed to exercise) its right to terminate pursuant to Article 3.2.1(e), termination shall be effective upon the receipt of such notice by Celltech.

14.2.2 (a) After expiry of Celltech's opt-out right as set out in Article 3.4(a), either Party may terminate this Agreement after completion of the first [*] of an Antibody Product by providing [*] prior written notice to the other Party. Termination shall be effective upon the expiry of the [*] notice period.

(b) Should a Party provide a notice pursuant to Article 2.7 (whether before or after the expiry of Celltech's opt-out right or [*] of a [*]), such Party shall be deemed to have served a termination notice pursuant to this Article.

(c) Within [*] of receipt of a termination notice pursuant to this Article 14.2.2 the non-terminating Party shall provide a written response to the terminating Party, setting out in such written response whether:

(i) the non-terminating Party wishes to assume the Research, Development and/or Commercialisation of Antibody Products (as appropriate); or

(ii) the non-terminating Party does not wish to continue to pursue the Research, Development and/or Commercialisation of Antibody Products (as appropriate).

If the non-terminating Party does not send such a written response within the said [*], it shall be deemed to have made the election set out in 14.2.2(c)(ii).

14.3 **Mutual Consent**. This Agreement shall terminate upon the mutual written consent of the Parties. Termination shall be effective upon the date specified in such written consent.

14.4 **Termination for Default.**

(a) In the event any material representation or warranty made hereunder by either Party shall have been untrue in any material respect and this has had a material and adverse effect on the other Party in relation to this Agreement ("**Representation Default**"), or upon any material breach or material default of a material obligation of this Agreement by a Party ("**Performance Default**"), the Party not in default ("**Non-Defaulting Party**") must first give the other Party ("**Defaulting Party**") written notice thereof ("**Notice of Default**"), which notice must state

the nature of the Representation Default or Performance Default in reasonable detail and must request the Defaulting Party cure such Representation Default or Performance Default within [*], or if such Default cannot be cured, take such action as will substantially mitigate the material adverse effect of such Default on the other Party. During any such [*] period after receipt or delivery of a Notice of Default under this Article 14.4(a) for which termination of this Agreement is a remedy, all of each Party's respective rights and obligations under this Agreement, including Research, Development, and Commercialisation, shall (to the extent applicable) remain in force and effect. If the Defaulting Party shall dispute the existence, extent or nature of any default set forth in a Notice of Default, the Parties shall use good faith efforts to resolve the dispute.

(b) In the event of a Representation Default or a Performance Default by Celltech that shall not have been cured or mitigated within the [*], as set forth in Article 14.4(a) above, Amgen, at its option, may immediately terminate this Agreement upon prior written notice to Celltech. Termination shall be effective upon the receipt of such notice by Celltech.

(c) In the event of a Representation Default or a Performance Default by Amgen that shall not have been cured or mitigated within the [*], as set forth in Article 14.4(a) above, Celltech, at its option, may immediately terminate this Agreement upon prior written notice to Amgen. Termination shall be effective upon the receipt of such notice by Amgen.

14.5 **Bankruptcy.**

(a) All rights and licences granted under or pursuant to this Agreement by Amgen or Celltech are, and shall otherwise be deemed to be licences of rights to "**intellectual property**". The Parties agree that the Continuing Party (as defined below) shall retain and may fully exercise all of its rights and elections under bankruptcy legislation in the Territory. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a bankrupt Party the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property which at that date is known to be necessary or useful to an Antibody Product (then the subject of Research or Development or Commercialisation) and all embodiments of such intellectual property; and same, if not already in the other Party's possession, shall be promptly delivered to the other Party (a) upon any such commencement of a bankruptcy proceeding, upon the other Party's written request therefor (which request must identify the specific intellectual property), unless the non-

bankrupt Party (or a trustee on behalf of the bankrupt Party) elects within [*] to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the bankrupt Party, upon written request therefor by the other Party.

(b) Without prejudice to Article 14.5(a) this Agreement may be terminated by a Party upon prior written notice to the other in the event that (i) the other Party shall make an assignment for the benefit of its creditors, file a petition in bankruptcy, petition or apply to any tribunal for the appointment of custodian, receiver or any trustee for it or a substantial part of its assets, or shall commence any proceeding under any bankruptcy, reorganisation, arrangement, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction (other than for the purposes of a solvent amalgamation or reconstruction), whether now or hereafter in effect; or (ii) if there shall have been filed against the other Party any such bona fide petition or application, or any such proceeding shall have been commenced against it, in which an order for relief is entered or which remains undismissed for a period of ninety (90) days or more; or (iii) if the other Party by any act or omission shall indicate its consent to, approval of or acquiescence in any such petition, application or proceeding or order for relief or the appointment of a custodian, receiver or trustee for it or any substantial part of its assets, and shall suffer any such custodianship, receivership or trusteeship to continue undischarged for a period of ninety (90) days or more (each an "**Insolvency Event"**). Termination shall be effective upon the date specified in such notice. Notwithstanding the foregoing, this Agreement shall not be terminated pursuant to this Article 14.5(b) if, prior to the effective date of termination stated in the written notice from the Party desiring to terminate this Agreement, the Party experiencing the Insolvency Event demonstrates to the other Party that it is not insolvent.

14.6 **Additional Termination Right of Celltech.** If in any suit or proceeding where Celltech or any of its Affiliates is a named party Amgen or any of its Affiliates asserts, or Amgen or any of its Affiliates provides Confidential Information, financial assistance or technical assistance in collusion with a Third Party to assist such Third Party in asserting that any claim within the [*] Patent Rights or any [*] Patent Rights is invalid, Celltech, at its option, may, within [*] of such assertion, terminate this Agreement upon [*] prior written notice to Amgen (with termination being effective upon expiry of the [*] notice period); *provided however*, that nothing contained herein shall prohibit Amgen or any of its Affiliates from asserting the invalidity of any claim within the [*] Patent Rights or any [*]

Patent Rights, where such assertion is raised as a defence against an assertion of such [*] Patent Rights or [*] Patent Rights in such suit or proceeding brought against Amgen or any of its Affiliates or any of its licensees (provided that such suit or proceeding relates to the licensed subject matter) or its intellectual property rights. If the inclusion of this Article 14.6 would make invalid or unenforceable any other provision of this Agreement, or any of the Patent Rights licensed pursuant to this Agreement, this Article 14.6 shall be automatically and without notice severed from this Agreement and the remaining provisions of this Agreement shall remain in force.

14.7 **Opt-Out by Celltech.** In the event Celltech shall provide notice of its election to opt-out of this Agreement pursuant to Article 3.4, this Agreement shall automatically terminate in accordance with that Article 3.4.

14.8 **Continuing Party; Effective Date of Termination.**

(a) For the purposes of this Article 14:

(i) Celltech under Article 14.2.1;

(ii) the Party who wishes to assume, or has agreed to assume, Research, Development and/or Commercialisation of Antibody Product under Articles 14.2.2 or 14.3;

(iii) the Non-Defaulting Party under Article 14.4;

(iv) the terminating Party under Article 14.5 or Article 14.6; and

(v) Amgen under Article 14.7, with respect to each Antibody Product and Subsequent Products included within Celltech's opt-out under Article 3.4;

shall be, in each case, the "**Continuing Party**";

(b) The effective date of termination of this Agreement, as set forth in each instance in Articles 14.2 through 14.7, is hereby referred to as the "**Termination Date**".

14.9 **Effects of Termination.** In addition to any other remedies which may be available at law or equity upon termination of this Agreement, the rights and obligations of the Parties shall be as set forth in this Article 14.9.

(a) Upon termination of this Agreement howsoever caused, the following rights and obligations shall apply:

(i) The following provisions shall remain in full force and effect after the expiration or termination of this Agreement if there is a Continuing Party: Article 1, [*], Article 8 (in case of any payments relating to the period prior to the Termination Date), Article 11.1, Article 12 , this Article 14.9, Article 14.10, Article 16, Article 18, Article 19, Schedule E, and all ancillary provisions necessary for the implementation of this Article 14.9.

(ii) The following provisions shall remain in full force and effect after the expiration or termination of this Agreement if there is no Continuing Party: Article 1, [*], Article 8 (in case of any payments relating to the period prior to the Termination Date), Article 11.1, Article 11.5, Article 11.8 (in the case of any infringement defence pursuant to Article 11.5), Article 11.9(b), Article 11.9(c), Article 12 (in relation to the other Party's Confidential Information only), Article 13, this Article 14.9, Article 14.10, Article 18, Article 19, and all ancillary provisions necessary for the implementation of this Article 14.9. (iii)All other rights and obligations under this Agreement shall terminate.

(iv) By the [*] of the Termination Date, each Party (unless there is a Continuing Party, in which case only the non-Continuing Party) shall destroy, or at the other Party's request return, all of the other Party's Confidential Information (other than with respect to maintaining one (1) archival copy of Confidential Information related thereto for its legal files, for the sole purpose of determining its obligations under this Agreement) and Materials. In each instance where a Party is required to destroy or return the other Party's Confidential Information under this Article 14.9(a)(iv), such Party shall provide the other Party with certification by an officer of such Party that all such Confidential Information and Materials have been destroyed or returned to the other Party, as appropriate.

(b) Upon

(i) Receipt of a notice of termination of this Agreement pursuant to Article 14.2.2, where the Continuing Party has served notice under Article 14.2.2 indicating that it wishes to assume the Research, Development and/or Commercialisation of Antibody Product, or

(ii) Mutual consent of the Parties to terminate this Agreement, under Article 14.3, where the Parties have agreed for one Party to assume, the Research, Development and/or Commercialisation of Antibody Product, or

(iii) Termination of this Agreement pursuant to Article 14.2, Article 14.4, Article 14.5, Article 14.6 or Article 14.7; the Collaboration Committee shall promptly meet to devise a transition plan which provides for an orderly and cost-effective transition or winding down of, and which sets forth the responsibilities and a timetable for transferring or winding down (in each case as appropriate), Research, Development and Commercialisation responsibilities ("**Transition Plan**"). Where the Collaboration Committee cannot agree the timetable the [*] shall have [*]. Such transition shall be completed as soon as practicable and, in any event, shall be no later than the [*] of the Termination Date. Such Transition Plan shall provide for transferring or winding down (as appropriate) Research, Development and Commercialisation responsibilities as expeditiously as possible in accordance with this Article 14 while (in the case of transition) maintaining a supply of Antibody Product to meet the Development and/or Commercialisation requirements (as appropriate), and minimizing interruption of Research, Development and/or Commercialisation of the Antibody Product, including the following:

(1) Until the [*] of the Termination Date each Party shall make its personnel and other resources reasonably available to the other Party, as necessary, and shall by the [*] of the Termination Date transfer copies of all relevant information, files or data containing Information and transfer all Materials to the other Party.

(2) By the [*] of the Termination Date, the other Party shall transfer to the Continuing Party all Regulatory Filings and Regulatory Approvals then in its name for all Antibody Products and shall notify the appropriate Regulatory Authorities and take any other action reasonably necessary to effect such transfer.

(3) By the [*] of the Termination Date, the other Party shall assign its rights or grant sufficient sublicence rights to the Continuing Party under the other Party's right, title and interest in the Product Trademarks (but otherwise not any of the other Party's Trademarks). The Continuing Party shall also have the right,

for a reasonable period not to exceed [*] from the Termination Date, to use the other Party's Trademarks solely in the selling of any existing inventory of Antibody Products (and to use Promotional Materials it then has on hand), with no obligation of accounting to the other Party.

(4) By the [*] of the Termination Date, the other Party shall, at the request of the Continuing Party, assign its rights or grant sufficient sublicence rights to the Continuing Party, under all of the other Party's rights (but only to the extent permitted by its terms and subject to the obligations) under any [*] to the extent the same relates to Researching, Developing, Commercialising, making, having made, using, selling, having sold, offering to sell or resell, importing, exporting, distributing or otherwise transferring physical possession of or otherwise transferring title in or to Antibody Products and shall not (until receiving notice of whether or not the Continuing Party desires such an assignment or sublicence) terminate or amend any such [*].

(5) To the extent the other Party is the Manufacturing Lead it shall remain responsible for supplying Antibody Raw Material (and if the Manufacturing Lead is a Third Party then Celltech shall remain responsible for fulfilling its obligations under Article 6.1(a)(iii)), and Amgen shall also remain responsible for supplying Antibody Product in Finished Form, in each case in the amount that it was supplying at the time of such termination (and in accordance with the terms of Articles 6.5, 6.6 and 6.8), for a reasonable period of time not to exceed [*] from the Termination Date, to allow the Continuing Party (or with respect to Antibody Product in Finished Form, Celltech) to obtain an alternate source of supply, if necessary. The other Party shall also assign its rights or grant sufficient sublicence rights (but only to the extent permitted by its terms and only to the extent the same relates to Antibody Raw Material and/or Antibody Product in Finished Form) under all Third Party manufacturing agreements relating to Antibody Product to the Continuing Party, if requested to do so by the Continuing Party. The other Party shall no longer be responsible for supplying Antibody Raw Material and/or Antibody Product in Finished Form, or for fulfilling its obligations under Article 6.1(a)(iii), (as appropriate) from the date of such assignment or sublicence or the rejection of a written

offer of such assignment or sublicence (such rejection to be deemed to be given if the offer is not accepted in writing within [*] of receipt by the Continuing Party of such written offer from the other Party). In the event the other Party is obligated to continue to supply Antibody Products under this Article, the Continuing Party shall use Commercially Reasonable Efforts to identify one or more viable Third Party manufacturers in order to transfer manufacturing operations as soon as commercially reasonable.

(6) By the [*] of the Termination Date, to the extent the other Party is the Manufacturing Lead it shall itself transfer any Information Controlled by it and, to the extent it is using a Third Party manufacturer(s), shall either use Commercially Reasonable Efforts to enforce or assign to the Continuing Party the right to enforce the terms and conditions of each Third Party Supply Agreement entered into by it including (but only to the extent permitted by each such Supply Agreement with the Third Party) the provision to the Continuing Party of any Information and assistance reasonably required by the Continuing Party from such Third Party pertaining to the manufacture and analysis of Antibody Raw Material with the objective of the Continuing Party being enabled to implement the [*] of [*], including Information contained in the [*] of any applicable Regulatory Filings and the results of any stability studies performed by or on behalf of the other Party.

(7) By the [*] of the Termination Date, to the extent Celltech is the Continuing Party, Amgen shall transfer any Information Controlled by it pertaining to the manufacture and analysis of Antibody Product in Finished Form, and to the extent it is using a Third Party manufacturer(s), shall either use Commercially Reasonable Efforts to enforce or assign to Celltech the right to enforce the terms and conditions of any Third Party supply agreement entered into relating to Antibody Product in Finished Form by it, including (but only to the extent permitted by any such supply agreement) the provision to Celltech of any Information and assistance reasonably required by Celltech from such Third Party pertaining to the manufacture and analysis of Antibody Product in Finished Form with the objective of Celltech being enabled to implement the [*] of [*], including Information contained in the [*] of any applicable

Regulatory Filings and the results of any stability studies performed by or on behalf of Amgen.

(8) The other Party shall continue to use Commercially Reasonably Efforts to Promote, Detail and otherwise Commercialise the Antibody Product in those countries where it is the Territorial Commercial Lead, and shall if required to do so complete those [*] to which it has committed for the relevant time period in those countries where it is [*], as modified by the Transition Plan, to enable the Continuing Party to assume the Commercialisation responsibilities previously carried out by the other Party with a minimum of disruption.

(9) By the [*] of the Termination Date, the other Party shall (a) assign its rights or grant sufficient sublicence rights under all other Third Party agreements (but only to the extent permitted by their terms and subject to the obligations) to the extent the same relate to the Antibody Products and as requested to do so by the Continuing Party; and (b) shall provide reasonable assistance to the Continuing Party in assuming management of such agreements.

(c) Each Party shall assist (and, other than Wind Down Costs, be responsible for its own costs and expenses) in the transition or wind down of affairs as set forth in the Transition Plan in a timely, reasonable and businesslike manner. After completion of the responsibilities set forth in the Transition Plan the Parties shall have no further obligation to assist in such transition or winding down (as appropriate).

(d) If, under Article 14.2.2 the Continuing Party elects to cease Research, Development and Commercialisation of Antibody Products under this Agreement, the Collaboration Committee shall establish, by unanimous decision, a wind down plan which sets forth the responsibilities and timing for ceasing the Research, Development and/or Commercialisation of Antibody Product as expeditiously and cost effectively as possible. Both Parties shall co-operate to achieve this end, including complying with its obligations under the wind down plan.

(e) During any period after receipt or delivery of a notice of termination to the Termination Date the Parties' respective rights and obligations under this Agreement shall (to the extent applicable) remain in full force and effect, including the sharing of the Product Contribution.

(f) In the event this Agreement is terminated by Celltech pursuant to Article 14.2.2 or by the

Parties pursuant to Article 14.3 and Amgen shall have elected or agreed (as appropriate) to assume Research, Development and/or Commercialisation of Antibody Product, or if this Agreement terminates pursuant to Article 14.7, or if this Agreement is terminated by Amgen pursuant to Article 14.4 or 14.5, the Antibody Licence Agreement attached as Schedule G shall come into full force and effect immediately on termination of this Agreement. In the event this Agreement is terminated by Amgen pursuant to Article 14.2.2 or by the Parties pursuant to Article 14.3 and Celltech shall have elected or agreed (as appropriate) to assume Research, Development and/or Commercialisation of Antibody Product, or if this Agreement is terminated by Celltech pursuant to Article 14.4, 14.5 or 14.6, or if this Agreement is terminated pursuant to Article 14.2.1, [*] shall grant to [*] a [*] licence under any [*] Technology (including the Information and [*] Patent Rights pertaining to the [*] of the [*] of Antibody Products) to Research, Develop, Commercialise, make, have made, use, sell, have sold, offer to sell or resell, import, export, distribute or otherwise transfer physical possession of or otherwise transfer title in or to Antibody Products.

Such [*] licence shall be on substantially the same terms as the Antibody Licence Agreement attached as Schedule G (but with Amgen as licensor and Celltech as licensee) *provided that* no [*] shall be payable and the [*] payable by Celltech to Amgen shall:

(i) be agreed by the Parties, or failing such agreement within [*] of the Termination Date;

(ii) be determined by an expert appointed by an independent accountant of internationally recognised standing reasonably acceptable to both Parties, taking into account:

(1) the value, if any, of any [*] Technology used or to be used by Celltech in connection with the Antibody Product(s) (then being [*] or then being [*] or [*]); and

(2) the value, if any, of the investment made by Amgen in the Antibody Product(s) (then being [*] or then being [*] or [*]), relative to the value of the investment made by Celltech in such Antibody Product(s); and

(3) the [*] on the Antibody Product(s) (then being [*] or then being [*] or [*]).

In any event, the [*] shall not be a [*] which would make Commercialisation of such Antibody Product(s) by Celltech [*].

(g) If a Party serves a notice pursuant to Article 2.7 after expiry of Celltech's opt-out right as set out in Article 3.4, but before completion of the Pivotal Studies of an Antibody Product as set out in the Late Stage Development Plan in effect at the date of such notice, the Party serving such notice shall, notwithstanding such termination, bear its share of all Research and Development Costs of such Pivotal Studies in accordance with Article 3.6 as though the Agreement had not been terminated. This is without prejudice to the other provisions of this Article 14.

(h) Termination of this Agreement by Celltech due to a notice served by it pursuant to Article 2.7 shall not relieve either Party of its obligations to share Research and Development Costs as set forth in Articles 3.6.1 and 3.6.2. Termination of this Agreement by Amgen due to a notice served by it pursuant to Article 2.7 shall not relieve either Party of its obligations to share Research and Development Costs as set forth in Articles 3.6.1 and 3.6.2 for a period of [*] from the date of Amgen's notice.

14.10 **Accrued Rights.** Termination, relinquishment or expiration of any licences under this Agreement or of this Agreement for any reason in accordance with this Article 14 shall be without prejudice to any rights which shall have accrued to the benefit of either Party or any liability incurred by either Party prior to such termination, relinquishment or expiration.

ARTICLE 15

DISPUTE RESOLUTION

15.1 **Referral of Unresolved Matters to** [*]**.** The Parties recognise that disputes as to certain matters may from time to time arise during the term of this Agreement which relate to either Party's rights and/or obligations hereunder and which are not resolved by the Collaboration Committee. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising from, concerning or in any way relating to this Agreement in an expedient manner by mutual co-operation and without resort to litigation. If the Collaboration Committee is unable to resolve any matter falling within its authority, the matter shall be referred to the respective [*] of Research or Development of

each Party (in the case of a dispute involving Research or Development respectively) or the respective [*] of Marketing of each Party (in the case of a dispute involving Commercialisation), or to such other senior officer of similar authority and standing as each Party may from time to time designate (collectively, the "[*]"), to be resolved by negotiation in good faith as soon as is practicable but in no event later than [*] after written request from either Party to the other Party for such a referral. If such [*] are unable to resolve the matter within the said [*] it shall be referred to the [*] (together, the [*] and [*], the "[*]") as soon as practicable but in any event no later than [*] after a written request from either Party to the other Party for such a referral. Each [*]shall have the right to engage the services of any number of independent experts in the field in question (such independent expert(s) to be engaged under obligations of confidentiality and the expense of the Party so engaging such expert(s)) to assist the [*] in making a determination on the unresolved matter, and each [*] shall consider in good faith the analyses and opinions of any such independent experts engaged by either of them in making a determination. In the event that following discussions between the [*], the [*] are unable to resolve such dispute within such [*] of the matter being referred to them, then either Party may at any time thereafter pursue any legal or equitable remedy available to it. Notwithstanding the above, either Party shall be entitled at all times and without delay to seek equitable relief.

ARTICLE 16

REPRESENTATIONS AND WARRANTIES

16.1 **Authority and Consents.** Celltech and Amgen each represent and warrant to the other Party that as of the Effective Date (a) it has full right, power and authority to enter into this Agreement and perform its obligations hereunder and has taken all necessary corporate action on its part required to authorise the execution and delivery of the Agreement and the performance of its obligations hereunder; (b) this Agreement has been duly executed by such Party and so far as it is aware (not having made enquiry) constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms subject to all limitations of bankruptcy, liquidation, principles of equity (including moratorium and enforcement of creditors' rights generally), general principles of equity (including, those relating to specific performance, injunctions and other remedies) and public policy constraints (including those pertaining to limitations and/or exclusions of liability, competition law, penalties and jurisdictional issues including conflicts of law); and (c) the execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate such Party's corporate charter and bylaws or so far as it is aware (not having made enquiry)

any requirement of applicable laws or regulations of any court, governmental body or administrative or other agency having jurisdiction over it and (ii) do not and shall not conflict with, violate or breach or constitute a default or require any consent under any contractual obligation of such Party.

16.2 **Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party that as of the Effective Date: (a) it is aware of no action, suit, inquiry or investigation instituted by any Third Party which questions or threatens the validity of this Agreement and (b) it is not aware of any facts or circumstances, individually or in the aggregate, which it knows are reasonably likely to have a material adverse effect on its ability to perform its obligations under this Agreement; and (c) it has acted in good faith in providing Information to the other Party and has not wilfully misled the other Party with respect to any such Information.

16.3 **Additional Representation and Warranty of Celltech.**

Celltech further represents and warrants to Amgen that as of the Effective Date (a) it is the exclusive owner of the Patent Rights listed in Parts A, B and C of Schedule F and the owner, licensee or holder of option rights under the Patent Rights listed in Part D of Schedule F; (b) it has disclosed to Amgen in good faith all Information which Celltech has and which it reasonably believes to be material to the validity of the [*] Patent Rights, *provided however*, that nothing herein shall be construed as a warranty or representation by Celltech of the validity of such Patent Rights; (c) it has disclosed to Amgen in good faith all Information Celltech has and which it reasonably believes to be material to the safety of [*] Antibodies for therapeutic use and (d) it has not received a written notice that Celltech is in material breach or material default of the agreements listed in Part E of Schedule F and disclosed to Amgen prior to the Effective Date.

16.4 **Mutual Covenants.** Each Party hereby covenants to the other Party as follows:

(a) No Misappropriation. It shall not knowingly misappropriate the trade secret of a Third Party in its activities to Research, Develop or Commercialise Antibody Products.

(b) No Debarment. In the course of the Development of Antibody Products and during the Term, such Party shall not knowingly use and shall not have knowingly used any employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge (not having made enquiry), who is or has been the subject of debarment proceedings by a Regulatory Authority.

(c) No Conflict. It will not enter into any agreement with a Third Party that is in conflict with

this Agreement, and will not take any action that would in any way prevent it from assuming its obligations or granting the rights granted to the other Party under this Agreement or that would otherwise materially conflict with or adversely affect its obligations or its assumption of the rights granted to the other Party under this Agreement.

(d) [*]. It shall work [*] with the other Party with respect to [*], and it shall not during the term of this Agreement grant any right, licence, consent or privilege to any Third Party(ies) in the Territory which would conflict with the rights granted to the other Party under this Agreement.

(e) Compliance. Notwithstanding anything to the contrary in this Agreement, each Party shall comply with all applicable statutes and regulations of Regulatory Authorities in carrying out its respective activities regarding the Research, Development and Commercialisation of Antibody Products in the Field in the Territory.

(f) Workmanship. Each Party shall commit the personnel, facilities and other resources reasonably necessary to conduct its obligations under this Agreement, and shall conduct its Research and/or Development obligations using the same standard of skill and care which it applies to its other products, but in no event less than commonly accepted good professional standards of workmanship.

16.5 **Disclaimer of Representation and Warranty.**

(a) Nothing in this Agreement shall be construed as a warranty or representation by either Party (i) that the Research, Development, Commercialisation, making, having made, using, selling, having sold, offering to sell or resell, importing, exporting, distributing or otherwise transferring physical possession of or otherwise transferring title in any Antibody Products under, or in connection with, this Agreement are or will be free from infringement of, or that the activities conducted pursuant to this Agreement will not infringe, Patents Rights, copyrights, Trademarks, industrial design or other intellectual property rights of any Third Party or (ii) that any Antibody Product Researched, Developed, Commercialised, made, have made, used, sold, have sold, offered to sell or resell, imported, exported, distributed or in which physical possession or title is transferred under this Agreement is or will be effective, valuable, safe, non-toxic or patentable. Each Party explicitly accepts all of the same, and accepts that the activities conducted and the Antibody Products are experimental as at the Effective Date. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES, AND RENOUNCES ANY

WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF EFFICACY, SAFETY, SATISFACTORY QUALITY OR FITNESS FOR A PARTICULAR PURPOSE.

(b) Notwithstanding Articles 16.5(a) and 19.14, nothing in this Agreement limits or excludes any Party's liability for fraud or for death or personal injury caused by that Party's own negligence.

ARTICLE 17

CHANGE OF CONTROL

17.1 **Change of Control.** In the event that, during the term of this Agreement, a Third Party (the "**Acquiring Party**") shall acquire, directly or indirectly: (i) fifty percent (50%) or more of the shares of a Party's stock entitled to vote for the election of directors of a Party, or (ii) a substantial equity interest in, together with the power to direct the management and policies of, a Party; the other Party (the "**non-Acquired Party"**) shall have the right, within [*] of such acquisition, to terminate the Acquired Party's right to [*] with its [*] right to [*] in accordance with Article 5.2. If such a termination notice is served, the Parties shall co-operate to ensure an orderly wind down of all [*] throughout the Territory as soon as practicable.

ARTICLE 18

INDEMNIFICATION; INSURANCE

18.1 **Indemnification by Amgen.** Amgen hereby agrees to defend, hold harmless and indemnify (collectively "**Indemnify**") Celltech and its Affiliates, agents, directors, officers and employees (the "**Celltech Indemnitees**") from and against any and all Third Party claims, suits, actions or demands and all out-of-pocket liabilities, damages, costs, settlements, expenses and/or losses paid to any Third Party bringing any such Third Party claim, as well as reasonable legal expenses and attorney and expert fees incurred in defending and/or compromising the same, ("**Celltech Loss(es)**") arising out of any of (a) Amgen's representations or warranties set forth in this Agreement being untrue in any material respect when made; (b) any material breach or material default by Amgen of its material covenants and material obligations under this Agreement; (c) Amgen's negligence or intentional misconduct in carrying out its activities set forth in this Agreement; and (d) any Trademark infringement claim, lawsuit or other action, resulting solely from Celltech's proper use of Amgen Trademarks in connection with an Antibody Product in accordance with the terms of this Agreement.

Celltech shall provide Amgen with prompt written notice of any claim (with a description of the claim and the nature and amount (if determinable) of any such Celltech Loss) giving rise to the indemnification obligation pursuant to this Article 18.1 and the exclusive ability to defend such Third Party claim; *provided however*, that Amgen shall be relieved of its obligations only to the extent the failure to be provided prompt written notice shall have been prejudicial to its ability to defend such action. Celltech shall co-operate as reasonably requested in the defence of the claim; *provided however*, that Celltech shall have the right to retain its own counsel, at its own expense, if representation of the counsel of Amgen would be inappropriate due to actual or potential differing interests between the Parties. Celltech shall not settle any claim for Celltech Losses for which any Celltech Indemnitee is seeking to be Indemnified by Amgen, without Amgen's prior written consent. Amgen's obligation to Indemnify the Celltech Indemnitees pursuant to this Article 18.1 shall not apply to the extent any Celltech Losses (i) arise from the negligence or intentional misconduct of any Celltech Indemnitee; (ii) arise from any material breach by Celltech of this Agreement; or (iii) for which Celltech is obligated to Indemnify the Amgen Indemnitees pursuant to Article 18.2 of this Agreement.

18.2 **Indemnification by Celltech.** Celltech hereby agrees to Indemnify Amgen and its Affiliates, agents, directors, officers and employees (the "**Amgen Indemnitees**") from and against any and all Third Party claims, suits, actions or demands and all out-of-pocket liabilities, costs, settlements, damages, expenses and/or losses paid to any Third Party bringing any such Third Party claim, as well as reasonable legal expenses and attorney and expert fees incurred in defending and/or compromising the same, ("**Amgen Loss(es)**") arising out of any of (a) Celltech's representations or warranties set forth in this Agreement being untrue in any material respect when made; (b) any material breach or material default by Celltech of its material covenants and material obligations under this Agreement; (c) Celltech's negligence or intentional misconduct in carrying out its activities set forth in this Agreement; and (d) any Trademark infringement claim, lawsuit or other action, resulting solely from Amgen's proper use of Celltech Trademarks in connection with an Antibody Product in accordance with the terms of this Agreement. Amgen shall provide Celltech with prompt written notice of any claim (with a description of the claim and the nature and amount (if determinable) of any such Amgen Loss) giving rise to the indemnification obligation pursuant to this Article 18.2 and the exclusive ability to defend such Third Party claim; *provided however*, that Celltech shall be relieved of its obligations only to the extent the failure to be provided prompt written notice shall have been prejudicial to its ability to defend such action. Amgen shall co-operate as reasonably requested in the defence of the claim; *provided however*, that Amgen shall have the right to retain its own counsel, at its own expense, if representation of the counsel of Celltech would be inappropriate due to actual

or potential differing interests between the Parties. Amgen shall not settle any claim for Amgen Losses for which any Amgen Indemnitee is seeking to be Indemnified by Celltech, without Celltech's prior written consent. Celltech's obligation to Indemnify the Amgen Indemnitees pursuant to this Article 18.2 shall not apply to the extent any Amgen Losses (i) arise from the negligence or intentional misconduct of any Amgen Indemnitee; (ii) arise from any material breach by Amgen of this Agreement; or (iii) for which Amgen is obligated to Indemnify the Celltech Indemnitees pursuant to Article 18.1 of this Agreement.

18.3 **Joint Liability.** Any and all liabilities, damages, costs, settlements expenses and/or losses ("**Joint Loss(es)**") arising from Third Party claims, suits, actions or demands (other than those subject to indemnification pursuant to Article 18.1 or 18.2) resulting directly or indirectly out of Researching, Developing, Commercialising, making, having made, using, selling, having sold, offering to sell or resell, importing, exporting, distributing or otherwise transferring physical possession of or otherwise transferring title in or to Antibody Products (including a claim that an Antibody Product caused death or personal injury of any kind) shall be charged to the Product Contribution account as a Commercialisation Expense at the time such claim is finally determined. In the event a Party becomes aware of a claim which, if resulting in a Joint Loss, it intends to charge to the Product Contribution account, such Party shall inform the other Party of such claim as soon as reasonably practicable after it receives notice thereof. Amgen shall have the right to assume direction and control of the defence of any claim alleging a date of injury (or in the event of a continuing injury alleging the then-most recent date of injury) to be prior to the completion of the first [*] for an Antibody Product; and, with respect to Third Party claims in a country, each Territorial Commercial Lead in such country shall have the right to assume direction and control of the defence of any claim alleging a date of injury (or in the event of a continuing injury alleging the then-most recent date of injury) to be upon or after completion of the first [*] for such Antibody Product. The Party not in control of such defence shall co-operate as reasonably requested in the defence of the claim; *provided however*, that such Party shall have the right to retain its own counsel (at its own expense) if representation of the counsel of the Party in control would be inappropriate due to actual or potential differing interests between the Parties. The Party in control shall not settle any such claim without the other Party's prior written consent, such consent not to be unreasonably withheld or delayed.

18.4 **Insurance.** Each Party shall maintain (through a captive insurer or Third Party insurer) appropriate product liability insurance with respect to Antibody Products and appropriate comprehensive general liability insurance to cover its obligations hereunder and which is/are consistent with normal business

practices of prudent companies similarly situated. Each Party shall use reasonable endeavours to ensure that any insurance policy required by, and procured under, this Article 18.4 by a Party shall name the other Party as an additional insured. Such insurance shall not be construed to create a limit of the insuring Party's liability with respect to its indemnification obligations under this Article 18. Each Party shall furnish the other Party with a certificate(s) or other evidence from an insurance carrier showing all such insurance. Each Party shall diligently pursue recovery of insurance proceeds when a claim arises. The Parties acknowledge that it is the normal business practice of prudent companies similarly situated to have a reasonable level of uninsured loss.

18.5 **No Liability.** Without prejudice to each Party's obligations as specified in this Agreement, a Party shall have no liability to the other Party with respect to (a) the results obtained in the Research, Development and Commercialisation of Antibody Product; or (b) [*], or any agreement relating thereto; or (c) the results obtained in the filing, prosecution, enforcement, maintenance or defence of any intellectual property; in each case when conducted in accordance with this Agreement. The Parties agree that the risks, liabilities and benefits relating to the Research, Development and Commercialisation of Antibody Product, including [*], and including the filing, prosecution, enforcement, maintenance or defence of any intellectual property, in each case when conducted, in accordance with this Agreement, is [*].

18.6 **Pre-Effective Date Losses.** In connection with this Agreement, neither Party shall assume or be liable for any liabilities, damages, expenses and/or losses resulting from or arising in connection with activities of the other Party which occurred on or prior to the Effective Date.

ARTICLE 19

MISCELLANEOUS

19.1 **Amendments.** This Agreement may not be modified or supplemented by any purchase order, change order, acknowledgement, order acceptance, standard terms of sale, invoice or the like. Any amendment or modification to this Agreement shall be made in a writing expressly stated for such purpose and signed by an authorised officer of each Party; except that the Research Plan and the Commercialisation Plan may be amended or updated by the Joint Research Committee and the Joint Commercialisation Committee, respectively, as expressly permitted hereby.

19.2 **Notices.** Any consent or notice required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing, delivered personally or by facsimile (and promptly

confirmed by personal delivery or courier), by a next business day delivery service of a nationally recognised overnight courier service or by courier, postage prepaid (where applicable), addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor in accordance with this Article 19.2 and shall be effective upon receipt by the addressee.

If to Celltech: Celltech R&D Limited
208 Bath Road
Slough SL1 3WE
Berkshire, England

Attention: Company Secretary
Facsimile: (XXX) (XX) XXXX XXXXXX

If to Amgen: Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799 U.S.A.

Attention: Vice President, Licensing
Marked to be copied to: Corporate Secretary
Facsimile: (XXX) (XXX) XXX-XXXX

19.3 **Force Majeure.** Neither Party shall 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 to the extent such failure or delay is caused by or results from Force Majeure, *provided however,* that the Party so affected shall use Commercially Reasonable Efforts to avoid, remove or mitigate such causes of non-performance and shall continue performance with reasonable dispatch wherever such causes are removed. Each Party shall provide the other Party with prompt written notice of any delay or failure to perform that occurs by reason of Force Majeure. Such excuse shall be continued so long as the condition constituting Force Majeure continues. The Parties shall mutually seek in good faith a resolution of the delay or failure to perform.

19.4 **Use of Names, Logos or Symbols.** Subject to Articles 5.11(h), 10.2 and 12.5, no Party hereto shall use and no rights are granted to the Trademarks (including the names “[*]” and “[*]”), physical likeness, employee names or owner symbol of the other Party for any purpose (including private or public securities placements) without the prior written consent of the other Party, such consent not

to be unreasonably withheld or delayed so long as use of such name is limited to objective statement of fact rather than for endorsement purposes. Neither Party shall use any Trademark or domain name in connection with the subject matter of this Agreement which either substantially resembles or is confusingly similar to, misleading or deceptive with respect to, or which dilutes any of the other Party's Trademarks or domain names, other than its own Product Trademark or domain names actually used in connection with an Antibody Product.

19.5 **Governing Law; Jurisdiction.**

(a) This Agreement shall be governed and interpreted in all respects under the substantive laws of the State of New York, United States, as applied to agreements executed and performed entirely in the State of New York by residents of the State of New York, without regard to conflicts of law rules and without regard to the United Nations Convention on International Contracts for the Sales of Goods.

(b) Each Party consents to the exclusive jurisdiction of the federal or state courts in the State of New York for any suit, action or other proceeding arising out of or relating to this Agreement whether denominated or arising in contract, tort or otherwise, and further agrees that any process, notice of motion or other application to either such court or judge thereof may be served outside of New York City, New York by personal service, *provided that* a reasonable time for appearance is allowed. Each Party hereby irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of or relating to this Agreement whether denominated or arising in contract, tort or otherwise, in the federal or state courts in the State of New York. Each Party hereby irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any action, suit or proceeding brought in any such court has been brought in inconvenient forum. As between the Parties, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent Rights claiming the use or sale of any Antibody Product or of any Trademark rights relating to an Antibody Product shall be submitted to a court of competent jurisdiction in the Territory in which such Patent Rights or Trademark rights were granted or arose which in the case of any United States Patent Rights and Trademark rights shall be a court of competent jurisdiction in the State of New York.

(c) Each Party hereby waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in respect to any litigation directly or indirectly arising out of or relating to this Agreement.

19.6 **Performance by Affiliates.**

(a) Each of Amgen and Celltech acknowledge that obligations under this Agreement may be performed on a subcontracting basis by Affiliates of Amgen and Celltech. Each of Amgen and Celltech remain responsible for the acts and omissions in the performance of this Agreement, by its Affiliates, notwithstanding any assignment to Affiliates in accordance with Article 19.7 of this Agreement. Wherever in this Agreement the Parties delegate responsibility to Affiliates, the Parties agree that such entities may not make decisions inconsistent with this Agreement, nor amend the terms of this Agreement or act contrary to its terms in any way.

(b) Each Party agrees that any information or material provided by the other Party's Affiliates or subcontractors shall be deemed to be the Information or Material of the other Party.

19.7 **Assignment.**

(a) This Agreement may not be assigned or otherwise transferred by any Party without the consent of the other Party not to be unnecessarily withheld or delayed; *provided however,* that either Celltech or Amgen may, without such consent, assign its rights and obligations under this Agreement (i) to any Affiliate, *provided* such interest shall be retransferred to the relevant Party if such entity ceases to be an Affiliate of such Party, and provided further that the assigning Party shall remain responsible for the acts and omissions in the performance of this Agreement, by its Affiliate, (ii) in connection with a merger, consolidation or sale of substantially all of the business to which this Agreement relates to an unrelated Third Party of [*], provided that the other Party shall have the right, within [*] of such acquisition, to terminate the assigning Party's right to [*] with its [*]right to [*] in accordance with Article 5.2. If such termination notice is served, the Parties shall co-operate to ensure an orderly wind down of all [*] throughout the Territory as soon as practicable.

(b) Except as aforesaid, any permitted assignee shall assume all rights and obligations of its assignor under this Agreement; accordingly, all references to the assigning Party shall be deemed references to the assignee to whom the Agreement is so assigned. The assigning Party shall forward to the other Party a copy of those portions of each such fully executed assignment agreement which relate to the assumption of the rights and responsibilities of the assigning Party, within [*] of the execution of such assignment agreements.

(c) Any assignment or attempted assignment by either Party in violation of the terms of this Article 19.7 shall be null and void and of no legal effect.

19.8 [*]**.** [*].

19.9 **Joint Committees.** Members of the Collaboration Committee, Joint Research Committee, Joint Development Committee, the Joint Commercialisation Committee and any subcommittees thereof shall be, and shall remain, employees of Celltech or Amgen, as the case may be. No Party shall incur any liability to the other Party for any act or failure to act by members of the Collaboration Committee, Joint Research Committee, Joint Development Committee, the Joint Commercialisation Committee and any subcommittees thereof who are employees of the other Party.

19.10 **Subcontracting.** The Parties acknowledge and agree that, notwithstanding anything to the contrary in this Agreement, elements of the work involved in Research, Development and Commercialisation of Antibody Products may be subcontracted to a Third Party by the responsible Party and that the Party entering into such subcontract may, as part of such subcontract, grant to such Third Party a licence or sublicence to [*] Technology or to [*] Technology, as applicable, only to the extent and only for so long as such licence or sublicence is necessary for such Third Party to perform such tasks; *provided however*, that the responsible Party shall remain responsible for the acts and omissions in the performance of such work by its subcontractors pursuant to the terms and conditions of this Agreement, and that each subcontractor shall enter into a written agreement binding such subcontractor to the obligations the responsible Party has to the other Party (and containing any other provisions normal and customary for similar types of agreements) including: (a) Amgen may, [*], subcontract to a Third Party various preclinical activities referred to in Article 3.2.1(c); (b) each Party may, [*], contract with / establish clinical sites, investigators and CROs pursuant to Article 3.2.2; (c) each Party may subcontract to a Third Party manufacturer pursuant to Article 6.4; and (d) each Territorial Commercialisation Lead may enter into agreements with distributors or agents for commercial distribution of Antibody Products pursuant to Article 5.3. The subcontracting Party shall use Commercially Reasonable Efforts to enter into an Agreement with the bidder that is best able to meet the Parties' mutual requirements, taking into consideration such factors as price, quality, capacity, quantity, reliability and reputation.

19.11 **No Strict Construction.** This Agreement has been prepared jointly and shall not be strictly construed against either Party.

19.12 **Interpretation and Schedules.** (a) The captions or headings of the Articles or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof. (b) Unless otherwise specified, (i) references in this Agreement to any Article, or Schedule shall mean references to such Article, or Schedule of this Agreement; and (ii) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto. (c) Any statute defined or referred to herein or in any agreement or instrument that is referred to herein means such statute as from time to time amended, modified or supplemented, including by succession of comparable successor statutes and references to all attachments thereto and instruments incorporated therein. References to a person are also to its permitted successors and assigns. (d) All Schedules annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any capitalised terms used in any Schedule but not otherwise defined therein, shall have the meaning as defined in this Agreement. (e) Whenever the words "**include**", "**includes**" or "**including**" are used in this Agreement, they shall be deemed to be followed by the words "without limitation".

19.13 **Severability.** If any provision hereof should be held invalid, illegal or unenforceable from which no appeal can be or is taken, in any respect in any jurisdiction, the invalidity, illegality or unenforceability of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the objectives contemplated by the Parties as evidenced by the terms and conditions of this Agreement when entering into such invalid or unenforceable one.

19.14 **No Consequential Damages.** NEITHER PARTY HERETO WILL BE LIABLE (WHETHER UNDER AN INDEMNITY OR OTHERWISE) FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING WITHOUT LIMITATION LOST PROFITS, ANTICIPATED PROFITS, LOST GOODWILL, LOST REVENUE, LOST PRODUCTION, LOST CONTRACTS AND LOST OPPORTUNITY, ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, WHETHER DENOMINATED IN OR

ARISING IN CONTRACT, TORT OR OTHERWISE REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS ARTICLE 19.14 IS INTENDED TO LIMIT OR RESTRICT ANY PAYMENT OBLIGATION EXPLICITLY SET FORTH UNDER THIS AGREEMENT.

19.15 **General Provisions.**

(a) The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and a person who is not a Party to this Agreement may not enforce any of its terms.

(b) A waiver (whether express or implied) by one of the Parties of any of the provisions of this Agreement or of any breach of or default by the other Party in performing any of those provisions must be in writing executed by a responsible officer of the Party providing the waiver and expressly waiving such provisions or breach or default by reference to this Agreement, and any waiver shall not constitute a continuing waiver, and that waiver shall not prevent the waiving Party from subsequently enforcing any of the provisions of this Agreement not waived or from acting on any subsequent breach of or default by the other Party under any of the provisions of this Agreement.

(c) Each Party undertakes to execute all documents which may be reasonably necessary to give full effect to this Agreement.

(d) Each Party shall pay its costs and expenses incurred by it in connection with negotiation and execution of this Agreement.

(e) It is expressly agreed that for tax, legal or all other purposes (i) this Agreement or any portion of this Agreement shall not be considered to be a partnership agreement, and (ii) the relationship between the two Parties shall not constitute an employee-employer, partnership, joint venture, agency or similar business relationship between the Parties. Neither Celltech nor Amgen shall have the authority to make any statements, representations, warranty, guarantee or commitments (express or implied) of any kind or to take any action which shall bind the other Party to a Third Party, without the prior consent of the other Party to do so. Each Party shall use its own discretion, shall have complete and authoritative control over its employees and the methods and means by which it performs its activities under this Agreement (including the management of permitted subcontractors).

(f) This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

19.16 **Whole Agreement.** This Agreement and the Schedules referred to in this Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all previous understandings, arrangements and agreements with respect to the subject matter hereof, whether written or oral. Each Party acknowledges that in entering into this Agreement it has not relied on any representation, warranty, collateral contract or other assurance (except those expressly set out in this Agreement together with the Schedules) made by or on behalf of any other Party before the signature of this Agreement. Each Party waives all rights and remedies which, but for this Article 19.16, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance. As of the Effective Date, the Confidential Disclosure Agreement dated [*] (Amgen Reference No. XXXXXXXX) and amended on [*] (Amgen Reference No. XXXXXXXX-XXX) is hereby superseded, provided that all Proprietary Information as defined in and disclosed pursuant to or covered by such Confidential Disclosure Agreement and its Amendment shall be treated as Confidential Information as if disclosed under, and shall be subject to the terms of, this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

AMGEN INC.	**CELLTECH R & D LIMITED**
By: /s/ R.M. Perlmutter	By: /s/ P.V. Allen
Name: R.M. Perlmutter	Name: P.V. Allen
Title: EVP, R&D	Title: CFO

SCHEDULE A

Research Plan

The primary objective of the Research Plan is the [*] that has suitable [*] attributes to designate it as a clinical development candidate. To accomplish this, there will be [*] major [*] work streams. The objective of the [*] workstream is to identify [*] that will be used to validate the [*], the [*] representing the most likely initial [*] for the corresponding [*]. The work includes, but may not be limited to, characterizing [*] in a number of [*] and [*] and then [*] of [*] to identify [*]. A reasonable number of [*] will then be profiled in both [*] and [*]. It is recognised that aspects of this program are iterative by their very nature and that revisions to plan may need to occur based on experimental results. This phase would be considered successful if a [*] proved to be [*].

In parallel with this [*], a [*] workstream will be engaged around generating [*] suitable for clinical testing. Similar to the activities above, [*] will be characterized in a number of [*] and then by [*] of [*] to identify [*]. The [*] will serve as the basis for the generation of [*] which at the present time are envisioned to represent the [*]. The choice of [*], as opposed to a [*], as a clinical candidate will be decided based on the properties of the [*] and also on background data provided by [*] on clinical experience with these [*], especially their [*]. As the [*] are converted to [*], the [*] of the newly generated [*] will be tested against appropriate [*] and [*]. The selection of the [*] candidate will be based on a number of criteria. At the end of this workstream, sufficient material to initiate [*] and perform [*] will be produced. It is recognised that [*] of the [*] workstream would interrupt this plan. In that case, an alternative research plan would be identified through discussions at the Joint Research Committee.

In the event that the [*] workstreams are successful and a clinical candidate is put forward, a [*] program will be engaged to identify additional clinical candidates should the first [*] for any reason. Additionally, it is recognised that additional work directed against understanding the [*] will take place. Such activities could include [*] studies, [*] identification and so forth.

On selection of a clinical candidate, [*] will start work on development of a suitable [*] for both [*] studies and ultimately for clinical evaluation. [*] will expect advice from [*] on the [*] of such a [*] based on [*]'s previous experience with such products. [*] will need sufficient quantities of [*] to enable it to start such studies. A preliminary estimate is [*] for these [*] studies. [*] will expect this material to be supplied by [*]

according to a timeline that will be agreed at the Joint Research Committee. Similarly, [*] will require suitable quantities of [*] to enable it to conduct [*] studies. The time line for this will also be agreed by the Joint Research Committee.

The initial work plan, which shall be agreed by the Joint Research Committee at their first meeting, is as follows:

BEER Draft Timeline

[*] [2 pages of redactions]

Milestone definitions

Milestone 1.

[*]:

a) [*] and

b) [*].

In addition, these [*] shall [*]. "[*]" and "[*]" shall mean [*].

Milestone 1 shall also be considered to have been met if [*].

Milestone 2.

[*]:

1. [*]. [*]. And,
2. [*], and
3. [*], and
4. [*].

Milestone 2 will also be considered to have been met upon [*].

Milestone 3.

[*].

Milestone 3 will also be considered to have been met if the [*].

SCHEDULE B

Costs and Calculation of Product Contribution

"Product Contribution" shall be calculated for each Calendar Quarter by subtracting the sum of (a) Other Expense, (b) Cost of Goods of Antibody Product sold, (c) Commercialisation Expense, and (d) Licence Fees, (in each case, incurred in that quarter) from Net Sales of Antibody Products and recoveries from legal actions pursuant to Articles 6 and 11 and from insurance claims referenced in Article 18 (in each case as recognised in that quarter). Definitions of capitalised terms used for the purposes of calculating Product Contribution are set forth below in this Schedule B:

Commercialisation Expense	means the sum of (a) Promotion Expense, (b) Marketing Expense, (c) Marketing Personnel Costs, (d) Drug Regulatory Expense, (e) Medical Affairs Expense, (f) Direct Sales Force Expense, (g) any out-of-pocket costs incurred in filing, prosecuting and maintaining applications and registrations for Antibody Product Trademarks in any country and (h) the costs of filing suit against or defending against infringers of Patent Rights pursuant to Article 11; (i) Distribution Costs; and (j) any other cost or expense expressly stated to be a Commercialisation Expense in this Agreement. Commercialisation Expense may occur prior to and subsequent to Regulatory Approval and First Commercial Sale.
Cost of Goods	means the FAMC for an Antibody Product as determined by reference to Schedule E.
Detail	Shall have the meaning set forth in Article 1.
Detail Cost	means the cost of a sales force Detailing Antibody Product calculated in accordance with the principles outlined in Schedule C.
Direct Sales Force Expense	means, for each country, the sum of : (a) the Detail Cost of each sales force; and (b) out-of-pocket costs and expenses paid to Third Parties for Details provided by such Third Parties.
Distribution Costs	means all out-of-pocket costs, expenses, and Personnel Costs incurred in the distribution of Antibody Products, including, without limitation, freight, insurance, warehousing, order entry, billing, credit and

	collection of debt to the extent that such costs are not included in the calculation of Net Sales or Cost of Goods.
Drug Regulatory Expense	means Personnel Costs, out-of-pocket costs and expenses (e.g., filing fees, user fees, annual product registration fees and the like) incurred for obtaining or maintaining Regulatory Approvals for an Antibody Product in a country and all out-of-pocket costs incurred in satisfying all registration and other requirements of Regulatory Authorities (including for example adverse event reporting) including costs associated with a change of site manufacture or change of container.
Licence Fees	means all upfront payments, milestone payments, licence fees, royalties or other payments, payable to any Third Party under any Third Party Licence Agreement following the first Regulatory Approval of an Antibody Product to the extent such payments are attributable to such Antibody Product. If the rights under any Third Party Licence Agreement are also attributable to products other than Antibody Products then only an equitable portion of any amounts payable under it shall be allocated to Antibody Products as Licence Fees.
Marketing Expense	means all out-of-pocket costs and expenses incurred (i.e., paid to Third Parties or accrued therefor) by Amgen or Celltech for the following functions to the extent directly attributable to the Antibody Product (a) market research on Antibody Product, (b) marketing communications, (c) corporate accounts, (d) managed care, (e) sales force training, (f) product hotlines, (g) reimbursement support, (h) contracting, (i) pricing, (j) conducting compassionate use programs for Antibody Products (including without limitation FAMC for any Antibody Product utilized in such compassionate use programs) and (k) telemarketing services.
Marketing Personnel Costs	means the Personnel Costs of marketing personnel and support staff working directly (either full time or part of the time) on the Commercialisation of Antibody Products. Examples of functions that would be included in the marketing headcount cost are: Marketing, marketing communications, clinical research and educational

	managers (CREMS), clinical support managers (CSS), corporate accounts, managed care, product hotlines, reimbursement support (Government economic managers), marketing research, contracting, pricing, regulatory, adverse event reporting, sales force training, and sales force operations, including dedicated IT support.
Medical Affairs Expense	means, for all Marketing Clinical Studies (a) all out-of-pocket costs and expenses incurred (i.e., paid to Third Parties or accrued therefor) by Amgen or Celltech for such studies, (b) Personnel Cost of personnel working directly on Marketing Clinical Studies Antibody Products and the Medical Affairs Supply Cost of such studies and (c) other out-of-pocket expenses directly attributable to Marketing Clinical Studies on Antibody Product but not included in (a) or (b).
Medical Affairs Supply Cost	means the sum of (a) the Cost of Goods of Antibody Product (as determined in accordance with Schedule D) utilized in performing Marketing Clinical Studies, and (b) out-of-pocket costs and expenses incurred in purchasing comparator and in packaging comparator and/or Antibody Product, shipping clinical supplies to centers or disposal of clinical supplies.
Other Expense	means the sum of all out-of-pocket costs and expenses incurred in processing and destroying of returns of Antibody Product.
Personnel Costs	means the costs of employment of personnel employed by or under contract to a Party, including, but not limited to, salaries, benefits (including the costs of cars or allowances therefor), travel, lodging, meals and entertainment, office and computing supplies, space costs, recruiting, relocation and subscriptions.
Promotion Expense	means all out-of-pocket costs and expenses incurred (i.e., paid to Third Parties or accrued therefor) by Amgen or Celltech for the Promotion of an Antibody Product including, but not limited to (i) marketing, advertising and promoting of Antibody Products (including, without limitation, educational expenses, advocate development programs and symposia, sales meetings, direct to consumer/patient advertising,

	samples, agency fees for the development of promotional materials and printing of promotional materials), (ii) FAMC for samples of Antibody Product distributed free of charge and (iii) training and communication materials for the Antibody Products.
Representative	means an individual (i) employed and trained by Amgen or Celltech or (ii) employed by a Third Party or self-employed and trained by or on behalf of Amgen or Celltech, in either case, to Detail an Antibody Product.
Sales Force Cost	means the Personnel Costs of Representatives and their support staff in a sales force engaged in the Detailing of Antibody Products, including training costs.

In calculating the Product Contribution the following shall apply:

1. There shall be no double counting of any costs or expenses or of any revenues, and to the extent a cost or expense has been included in one category or sub-category, it shall not be included in another; similarly, to the extent any revenue has been taken into account in one category or sub-category it shall not be taken into account in another.

2. When allocating costs and expenses under this Agreement, each Party shall utilise the same policies and principles as it utilises consistently within its group and business units when making internal cost allocations.

3. Each Party shall bear its own out-of pocket costs (without limitation, travel costs, meals and accommodation) associated with attendance at meetings of the Joint Research Committee, Joint Development Committee, Joint Commercialisation Committee, Collaboration Committee or such other joint meetings that the Parties agree shall be held in the furtherance of the Research, Development or Commercialisation of Antibody Products.

4. To the extent an item of income or revenue is received by a Party or a cost or expense is incurred by a Party, and is necessary and specifically and directly identifiable, attributable and allocable to the Commercialisation of Antibody Product and is not otherwise accounted for in the calculation of Product Contribution, such Party shall credit such income or revenue and shall be permitted to charge such cost or expense to the Product Contribution.

SCHEDULE C

Principles for Detail Cost

Each Party shall determine the Sales Force Costs for each Calendar Quarter for each sales force Detailing Antibody Products.

Each Party shall undertake to promote Antibody Product as a Primary Detail, Secondary Detail or Tertiary Detail throughout a Calendar Quarter.

The Detail Cost for each sales force in each country for each Party for each Calendar Quarter shall be calculated by multiplying the Sales Force Costs for that sales force in that country by [*]% when Antibody Product has been promoted as Primary Detail in that Calendar Quarter, and by [*]% when Antibody Product has been promoted as Secondary Detail in that Calendar Quarter and [*]% where Antibody Product has been promoted as Tertiary Detail in that Calendar Quarter, provided that a Party may not charge for a Tertiary Detail for Antibody Product in a country during the [*] following the date of First Commercial Sale of such Antibody Product in a country. For a period not to exceed [*] from the date of First Commercial Sale of an Antibody Product in any country and when a sales force has promoted only an Antibody Product and no other product in a Calendar Quarter in that country, the Detail Cost shall be [*]% of the Sales Force Cost, excluding extraordinary bonuses and the like.

SCHEDULE D

Net Sales Definition

Net Sales means with respect to any Antibody Product, all revenues recognised in accordance with GAAP, consistently applied as between the Parties, from sales of an Antibody Product by a Party, its Affiliate, sublicensees, and agents, to Third Parties (but not including sales relating to transactions between a Party, its Affiliates, and their respective sublicensees and agents), less the total of the following (if not already deducted in the amount invoiced or not otherwise accounted for in Commercialisation Expenses or Cost of Goods):

1. Normal or customary trade, cash, prompt payment and/or quantity discounts actually allowed and taken;

2. Returns, allowances, free goods, rebates, chargebacks, other allowances or payments to government agencies actually allowed and taken;

3. Retroactive price reductions applicable to sales of such product actually allowed and taken;

4. Fees paid to distributors, selling agents (excluding any sales representatives of a Party or any of its Affiliates), group purchasing organisations and managed care entities;

5. Credits or allowances (actively paid or allowed) for wastage replacement, whether cash or trade;

6. Non-recoverable sales taxes, excise taxes, tariffs and duties (excluding taxes when assessed on income derived from sales); and

7. [*] percent of the amount invoiced to cover bad debt, freight or other transportation charges, insurance charges, additional special packaging, and other governmental charges.

In the case of any sale of an Antibody Product between or among a Party and its Affiliates or sublicensees for resale, Net Sales shall be calculated as above only on the first arm's length sale by any such Party, Affiliate or sublicensee to a Third Party.

Upon any sale or other disposal of any Antibody Product for any consideration other than an exclusively monetary consideration on bona fide arm's length terms then for the purposes of calculating the Net Sales under this Agreement, such Antibody Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for such Antibody Product in the country

in which such sale or other disposal occurred when such Antibody Product is sold alone and not with other products.

Where an Antibody Product is sold together with other pharmaceutical products for a single price (whether sold together in the same package, or merely price bundled), then for the purposes of calculating the Product Contribution payable under this Agreement such Antibody Product shall be deemed sold for an amount equal to the following:

(X divided by Y) multiplied by Z

where X is the average sales price during the applicable reporting period generally achieved for such Antibody Product in the country in which such sale or other disposal occurred when such Antibody Product is sold alone and not with other pharmaceutical products; Y is the sum of the average sales price during the applicable reporting period generally achieved in that country when sold alone by each product (including the Antibody Product) included in the bundle of pharmaceutical products that is sold for the single price; and Z equals the single price at which the bundle of pharmaceutical products represented in Y was actually sold. In the event one or more of the products in the bundled product are not sold separately, the parties shall confer in good faith to determine a fair market price that shall equitably compensate the Product Contribution for the value of the Antibody Product(s) within the bundled product.

SCHEDULE E

Calculation of Fully Absorbed Manufacturing Cost

DEFINITION OF FULLY ABSORBED MANUFACTURING COSTS ("FAMC")

I. FAMC includes the costs of all [*] consumed, provided or procured by manufacturing facilities in the manufacture of Antibody Product in Finished Form, together with (i) [*], (ii) [*] and (iii) [*].

A. [*] costs are:

1. The cost of [*] materials used in production.

2. [*] materials, [*] ([*] of [*]in excess of a [*] limits).

3. Other costs of materials used in the manufacture of Antibody Products not included in the preceding two paragraphs.

B. [*] costs are:

The [*] involved in the manufacture of Antibody Products, but excluding such costs to the extent that they are included within [*].

C. [*] costs are**:**

The amounts paid or payable to [*] for the manufacture of Antibody Product in Finished Form or any component thereof ([*] of Antibody Products).

D. [*] are all [*] and [*] manufacturing costs that [*] with [*] and, therefore, cannot be included in [*] FAMC as [*]. Such [*] costs are:

1. [*], including, but not limited to, [*].

2. [*], which reflects on a [*] basis, the [*] used for manufacturing the Antibody Product.

3. The [*] allocations from [*], including [*] and other services required to be performed in connection with the manufacturing of the Antibody Product.

4. The [*] allocations for [*] services used at the [*] including [*].

5. [*] and other [*] costs on Antibody Raw Materials and Antibody Product, [*], [*] Antibody Raw Material or Antibody Product in Finished Form.

6. [*] and other costs allocable to the [*] used to manufacture the Antibody Product.

7. [*] cost incurred for [*] or otherwise in connection with compliance with [*] as a [*] of the manufacture of the Antibody Product.

E. Allowances for [*] include [*] variances within [*] and [*].

F. Allowances for [*] to [*] include [*] charges for [*] charges.

II. FAMC *does not* include:

A. [*], except the [*] allowance included under item IA.2**.**

B. The value of [*] in the manufacturing operation (other than [*] as stated above).

C. [*] on [*] shipment.

D. [*].

E. Costs associated with the [*] and the [*], including without limitation the costs of [*], to the extent that such costs are included under other elements of [*].

F. Any [*] on [*] manufacturing plants or [*].

G. [*] related to [*].

H. [*] categorized separately in Schedule A.

I. [*] expenses.

III. Calculation of FAMC

FAMC will be calculated in accordance with GAAP, applied on a consistent basis as between the Parties. Such calculations shall allocate to Antibody Products a fair and reasonable portion of manufacturing overhead consistent with the allocation of such manufacturing overheads to all products manufactured at the relevant facility. Actual FAMC incurred will be charged against Product Contribution as Antibody Product is sold on a first in-first out basis. FAMC incurred for launch inventory build up shall be [*] as Antibody Product is [*]. Such FAMC shall include, without limitation, costs incurred in [*] of Antibody Products in Finished Form.

SCHEDULE F

PART A

[*] **PATENT RIGHTS**

a) Product

[*] Ref. No: [*]

Subject Matter: [*]

Title: [*]

Inventors: [*]
[*]
[*]
[*]
[*]
[*]
[*]

Priority Application Date: [*]
Earliest Publication Date/No: [*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		

*[*]

SCHEDULE F

PART B

[*] **PATENT RIGHTS**

b) [*]

[*] Ref. No: [*]

Subject Matter: [*]

Title: [*]

Inventors: [*]
[*]

Priority Application Date: [*]
Earliest Publication Date/No: [*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]

*[*]

SCHEDULE F

PART B

[*] **PATENT RIGHTS**

b) [*]

[*] Ref. No: [*]

Subject Matter: [*]

Title: [*]

Inventors: [*]
[*]

Priority Application Date: [*]
Earliest Publication Date/No: [*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]

*[*]

SCHEDULE F

PART B

[*] **PATENT RIGHTS**

c) [*]

[*] Ref. No: [*]

Subject Matter: [*]

Title: [*]

Inventors: [*]
[*]

Priority Application Date: [*]
Earliest Publication Date/No: [*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		

*[*]

SCHEDULE F

PART B

[*] **PATENT RIGHTS**

c) [*]

[*] Ref. No: [*]

Subject Matter: [*]

Title: [*]

Inventors: [*]
[*]

Priority Application Date: [*]
Earliest Publication Date/No: [*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		

*[*]

SCHEDULE F

PART C

[*] **PATENT RIGHTS ([*])**

d) [*]

[*] Ref. No: [*]

Subject Matter: [*]

Title: [*]

Inventors: [*]
[*]
[*]
[*]

Priority Application Date: [*]
Earliest Publication Date/No: [*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		

*[*]

SCHEDULE F

PART C

[*] **PATENT RIGHTS ([*])**

d) [*]

[*] Ref. No: [*]

Subject Matter: [*]

Title: [*]

Inventors: [*]
[*]
[*]

Priority Application Date: [*]
Earliest Publication Date/No: [*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]

*[*]

SCHEDULE F

PART C

[*] PATENT RIGHTS ([*])

d) [*]

[*] Ref. No: [*]

Subject Matter: [*]

Title: [*]

Inventors: [*]
[*]
[*]

Priority Application Date: [*]
Earliest Publication Date/No: [*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		

*[*]

SCHEDULE F

PART D

[*] PATENT RIGHTS ([*])

[*]

Applicants:	[*]
Inventor:	[*]
Priority Application Date:	[*]
Earliest Publication Date/No:	[*]
Title:	[*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]

*[*]

Whether or not the above Patent Rights fall within the [*] Patent Rights is determined by the [*] relating to these Patent Rights as such [*] have been disclosed to [*] prior to [*].

SCHEDULE F

PART D

[*] **PATENT RIGHTS ([*])**

[*]

Applicants: [*]

Inventors: [*],[*],[*]
[*],[*]

Priority Application Date: [*]
Earliest Publication Date/No: [*]

Title: [*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]			
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]

*[*]

Whether or not the above Patent Rights fall within the [*] Patent Rights is determined by the [*] relating to these Patent Rights as such [*] have been disclosed to [*] prior to [*].

SCHEDULE F

PART D

[*] **PATENT RIGHTS ([*])**

[*]

Applicants: [*]

Inventors: [*],[*],[*],[*]
[*]

Priority Application Date: [*]
Earliest Publication Date/No: [*]

Title: [*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]

*[*]

Whether or not the above Patent Rights fall within the [*] Patent Rights is determined by the [*] relating to these Patent Rights as such [*] have been disclosed to [*] prior to [*].

SCHEDULE G

ANTIBODY LICENCE AGREEMENT

ANTIBODY LICENCE AGREEMENT

BY AND BETWEEN

AMGEN INC.

AND

CELLTECH R&D LIMITED

ANTIBODY LICENCE AGREEMENT

INDEX

ANTIBODY LICENCE AGREEMENT

This Antibody Licence Agreement (the "**Licence Agreement**") is made effective as of the Effective Date of Termination of the Collaboration Agreement (as defined in *Schedule One*) (the "**Licence Agreement Effective Date**") by and between Amgen Inc., a corporation organised and existing under the laws of the State of Delaware and having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799 ("**Amgen**") and Celltech R & D Limited, a company organised and existing under the laws of England and having its principal office at 208 Bath Road, Slough, Berkshire SL1 3WE, United Kingdom ("**Celltech**").

RECITALS

Whereas, Celltech and Amgen, under the terms and conditions of the Collaboration Agreement, as defined in *Schedule One* attached hereto, have been collaborating in the Joint development and commercialisation of certain Antibody Products (as defined therein;)

Whereas, pursuant to Article 14 of the Collaboration Agreement, the Collaboration Agreement is now terminated, in whole or part, and Amgen is the Continuing Party as defined in the Collaboration Agreement.

Whereas, in accordance with Article 14 of the Collaboration Agreement, Celltech now wishes to grant to Amgen and Amgen wishes to obtain from Celltech a license under certain Celltech rights to Research, Develop, and Commercialise such certain Antibody Products (for purposes of this Licence Agreement termed "**Licensed Antibody Products**", all terms as hereinafter defined in the attached *Schedule One*), on the terms and conditions herein;

Now Therefore, based on the foregoing premises and the mutual covenants and obligations set forth below, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

Capitalised terms used but not otherwise defined herein have the meanings provided in ***Schedule One*** hereto.

ARTICLE 2

GRANT OF LICENCES AND OTHER RIGHTS

2.1 Patent Licences.

(a) Celltech hereby grants to Amgen:

(i) an exclusive licence even as to Celltech under the [*] Patent Rights, [*] Patent Rights, [*] Patent Rights, [*] Know-How [*],[*] Know-How and [*] Know-How, with the right to sublicense in accordance with Article 2.3; and

(ii) a non-exclusive licence to all other [*] Technology, with the right to sublicense in accordance with Article 2.3;

to Research, Develop, Commercialise, make, have made, use, sell, have sold, offer to sell or resell, import, export, distribute or otherwise transfer physical possession of or otherwise transfer title in or to Licensed Antibody Products in the Field in the Territory, solely in compliance with the terms and conditions of this Licence Agreement.

(b) Certain licence rights granted to Amgen under this Article 2 may include a sublicence of Patent Rights and/or know-how of Third Parties under Third Party licences. Notwithstanding anything to the contrary in this Licence Agreement, Amgen shall, in exercising such sublicence rights be subject to and so far as the terms are applicable to its activities, comply with the provisions of such Third Party licences relating to Licensed Antibody Products to the extent Celltech has notified in writing the terms of such Third Party licence to Amgen. Celltech shall promptly provide to Amgen a copy of any notice of breach received by it under such Third Party licence.

2.2 Trademark; Copyright Licences.

(a) Celltech hereby grants to Amgen an exclusive royalty-free licence, with the right to grant sublicences (subject to Amgen's compliance with Article 2.3 of this Licence Agreement), under Celltech's entire right, title and interest in and to the Product Trademarks, to use and display the Product Trademarks in connection with relevant Licensed Antibody Products in the Territory; *provided however*, that Amgen shall not have any licence to use and display Celltech Trademarks other than as set forth in Article 14.9(b)(iii)(3) of the Collaboration Agreement (sale of then-existing inventory). For the avoidance of doubt, Amgen shall have the right to select for and use and display with Licensed Antibody Products such Trademarks as it desires.

(b) Celltech hereby grants to Amgen a royalty-free licence under Celltech's entire right, title and interest in any copyrights in and to Promotional Materials, with the right to grant sublicences (subject to Amgen's compliance with Article 2.3 of this Licence Agreement), to reproduce, distribute copies of, prepare derivative works of and publicly perform and display such Promotional Materials in connection with Licensed Antibody Products in the Territory solely in compliance with the terms and conditions of this Licence Agreement; *provided however*, that Amgen shall not have any licence to use and display Celltech Trademarks other than as set forth in Article 14.9(b)(iii)(3) of the Collaboration Agreement (sale of then-existing inventory). Such licence shall be exclusive to the extent the Promotional Materials are exclusive to Licensed Antibody Products and otherwise shall be non-exclusive.

2.3 Sublicensing.

(a) Amgen shall have the sole right to determine whether to sublicense any or all of its rights under Article 2.1 or Article 2.2. Any such sublicence shall require the Sublicensee to comply with the obligations of Amgen as contained herein. Any such sublicence shall provide for the termination of such sublicence, or the conversion to (with respect to [*] Technology) a licence directly between such Sublicensee and Celltech, [*], upon termination of this Licence Agreement.

(b) Notwithstanding the sublicensing of all or part of Amgen's rights and obligations hereunder, Amgen shall remain responsible for the actions and omissions of its Sublicensees and for the full and complete performance of all of Amgen's obligations and duties under this Licence Agreement.

ARTICLE 3

RESEARCH, DEVELOPMENT AND COMMERCIALISATION

3.1 Diligence.

3.1.1 From and after the Licence Agreement Effective Date Amgen shall:

(a) use diligent and timely efforts to satisfactorily complete Research of Licensed Antibody Products and obtain in [*] for a Licensed Antibody Product an IND. For the avoidance of doubt, nothing in this Licence Agreement shall preclude Amgen from filing INDs in [*];

(b) use Commercially Reasonable Efforts to satisfactorily complete all Development activities with respect to a Licensed Antibody Product; and

(c) use Commercially Reasonable Efforts to obtain Regulatory Approval to Commercialise a Licensed Antibody Product;

in each case for the [*] or if the [*] is dropped, [*]; and

(d) use Commercially Reasonable Efforts to maximise Net Sales of each Licensed Antibody Product in the Territory.

For the avoidance of doubt, the Parties acknowledge that the diligence obligations may have been met, in whole or in part, by activity conducted under the Collaboration Agreement.

3.1.2 Amgen acknowledges that using Commercially Reasonable Efforts requires it to take ongoing actions that are consistent with a good faith intention to achieve the objective of Developing a Licensed Antibody Product and obtaining Regulatory Approvals to Commercialise such Licensed Antibody Product for the [*] (or if the [*] is dropped, [*]) in the Field, and to Commercialise such Licensed Antibody Product [*]. For the avoidance of doubt, Development and Commercialisation in each instance includes the manufacture and supply of Licensed Antibody Product. If Amgen decides that deployment of Commercially Reasonable Efforts does not justify it making continued, ongoing efforts towards this objective it shall promptly notify Celltech in writing.

3.1.3 Amgen shall not be in breach of any obligation under this Licence Agreement to the extent its inability to perform such obligation is caused by Celltech's failure to perform any of its obligations under this Licence Agreement or under Article 14.9 of the Collaboration Agreement. Celltech acknowledges that in applying the Commercially Reasonable Efforts standard to Amgen's obligation pursuant to Article 3.1.1, a relevant factor to be taken into account shall be [*].

3.1.4 Amgen acknowledges that the obligations it undertakes pursuant to this Article 3.1 are [*].

3.2 Research, Development and Commercialisation. Subject to and consistent with its obligations set out in this Licence Agreement, as between the Parties, Amgen shall have sole and full control, discretion, authority and right for conducting, funding and pursuing all aspects of Research, Development and Commercialisation (including the manufacture and supply for Research, Development and Commercialisation) of Licensed Antibody Products in the Territory. Amgen shall conduct its Research activities and Development activities in compliance with all laws, regulations

and guidelines that are applicable to the particular stage of Research or Development for the Licensed Antibody Product, including, GLP, GCP and GMP, of the relevant jurisdiction as the same may be amended from time to time.

3.3 Regulatory Filings and Regulatory Approvals. With respect to each Licensed Antibody Product, in a manner consistent with its obligations set out in this Licence Agreement, Amgen shall have the sole and full control, discretion authority and right to prepare, file and pursue and shall own all right, title and interest in Regulatory Filings and Regulatory Approvals relating to each said Licensed Antibody Product in the Territory.

3.4 Notification Due to Regulatory Obligation. Notwithstanding any other term of this Agreement, if any other Antibody being developed by Celltech is [*] by a Regulatory Authority for reasons which Celltech believes are attributable to [*] rather than to [*], Celltech shall notify Amgen of this as soon as reasonably practicable after receipt of written notice of [*] from the Regulatory Authority.

ARTICLE 4

CONSIDERATION

4.1 Milestones.

(a) Within [*] following the first achievement or occurrence with the first Licensed Antibody Product(s) of each of the following milestone events by performance of Amgen or an Affiliate or Sublicensee of Amgen ("**Milestone Event(s)**"), Amgen shall pay to Celltech the corresponding non-creditable, non-refundable milestone payments set forth herein ("**Milestone Payment(s)**"):

Milestone Event	**Milestone Payment**
(i)[*]	$[*]
(ii)[*]	$[*]
(iii)[*]	$[*]
Total	**$**[*]

(b) Subject to Article 4.1(c) below, if any Milestone Event set forth above is achieved prior to or in the absence of the achievement of any preceding Milestone Event then, effective upon achievement of any such Milestone Event, all previously unpaid Milestone Payments set forth

in Article 4.1(a) shall also become due and payable. Each Milestone Payment shall be payable only once, no matter how many times achieved by one or more Licensed Antibody Product(s). Each Milestone Payment shall be non-refundable and non-creditable whether against Royalties payable pursuant to Article 4.2, any other fees, other Milestone Payments, or any other payments due to Celltech with respect to Licensed Antibody Product(s) under this Licence Agreement, or any other amounts accrued and owed prior to termination of the Collaboration Agreement or otherwise.

(c) If the Licence Agreement Effective Date is after the date of achievement of any Milestone Event(s) set forth in Articles 4.1(a)(i)-(iii), then the Milestone Payment(s) payable in respect of such Milestone Event(s) shall be deemed waived and not payable to Celltech (but without prejudice to any amounts accrued and owed prior to termination of the Collaboration Agreement, and without prejudice to any Milestone Payment payable in respect of a Milestone Event occurring after the Licence Agreement Effective Date).

4.2 Royalties.

(a) Subject to Articles 4.4 and 4.5 below, if the FAMC of the Antibody Raw Material is more than [*] ($[*]) [*], Amgen shall pay to Celltech a Royalty, based on the following Royalty rates, for annual Net Sales of each Licensed Antibody Product (on a Licensed Antibody Product-by-Licensed Antibody Product basis of cumulative Net Sales in those countries for which a Royalty is due in accordance with Article 4.8) by Amgen, its Affiliates, and its Sublicensees in the Territory:

(i) a Royalty rate of [*] ([*]%) of that portion of annual Net Sales in the Territory of each such Licensed Antibody Product that is less than [*] ($[*]);

(ii) a Royalty rate of [*] ([*]%) of that portion of annual Net Sales in the Territory of each such Licensed Antibody Product that is equal to or greater than [*] ($[*]) and less than or equal to [*] ($[*]); and

(iii) a Royalty rate of [*] ([*]%) of that portion of annual Net Sales in the Territory of each such Licensed Antibody Product that is greater than [*] ($[*]).

(b) Subject to Articles 4.4 and 4.5, below, if the FAMC of the Antibody Raw Material is less than or equal to [*] Dollars ($[*]) [*] and greater than [*] Dollars ($[*]) [*], Amgen shall pay to Celltech a Royalty based on the following Royalty rates for annual Net Sales of each Licensed

Antibody Product (on a Licensed Antibody Product-by-Licensed Antibody Product basis of cumulative Net Sales in those countries for which a Royalty is due in accordance with Article 4.8) by Amgen, its Affiliates, and its Sublicensees in the Territory:

(i) a Royalty rate of [*] ([*]%) of that portion of annual Net Sales in the Territory of each such Licensed Antibody Product that is less than [*] Dollars ($[*]);

(ii) a Royalty rate of [*] ([*]%) of that portion of annual Net Sales in the Territory of each such Licensed Antibody Product that is equal to or greater than [*] Dollars ($[*]) and less than or equal to [*] Dollars ($[*]); and

(iii) a Royalty rate of [*] ([*]%) of that portion of annual Net Sales in the Territory of each such Licensed Antibody Product that is greater than [*] Dollars ($[*]).

(c) Subject to Articles 4.4 and 4.5 below, if the FAMC of the Antibody Raw Material is less than or equal to [*] Dollars ($[*])[*], Amgen shall pay to Celltech a Royalty based on the following Royalty rates for annual Net Sales of each Licensed Antibody Product (on a Licensed Antibody Product-by-Licensed Antibody Product basis of cumulative Net Sales in those countries for which a Royalty is due in accordance with Article 4.8) by Amgen, its Affiliates, and its Sublicensees in the Territory:

(i) a Royalty rate of [*] ([*]%) of that portion of annual Net Sales in the Territory of each such Licensed Antibody Product that is less than [*] Dollars ($[*]);

(ii) a Royalty rate of [*] ([*]%) of that portion of annual Net Sales in the Territory of each such Licensed Antibody Product that is equal to or greater than [*] Dollars ($[*]) and less than or equal to [*] Dollars ($[*]); and

(iii) a Royalty rate of [*] ([*]%) of that portion of annual Net Sales in the Territory of each such Licensed Antibody Product that is greater than [*] Dollars ($[*]).

(d) In the event that the Antibody Raw Material is not a [*] Antibody, the Royalty rates set forth in Article 4.2 (a) (i), (ii) and (iii) shall apply regardless of the FAMC of the Antibody Raw Material.

4.3 **FAMC.** Amgen shall use Commercially Reasonable Efforts to ensure that the FAMC of the Antibody Raw Material is an FAMC that [*].

4.4 **Third Party Licences.** To the extent not sublicensed by Celltech hereunder, Amgen shall be responsible for obtaining any licences for rights to any Third Party intellectual property required to Research, Develop, Commercialise, make, have made, use, sell, have sold, offer to sell or resell, import, export, distribute or otherwise transfer physical possession of or otherwise transfer title in or to, a Licensed Antibody Product in one or more countries in the Territory. Amgen shall be responsible for making all Third Party Payments for rights to any Third Party intellectual property (when licensed directly by Amgen) required to Research, Develop, Commercialise, make, have made, use, sell, have sold, offer to sell or resell, import, export, distribute or otherwise transfer physical possession of or otherwise transfer title in or to, a Licensed Antibody Product in one or more countries in the Territory. Where Celltech has sublicensed Third Party intellectual property rights to Amgen pursuant to this Licence Agreement, in addition to the Royalties payable by Amgen under Article 4.2, but subject to Article 4.5, Amgen shall pay Celltech against invoice for, and Celltech shall be responsible for making, all Third Party Payments in connection with the rights sublicensed to Amgen pursuant to this Licence Agreement, unless the Parties agree that such Third Party Payments shall be made by Amgen directly to such Third Party.

4.5 **Royalty Reduction.** If, and for so long as Amgen is required to pay Third Party Payments, as set forth in Article 4.4, as royalties for such licence in respect of sale or other disposal of a Licensed Antibody Product in a country in the Territory, such royalties shall be creditable by Amgen against any Royalties due to Celltech under Article 4.2 above for the Net Sales of such Licensed Antibody Product in such country as follows:

(a) [*] ([*]%) of Third Party royalties payable by Amgen equal to or less than [*] ([*]%) in aggregate of Net Sales of such Licensed Antibody Product in such country shall be creditable against Royalties payable to Celltech

(b) [*] ([*]%) of Third Party royalties payable by Amgen greater than [*] ([*]%) in aggregate of Net Sales of such Licensed Antibody Product in such country shall be creditable against Royalties payable to Celltech

provided however, that on a Licensed Antibody Product-by-Licensed Antibody Product basis, the Royalty rate payable by Amgen pursuant to this Licence Agreement in any given Calendar Year shall not be less than [*] ([*]%) of Net Sales of such Licensed Antibody Product in such country. Subject

to the foregoing, Amgen shall have sole discretion, authority and right with respect to determining whether to enter into an agreement for a licence (or to accept, pursuant to Article 3, a sublicence) or other rights and to incur an obligation for any Third Party Payments.

4.6 **Competition Reduction.** Upon [*], Amgen shall have the immediate and continuing right to reduce the Royalty rates set forth in Article 4.2 on Net Sales of each such Licensed Antibody Product(s) in such country to:

(a) [*] ([*]%) during the first [*] period following such sale of commercial quantities and thereafter; and

(b) [*] ([*]%) for each [*] period thereafter until expiration of the obligation to pay a Royalty for such Licensed Antibody Product under Article 4.8;

4.7 **No Competition Reduction.** With respect to a Competitive Product, in any country in the Territory where such Competitive Product either is being or has been sold:

(a) If

(i) Celltech provides a written request pursuant to Article 5.3.2 and Amgen does not bring suit or action within the time frame for bringing suit in accordance with Article 5.3.2 or,

(ii) Amgen having brought a suit or action described in Article 5.3.1, ceases to progress it and Celltech then requests Amgen in writing to progress such suit or action;

and Amgen elects, at its option, (or is deemed to have so elected by failing to respond to Celltech's written notice pursuant to Article 5.3.2 or within [*] of Celltech's written request pursuant to Article 4.7(a)(ii)) that Celltech shall not have the right to bring any such suit or action, then the Royalty reduction to which Amgen is entitled under Article 4.6 (the "**Royalty Reduction**") shall not apply with respect to that Competitive Product in that country for the period from the date of expiry of the relevant time frame under (i) above or the date Amgen ceases to progress such suit or action under (ii) above, as appropriate.

(b) If Celltech provides a written request pursuant to Article 5.3.2 or Article 4.7(a)(ii) and Amgen, within the time frame for bringing suit in accordance with Article 5.3.2 (or within [*] of Celltech's written request pursuant to Article 4.7(a)(ii)), provides Celltech with written notice of Amgen's election, at its option, that Celltech shall have the right to bring any suit or action

described in Article 5.3.2, then the Royalty Reduction shall not apply for the period commencing on the date of Celltech's written notice and ending [*] after the date Amgen notifies Celltech in writing of Amgen's election that Celltech shall have such right to bring such suit or action with respect to such Competitive Product in such country.

(c) If Celltech provides a written request pursuant to Article 5.3.2 or Article 4.7(a)(ii) and Amgen, within the time frame for bringing suit in accordance with Article 5.3.2, or within [*] of Celltech's written request pursuant to Article 4.7(a)(ii), elects, at its option (as notified to Celltech in writing), that Celltech shall have the right to bring any suit or action described in Article 5.3.2 and

(i) Celltech exercises such right; and

(ii) the court concludes that Celltech has been prejudiced in obtaining a preliminary injunction by the delay from Celltech's written request to the date of Amgen's election to allow Celltech to exercise such right, or by Amgen failing to progress such action, then

the Royalty Reduction shall not apply and Amgen shall pay Celltech all Royalties Celltech would otherwise have been entitled to receive plus interest (at the rate provided in Article 6.1(d)) on such sum for the period from the later of Celltech's written request or the date of first commercial sale of such Competitive Product in such country up to the date of the final court decision, such sum plus interest to be paid within [*] of such final court decision.

(d) From such time as a Competitive Product is ordered to be withdrawn from sale or otherwise ceases to be sold as a result of any suit or action brought by Celltech or by Amgen, the Royalty Reduction set forth in Article 4.6 shall not apply.

4.8 Term of Royalties. Amgen's obligations to pay Royalties under Article 4.2 shall expire, on a Licensed Antibody Product-by-Licensed Antibody Product and country-by-country basis, upon the later of: (a) the expiration of the last-to-expire of the [*] Patent Rights, the [*] Patent Rights, [*] Patent Rights and/or [*] Patent Rights containing a Valid Claim that, but for the licence granted by Celltech to Amgen, would be [*] in such country; or (b) [*] after the [*] of the first Licensed Antibody Product in such country.

4.9 Revival of Royalty Where Patent Application Becomes a Valid Claim. If, in respect of any Licensed Antibody Product in any country, (a) Amgen's obligation to pay Royalties under Article 4.2 has expired,

in accordance with Article 4.7 and (b) after such expiry the use, manufacture, sale or other disposal of such Licensed Antibody Product in such country would, but for this licence, [*] of any [*] Patent Right, [*] Patent Right, [*] Patent Right and/or [*] Patent Right, Amgen shall pay to Celltech: (i) within [*] of receipt of invoice a sum equal to the Royalties set out in Article 4.2 calculated from the date such claim published to the date such claim issued (and became a Valid Claim) together with interest at the rate set out in Article 6.1(d) on such sum from the date such claim published until the date of payment and (ii) the Royalties set out in Article 4.2 until expiry of such Valid Claim as set out in Article 4.8.

ARTICLE 5

INTELLECTUAL PROPERTY

5.1 Technology Ownership.

5.1.1 As between the Parties, [*] shall own all right, title and interest in and to all [*] Technologies, subject to the rights and licenses granted to Amgen hereunder.

5.1.2 Other than as expressly set forth in this Licence Agreement, neither Party shall have any right in and to any intellectual property owned or controlled by the other Party and neither Party shall have an obligation to grant the other Party any rights therein.

5.1.3 Other than as expressly set forth in Articles 5.2, 5.3 and 5.4, neither Party shall have the right to prepare, file, prosecute, maintain, defend, settle and/or enforce Patent Rights or Trademarks Controlled by the other Party, such activity being the exclusive right (but not the obligation) of the Party Controlling the same.

5.2 Prosecution.

5.2.1 Promptly after the Licence Agreement Effective Date, and to the extent not already provided under the Collaboration Agreement, Celltech shall provide Amgen with copies of all material documents in Celltech's possession pertaining to [*] Patent Rights existing as of the Licence Agreement Effective Date. During the term of this Agreement, each Party shall as soon as practicable provide the other Party (as appropriate) with all material documents and any other document Controlled by a Party reasonably requested by the other Party (such request to identify the specific documents required), pertaining to [*] Patent Rights and [*] Patent Rights.

5.2.2 (a) Amgen shall have the first right (but not the obligation) at its expense to have mutually acceptable outside counsel (i) at any time prepare, file, prosecute, maintain and defend the Product Trademarks and [*] Patent Rights throughout the Territory; (ii) prior to, on and following the Transition Date (as defined in Article 5.2.7 below) prepare, file, prosecute and maintain any [*] Patent Rights and the [*] Patent Rights that are [*] to any Antibody Products ("[*] **Patent Rights**"); and (iii) on and following the Transition Date, defend any [*] Patent Rights and [*] Patent Rights throughout the Territory.

(b) Celltech shall have the right to review and comment on any papers pertaining to proposed applications, responses, interferences and oppositions before the filing thereof by such counsel with any patent or trademark office (e.g., national, regional or international) ("**Consultation Rights**"), regarding [*] Patent Rights, [*] Patent Rights and [*] Patent Rights. If such outside counsel concludes that taking, or failing to take, any specific action(s) would be inconsistent with its instructions under Article 5.2.4, then Amgen shall not take, or shall take (as the case may be), such specific action(s) unless the prior express written consent of Celltech shall have been obtained. Amgen shall have the right to propose an alternative strategy for Celltech's consideration. To that end, Amgen shall instruct such outside counsel to furnish Celltech with a reasonably complete draft of each submission to a patent or trademark authority regarding any such [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and Product Trademarks no later than [*] prior to the date such submission is proposed to be made, or if given less than [*] to respond as soon as practicable, and will consider any of Celltech's reasonably timely comments thereon. Additionally, Amgen shall instruct such outside counsel to provide Celltech with a copy of each submission made to and document received from a patent or trademark authority regarding any such [*] Patent Rights, [*] Patent Rights, [*] Patent Rights and Product Trademarks reasonably promptly after making such filing.

(c) Amgen shall have the right, at any time and at its sole option, to elect not to proceed with and/or to abandon the preparation, filing, prosecution, maintenance and/or defence of any Patent Right or any Product Trademark it is permitted to pursue under Article 5.2.2(a), *provided that* it shall give Celltech notice of such intention at least [*] before a final due date which would result in the abandonment, cancellation or lapse of an issued patent or pending patent application or abandonment, cancellation or lapse of such granted trademark or pending trademark application. In such case, Celltech, at its option, may assume the right to prepare, file, prosecute, maintain and/or defend any such Patent Right or Product Trademark. Amgen shall have Consultation Rights in respect of any such Patent Right and Product Trademark

and if such outside counsel concludes that taking, or failing to take (as the case may be), any specific action(s) would be inconsistent with its instructions under Article 5.2.4, then Celltech shall not take, or shall take (as the case may be), such specific action(s) unless the prior express written consent of Amgen has been obtained. Celltech shall have the right to propose an alternative strategy for Amgen's consideration. To that end, Celltech shall instruct such outside counsel to furnish Amgen with a reasonably complete draft of each submission to a patent or trademark authority regarding any such Patent Rights and Product Trademark no later than [*] prior to the date such submission is proposed to be made, or if given less than [*] to respond as soon as practicable, and will consider any of Amgen's reasonably timely comments thereon. Additionally, Celltech shall instruct such outside counsel to provide Amgen with a copy of each submission made to and document received from a patent or trademark authority regarding any such Patent Rights and Product Trademark reasonably promptly after making such filing.

(d) A decision by Amgen not to exercise its right pursuant to Article 5.2.2(a) to prepare, file, prosecute, maintain and/or defend any Patent Right or any Product Trademark as permitted by the terms of that Article shall not affect any of Amgen's licence or other rights under this Licence Agreement.

5.2.3 (a) Celltech shall have the first right (but not the obligation), at its expense, to have mutually acceptable outside counsel prior to the Transition Date defend any [*] Patent Rights and [*] Patent Rights.

(b) Celltech shall have the right, at any time and at its sole option, to elect not to proceed with and/or to abandon the defence of any Patent Right it is permitted to pursue under Article 5.2.3(a). In such case Amgen, at its option, may assume the right to have mutually acceptable outside counsel defend any such Patent Right.

(c) A decision by Celltech or Amgen not to exercise its right pursuant to Article 5.2 to defend any Patent Right as permitted by the terms of that Article shall not affect any of its licence or other rights under this Licence Agreement.

5.2.4 Outside counsel retained under this Article 5 shall be instructed to act in the best interests of both Parties under this Licence Agreement and such counsel shall also be instructed to secure claims of the broadest possible scope without jeopardising validity.

5.2.5 The Parties shall closely co-ordinate the defence of any attack on the validity and/or any enforcement (against a Third Party developing or commercialising an Antibody that [*]) of the [*] Patent Rights, [*] Patent Rights, and/or the [*] Patent Rights (including the right of the Party not responsible for such defence or enforcement to review and comment on any papers relating thereto which are material to the conduct of such defence or enforcement). Notwithstanding anything to the contrary in this Article 5, prior to the Transition Date, Amgen shall not have any right to enforce or defend the validity of Patent Rights Controlled by Celltech, which right shall be exclusively that of Celltech. The Party responsible for such defence or enforcement shall not take (nor fail to take) any action with respect to any such defence and/or enforcement which would, in the opinion of the retained outside counsel, be inconsistent with the instructions given to outside counsel under Article 5.2.4.

5.2.6 Notwithstanding any other provision of this Article 5, neither Party shall have an obligation, which is in violation of, or not permitted by, the terms of a Third Party agreement, to prosecute or maintain, or take or defend any action in respect of, nor shall either Party have any right, in violation of the terms of a Third Party agreement, to take or defend any action in respect of, any Patent Right which is owned by a Third Party and licensed to such Party under such Third Party agreement.

5.2.7 For purposes of this Article 5, "**Transition Date**" means the date of [*].

5.3 Enforcement.

5.3.1 Amgen, at its expense, shall have the first right but not the obligation to bring any suit or action (or to otherwise seek payment and/or claim) against a Third Party developing or commercialising an Antibody product which [*], and Celltech agrees to be joined as a plaintiff to any such suit or action if Amgen so requests, at Amgen's expense:

(a) after the Transition Date, for infringement of a claim within the [*] Patent Rights, [*] Patent Rights and/or [*] Patent Rights, in each case in the Territory; and/or

(b) regarding any Product Trademark in the Territory.

Amgen shall, subject to prior consultation with Celltech, have the right to determine the strategy and to exclusively control the conduct and all aspects of any such proceedings including the right to settle or compromise such proceedings (by, for example, granting any such Third Party a sublicence, covenant not to sue, or other rights to the Patent Rights or Trademarks being enforced); *provided however*, that in any such settlement or compromise Amgen will not admit the invalidity of any claim within [*] Patent Rights, [*] Patent Rights, and/or [*] Patent Rights without the prior written approval

of Celltech. Any amount recovered by Amgen by way of costs and damages pursuant to any such claim or action shall be:

(i) [*]; and

(ii) [*].

5.3.2 If Celltech provides Amgen with a written request for Amgen to bring a suit or action described in Article 5.3.1, and Amgen does not, within [*] after receipt of such written request from Celltech to do so (*provided however,* Celltech may only make a written request to bring a suit or action in any country after a Third Party has filed for Regulatory Approval for an Antibody that [*] in that country and [*] that such Antibody falls within the scope of one or more claims of any of the Patent Rights referred to in Article 5.3.1(a)), bring a suit or action described in Article 5.3.1, then, at Amgen's option (to be notified in writing to Celltech prior to the expiry of the [*] period), Celltech shall have the right but not the obligation within [*] after Amgen's written notification to Celltech to bring any such suit or action (or to otherwise seek payment and/or claim) against any such Third Party, and Amgen agrees to be joined as a plaintiff to any such suit or action if Celltech so requests, at Celltech's expense. Celltech shall, subject to prior consultation with Amgen, have the right to determine the strategy and to exclusively control the conduct and all aspects of any such proceedings, including the right to settle or compromise such proceedings (by, for example, granting any such Third Party a licence, a covenant not to sue, or other rights to the Patent Rights being enforced); *provided however* that in any such settlement or compromise Celltech will not admit the invalidity of any claim within the [*] Patent Rights, [*] Patent Rights and/or [*] Patent Rights without the prior written approval of Amgen. Any amount recovered by Celltech by way of costs and damages pursuant to any such claim or action shall be:

(a) [*]; and

(b) [*].

5.3.3 Amgen may, but shall not be obligated to, elect to defend the Product Trademarks against any challenges in the Territory and/or to enforce the Product Trademarks against any actual, alleged or threatened infringement by Third Parties or against any unfair trade practices, trade dress imitation, passing off of counterfeit goods or like offences in the Territory. In the event it elects such defence or enforcement action, Amgen shall determine the strategy.

5.4 **Infringement Defence.** Amgen, at its own expense, shall subject to prior consultation with Celltech where Celltech is a named party, have the first right to defend any actual, alleged or threatened claim or action in the Territory which names Amgen and/or Amgen and Celltech and which claims (a) the infringement of Third Party Patent Rights or know-how through Researching, Developing, Commercialising, making, having made, using, selling, having sold, offering to sell or resell, importing, exporting, distributing or otherwise transferring physical possession of or otherwise transferring title in or to a Licensed Antibody Product or (b) that any Product Trademark infringes any Third Party Trademark or its use constitutes any unfair trade practice, trade dress imitation, passing off of counterfeit goods or like offence. If Amgen shall decide not to defend such an action, Celltech (to the extent it is named) may, at its own expense, defend any such claim or action. The Party defending such claim or action shall have the right, subject to prior consultation with the other Party where both Parties are named, to determine the strategy and to exclusively control the conduct and all aspects of any such proceedings; *provided however* that the Party defending such claim or action shall not settle or compromise such proceedings that affect the other Party's rights or interests, without the prior written consent of the other Party (which consent shall not be unreasonably withheld or delayed). When named, the Party not defending such claim or action shall be entitled, at its own expense, to participate in and to have counsel selected by it participate in any action in which the other Party is a named party.

5.5 **Patent Marking.** To the extent practical, Amgen will mark the Licensed Antibody Product(s) sold in its Territory with all applicable patent numbers of Patent Rights of Celltech to the extent permitted by law in the Territory in which such markings have notice value as against infringers of patents.

5.6 **Co-operation.**

(a) Each Party agrees to co-operate with the other Party in the preparation, filing, prosecution, maintenance and defence of intellectual property rights as set forth in this Article 5.6, including the signing of any necessary legal papers, and to provide the other Party with data or other information in support thereof, and to use best efforts to ensure the co-operation of any of their respective personnel as might reasonably be requested in any such matters.

(b) Each Party shall promptly notify the other Party upon becoming aware of (i) any actual, alleged or threatened Third Party claim or action against Celltech and/or Amgen for infringement of any Third Party Trademark through the Development or Commercialisation of a Licensed Antibody Product; or of any Third Party Patent Rights through Researching, Developing, Commercialising, making, having made, using, selling, having sold, offering to sell or resell,

importing, exporting, distributing or otherwise transferring physical possession of or otherwise transferring title in or to Licensed Antibody Products in the Field in the Territory; or (ii) any Third Party infringement of the Product Trademarks or any Patent Rights of either Party relating to an Antibody that [*]; or (iii) in respect of any Licensed Antibody Product, any unfair trade practices, trade dress imitation, passing off of counterfeit goods or like offences.

(c) The other Party shall assist and cooperate with the Party bringing or defending such suit, and if the Party bringing or defending such suit finds it necessary or desirable to join the other Party in such suit, the other Party shall execute all papers or perform such other acts as may reasonably be required by the Party bringing or defending such suit. The Party bringing or defending such suit shall notify the other Party of all substantive developments with respect to such enforcement or defensive actions including all material filings, court papers and other related documents, substantive settlement negotiations and offer of settlement.

ARTICLE 6

PAYMENTS; RECORDS; AUDIT

6.1 Payments.

(a) No later than [*] after the conclusion of each Calendar Quarter after First Commercial Sale of a Licensed Antibody Product in each country and extending until the Calendar Quarter during which Amgen's obligation to pay Royalties for all Licensed Antibody Product(s) expires under Article 4.8, Amgen shall submit to Celltech a report setting forth (i) the Net Sales of each Licensed Antibody Product sold by Amgen, and its Affiliates and/or Sublicensees during the previous Calendar Quarter [*]; (ii) any Third Party royalties payable in respect of such Net Sales ([*]) and (iii) the amount of Royalty due hereunder. The report shall be accompanied by a remittance of the corresponding Royalty payment.

(b) All payments to be made under this Licence Agreement shall be made in U.S. Dollars by bank wire transfer in immediately available funds to a bank account designated from time to time in writing by Celltech.

(c) Net Sales or other revenues received or payments due in currencies other than Dollars shall first be calculated in the relevant foreign currency and then converted to Dollars against the currency in question on the rate of exchange applicable on the last Business Day of the Calendar

Quarter in respect of which the funds are payable using the currency exchange rates quoted by *Bloomberg Professional*, a service of Bloomberg L.P., during the period of such Net Sales, or in the event *Bloomberg Professional* is not available then *The Wall Street Journal*.

(d) Any payment of any amount under this Licence Agreement not received by the due date specified herein shall accrue interest thereafter on the sum due and owing from the date payment is due until the date payment is received at the rate equal to [*] ([*]%) [*].

(e) All amounts due under this Licence Agreement shall be paid in full without deduction for any applicable taxes, levies, imposts, duties and fees of whatever nature imposed by or under the authority of any government or public authority, except for tax legally required to be deducted or withheld. Where any sum due to be paid to Celltech is subject to any withholding or similar or other tax, the Parties shall take all reasonable steps to do all such acts and things and to sign all such deeds and documents as will enable them to take advantage of any applicable double taxation agreements to reduce the rate of withholding or similar taxes with the object of paying the sums due under deduction of a reduced rate of withholding tax or on a gross basis. In the event there is no double taxation agreement or the reduced rate of withholding tax under the relevant double taxation agreement is greater than [*] ([*]%), the Party making payment shall pay such withholding or similar tax, deduct the relevant amount from the payment due to the other Party, and secure and send to the other Party proof of such withholding or similar tax in a form in accordance with the relevant taxation authority as evidence of such payments. Each Party agrees to inform the other Party forthwith if it concludes that there is any law or practice or any change in such law or practice which requires it to deduct or withhold tax in respect of any payments due pursuant to this Licence Agreement at any time after the Licence Agreement Effective Date with a view to the Parties using their best endeavours to agree on the manner in which subsequent payments shall be made to reduce or eliminate the liability of both Parties to deduct or withhold any amount on account of tax.

(f) All amounts due under this Licence Agreement shall be paid exclusive of any Value Added Tax (which, if applicable shall be payable by a Party in addition upon receipt of a valid Value Added Tax invoice). Each Party agrees to inform the other Party forthwith if it concludes that there is a Value Added Tax law or practice, or a change in such law or practice, which requires it to account for Value Added Tax on any payments due pursuant to this Licence Agreement at any time after the Licence Agreement Effective Date, with a view to the Parties using their

best endeavours to agree on the manner in which subsequent payments shall be made to reduce or eliminate the liability of the Parties to pay Value Added Tax.

6.2 **Records; Audit.** Amgen and its Affiliates shall keep and maintain complete and accurate records and books of account documenting in a detail sufficient to track and determine, in a manner consistent with GAAP, all revenues, expenses and Royalties due or other sums payable pursuant to this Licence Agreement and in compliance with the terms of this Licence Agreement. Such records shall be retained for a period of the later of (a) a [*] following the year in which any payments were made hereunder; (b) the expiration of the applicable tax statute of limitations (or any extensions thereof); or (c) such longer period as may be required by law. Amgen and its respective Affiliates shall permit independent accountants of internationally recognised standing retained by Celltech and reasonably acceptable to Amgen, upon reasonable prior written notice, to have access to its and its Affiliates' records and books and premises for the sole purpose of determining the correctness of any payment of Royalties and other amounts due and payable under this Licence Agreement for any year ending no more than [*] prior to the date of such request; *provided however*, that the books and records for any particular Calendar Year shall only be subject to one audit. Such examination shall be conducted during regular business hours and no more than once in each Calendar Year. The report of such accountant shall be limited to a certificate verifying (or not verifying, as the case may be) any report made or payment submitted by Amgen during such period. In the event the accountant shall be unable to verify the correctness of any such payment, the accountant's report shall specify why such payment is unverifiable and the amount of any discrepancy. Amgen shall receive a copy of each such report concurrently with receipt by Celltech, and the Parties shall use good faith efforts to resolve any discrepancies. All information contained in any such report shall be deemed Confidential Information hereunder. If such examination reveals that such costs or payments have been misstated, any adjustment shall be promptly refunded or paid, as appropriate. Celltech shall pay the fees and expenses of the accountant engaged to perform the audit, unless such audit reveals a net discrepancy of [*] ([*]%) or more for the period examined which is to the disadvantage of Celltech, in which case Amgen shall pay all reasonable costs and expenses incurred by Celltech in the course of making such determination. Upon the expiration of [*] following the end of any Calendar Year, the calculation of any such amounts payable with respect to such year shall be binding and conclusive upon Celltech and Amgen shall be released from any liability or accountability with respect to such amounts for such year.

ARTICLE 7

PUBLICATIONS

7.1 **Procedure.** Each Party (or its appropriate designees) shall determine the strategy for and co-ordinate the publication and presentation of results of studies of Licensed Antibody Products carried out under the Collaboration Agreement or which incorporate data generated under the Collaboration Agreement. Each Party to this Licence Agreement recognises that the publication of papers regarding results of and other information regarding activities under the Collaboration Agreement, including oral presentations and abstracts, may be beneficial to both Parties *provided* such publications are subject to reasonable controls to protect Confidential Information. In particular, it is the intent of the Parties to maintain the confidentiality of any Confidential Information included in any patent application until such patent application has been published. Accordingly, each Party will have the right to review and approve any paper proposed for publication by the other Party, including oral presentations and abstracts, which incorporates data generated under the Collaboration Agreement and/or includes Confidential Information of the other Party. Before any such paper is submitted for publication or an oral presentation is made, the publishing or presenting Party will deliver a complete copy of the paper or materials for oral presentation to the other Party at least [*] prior to submitting the paper to a publisher or making the presentation. The other Party will review any such paper and give its comments to the publishing Party within [*] of the delivery of such paper to the other Party. With respect to oral presentation materials and abstracts, the other Party will make reasonable efforts to expedite review of such materials and abstracts, and will return such items as soon as practicable to the publishing or presenting Party with appropriate comments, if any, but in no event later than [*] from the date of delivery to the other Party. Failure to respond within such [*] shall be deemed approval to publish or present. Celltech may withhold approval of any proposed Amgen publication or presentation to the extent such publication or presentation contains the Confidential Information of Celltech. Amgen may withhold approval of any proposed Celltech publication or presentation to the extent such publication or presentation is contrary to Amgen's publication strategy. The publishing or presenting Party will comply with the other Party's request to delete references to the other Party's Confidential Information in any such paper and agrees to withhold publication of same for an additional [*] in order to permit the Parties to obtain patent protection, if either of the Parties deems it necessary, in accordance with the terms of this Licence Agreement. [*].

7.2 **Credit.** Any such publication will include recognition of the contributions of the other Party according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate.

ARTICLE 8

CONFIDENTIALITY

8.1 **Confidential Information.** Except as otherwise provided in this Article 8, (a) the Parties shall maintain in confidence and use only for purposes specifically authorised under this Licence Agreement any Confidential Information of the other Party; (b) Celltech shall keep confidential all [*] Know-How which is [*] to [*] and/or which is [*] to [*] to [*], and all [*] Know-How and [*] Know-How which is [*] to Licensed Antibody Products and/or [*] (whether generated prior to or during the term of this Licence Agreement), *provided however*, where such [*]Know-How may have [*] outside [*], or where such [*] Know-How or [*] Know-How may have [*] outside Licensed Antibody Products and/or [*], Celltech shall be free to use and exploit the same and to disclose the same to Third Parties subject always to obligations of confidentiality; and (c) Amgen shall keep confidential all [*] Know-How which is [*] to Licensed Antibody Products and/or [*] (whether generated prior to or during the term of this Licence Agreement) and, *provided however*, where such [*] Know-How may have [*] outside Licensed Antibody Products and/or [*], Amgen shall be free to use and exploit the same and to disclose the same to Third Parties subject always to obligations of confidentiality.

8.2 **Authorised Disclosure.**

8.2.1 To the extent it is reasonably necessary or appropriate to fulfil its obligations or exercise its rights under this Licence Agreement, a Party may disclose such Confidential Information of the other Party as it is obliged under Article 8.1 not to disclose as follows:

(a) Each Party may disclose such Confidential Information of the other Party, to its Affiliates, consultants and outside contractors and Amgen may disclose such Confidential Information to its (whether actual or potential) Sublicensees and clinical investigators, in each case on a need-to-know basis and on the condition that such entities or persons agree to keep the Confidential Information confidential for the same time periods and to the same extent as each Party is required to keep such Confidential Information confidential;

(b) Amgen may disclose such Confidential Information of Celltech, as it is otherwise obliged not to disclose under Article 8.1, to Regulatory Authorities to the extent that such disclosure is reasonably necessary to obtain authorisations to conduct clinical studies or to file, obtain and maintain Regulatory Approvals and to Commercialise the Licensed Antibody Products;

(c) Each Party may disclose such Confidential Information of the other Party, as it is otherwise obliged not to disclose under Article 8.1, to the extent that such disclosure is reasonably necessary in connection with preparing, filing, prosecuting, defending or maintaining and/or enforcing Patent Rights in accordance with Article 5; and

(d) Either Party may disclose such Confidential Information of the other Party, as it is otherwise obliged not to disclose under Article 8.1, in prosecuting or defending litigation as explicitly authorised under this Licence Agreement; and in establishing rights or enforcing obligations under this Licence Agreement or in complying with applicable laws, regulations and/or court orders, other than as set forth in Article 8.2.1(b); *provided that* it shall (i) give reasonable advance notice to the other Party of such disclosure requirement; (ii) provide a copy of the proposed disclosure to the other Party; and (iii) at the request of the other Party, use Commercially Reasonable Efforts in assisting the other Party to secure confidential treatment of such Confidential Information required to be disclosed, including cooperating with the other Party to obtain a protective order of the other Party's Confidential Information.

8.2.2 Notwithstanding Article 8.1, Celltech may disclose [*] Know-How, [*] Know-How and [*] Know-How and Amgen may disclose [*] Know-How which is subject to an obligation of confidentiality under Article 8.1 in any of the following circumstances:

(a) where such disclosure would [*];

(b) to its Affiliates and with respect to products other than Licensed Antibody Products, to its (whether actual or potential) sublicensees, consultants, outside contractors and clinical investigators, on a need-to-know basis and on the condition that such entities or persons agree to keep the Know-How confidential for the same time periods and to the same extent as such Party is required to keep such Know-How confidential;

(c) to Regulatory Authorities to the extent that such disclosure is reasonably necessary to obtain authorisations to conduct clinical studies or to file, obtain and maintain regulatory approvals and to commercialise products other than Licensed Antibody Products;

(d) without prejudice to Article 5 to the extent that such disclosure is reasonably necessary in connection with preparing, filing, prosecuting, maintaining and/or defending and/or enforcing Patent Rights; or

(e) in prosecuting or defending litigation and in establishing rights or enforcing obligations under this Licence Agreement or in complying with applicable laws, regulations, court or administrative orders, the rules of any relevant stock exchange or the U.S. Securities and Exchange Commission; *provided however*, in the case of [*] Know-How which is [*] and/or which is [*] to Antibodies to [*],[*] Know-How and [*] Know-How only, to the extent practicable it shall (i) give reasonable advance notice to the other Party of such disclosure requirement; (ii) provide a copy of the proposed disclosure to the other Party; and (iii) at the request of the other Party, use Commercially Reasonable Efforts to secure confidential treatment of such [*] Know-How which is [*] to [*] and/or which is exclusive to Antibodies to [*],[*] Know-How and [*] Know-How required to be disclosed, including seeking a protective order of such [*] Know-How which is [*] to [*]and/or which is [*] to Antibodies to [*],[*] Know-How and [*] Know How.

8.3 Exceptions. The obligation not to disclose Confidential Information under this Article 8 shall not apply to any part of such Confidential Information that:

(a) is or becomes published or otherwise becomes publicly known other than by acts of the Party obligated not to disclose such Confidential Information or its Affiliates or permitted Third Parties pursuant to Article 8.2.1(a) or 8.2.2(b) in breach of this Licence Agreement;

(b) was disclosed to the receiving Party or its Affiliates or sublicensees by a Third Party, *provided that* such Confidential Information was not obtained by such Third Party from the disclosing Party under an obligation of confidentiality;

(c) prior to disclosure under the Collaboration Agreement or this Licence Agreement, was already in the possession of the receiving Party or its Affiliates or sublicensees, *provided that* such Confidential Information was not obtained from the disclosing Party under an obligation of confidentiality;

(d) can be shown by written documents to have been independently developed by the receiving Party or its Affiliates without breach of any of the provisions of this Licence Agreement or

the Collaboration Agreement or access to any Confidential Information provided by the disclosing Party; or

(e) is required to be disclosed by the receiving Party to comply with applicable laws, or with a court or administrative order or the rules of any relevant stock exchange, or the U.S. Securities and Exchange Commission; *provided however*, that this Article 8.3(e) shall not permit a Party to disclose the other Party's Confidential Information for the purpose of obtaining Patent Rights and, *further provided however*, the receiving Party shall, if practicable, notify the disclosing Party in writing (and if practicable provide a copy of the proposed disclosure) prior to any such disclosure and shall use reasonable efforts to secure confidential treatment thereof prior to its disclosure (whether by protective order or otherwise).

8.4 Materials. The Parties anticipate that Celltech may transfer certain of its Materials to Amgen. Amgen agrees that it will use such Materials of Celltech only in accordance with the terms and conditions of, and solely for the purposes of the activities conducted pursuant to, this Licence Agreement, and will not transfer such Materials of Celltech to any Third Party without the consent of Celltech, except as expressly permitted under and subject to the terms of this Licence Agreement.

8.5 Terms of Agreement. Except as permitted by the foregoing provisions or as otherwise required by law or the rules of any relevant stock exchange or the U.S. Securities and Exchange Commission, the Parties shall not disclose any terms or conditions of this Licence Agreement to any Third Party without the prior consent of the other Party; *provided however*, that each Party shall be entitled to disclose the terms of this Licence Agreement without such consent on a need-to-know basis to its financial and legal advisors and potential investors or other financing sources on the condition that such entities or persons agree to keep such terms confidential for the same time periods and to the same extent as such Party is required to keep such terms confidential. Each Party shall give the other Party a reasonable opportunity to review all filings with the United States Securities and Exchange Commission or any stock exchange describing the terms of this Licence Agreement prior to submission of such filings, and shall give due consideration to any reasonable comments by the non-filing Party relating to such filing, including the provisions of this Licence Agreement for which confidential treatment should be sought.

8.6 Public Announcements. Except to the extent required by law or the rules of a relevant stock exchange or as otherwise permitted in accordance with this Article 8, neither Party shall make any further public announcements concerning this Licence Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed. The Parties agree

to consult with each other reasonably and in good faith with respect to the text and timing of any press releases prior to the issuance thereof.

8.7 Third Party Obligations. Other than with respect to Article 9.2(b), neither Party is obliged to disclose to the other any Information if to do so would put the disclosing Party in breach of an existing or future obligation owed to a Third Party. Without limitation to the foregoing, Amgen acknowledges that Celltech is not obliged to disclose to Amgen, and will not disclose to Amgen, any Information, data or know-how concerning Celltech's products [*] whether arising out of Celltech's [*] or otherwise.

ARTICLE 9

COVENANTS

9.1 Mutual Covenants. Each Party hereby covenants to the other Party as follows:

(a) No Misappropriation. It shall not knowingly misappropriate the trade secret of a Third Party in its activities to Research, Develop or Commercialise Licensed Antibody Product.

(b) No Conflict. It will not enter into any agreement with a Third Party that is in conflict with this Licence Agreement, and will not take any action that would in any way prevent it from assuming its obligations or granting the rights granted to the other Party under this Licence Agreement or that would otherwise materially conflict with or adversely affect its obligations or its assumption of the rights granted to the other Party under this Licence Agreement.

(c) [*]. It shall work [*] with the other Party with respect to [*], and it shall not during the term of this Licence Agreement grant any right, licence, consent or privilege to any Third Party(ies) in the Territory which would conflict with the rights granted to the other Party under this Licence Agreement.

9.2 Covenants of Amgen.

(a) No Debarment. In the course of the Development of Licensed Antibody Products and during the Term, Amgen shall not knowingly use and shall not have knowingly used any employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of Amgen's knowledge (not having made enquiry), who is or has been the subject of debarment proceedings by a Regulatory Authority.

(b) Compliance. Amgen shall comply with all applicable statutes and regulations of Regulatory Authorities in carrying out its activities regarding the Research, Development, and Commercialisation of Licensed Antibody Products in the Field in the Territory.

(c) Workmanship. Amgen shall commit the personnel, facilities and other resources reasonably necessary to conduct its obligations under this Licence Agreement, and shall conduct its Research and/or Development obligations using the same standard of skill and care which it applies to its other products, but in no event less than commonly accepted good professional standards of workmanship.

9.3 Disclaimers.

(a) Nothing in this Licence Agreement shall be construed as a warranty or representation by either Party (i) that the Research, Development, Commercialisation, making, having made, using, selling, having sold, offering to sell or resell, importing, exporting, distributing or otherwise transferring physical possession of or otherwise transferring title in any Licensed Antibody Products under or in connection with this Licence Agreement are or will be free from infringement of, or that the activities conducted pursuant to this Licence Agreement will not infringe, Patents Rights, copyrights, Trademarks, industrial design or other intellectual property rights of any Third Party or (ii) that any Licensed Antibody Product Researched, Developed, Commercialised, made, have made, used, sold, have sold, offered to sell or resell, imported, exported, distributed or in which physical possession or title is transferred under this Licence Agreement is or will be effective, valuable, safe, non-toxic or patentable. EXCEPT AS EXPRESSLY SET FORTH IN THIS LICENCE AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES, AND RENOUNCES ANY WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF EFFICACY, SAFETY, SATISFACTORY QUALITY OR FITNESS FOR A PARTICULAR PURPOSE.

(b) Notwithstanding Articles 9.3(a) and 13.9, nothing in this Licence Agreement limits or excludes any Party's liability for fraud or for death or personal injury caused by that Party's own negligence.

ARTICLE 10

INDEMNIFICATION

10.1 **Indemnification by Celltech.** Celltech hereby agrees to defend, hold harmless and indemnify (collectively, "**Indemnify**") Amgen and its Affiliates, agents, directors, officers and employees (the "**Amgen Indemnitees**") from and against any and all Third Party claims, suits, actions or demands and all out-of-pocket liabilities, costs, settlements, damages, expenses and/or losses paid to any Third Party bringing any such Third Party claim, as well as reasonable legal expenses and attorney and expert fees incurred in defending and/or compromising the same ("**Amgen Loss(es)**") arising out of any of (a) any material breach or material default by Celltech of its material covenants and material obligations under this Licence Agreement; and (b) Celltech's negligence or intentional misconduct in carrying out its activities set forth in this Licence Agreement. Amgen shall provide Celltech with prompt written notice of any claim (with a description of the claim and the nature and amount, if determinable, of any such Amgen Loss) giving rise to the indemnification obligation pursuant to this Article 10.1 and the exclusive ability to defend such Third Party claim; *provided however*, that Celltech shall be relieved of its obligations only to the extent the failure to be provided prompt written notice shall have been prejudicial to its ability to defend such action. Amgen shall co-operate as reasonably requested in the defence of the claim; *provided however*, that Amgen shall have the right to retain its own counsel, at its own expense, if representation of the counsel of Celltech would be inappropriate due to actual or potential differing interests between the Parties. Amgen shall not settle any claim for Amgen Losses for which any Amgen Indemnitee is seeking to be Indemnified by Celltech, without Celltech's prior written consent. Celltech's obligation to Indemnify the Amgen Indemnitees pursuant to this Article 10.1 shall not apply to the extent any Amgen Losses (i) arise from the negligence or intentional misconduct of any Amgen Indemnitee; (ii) arise from any material breach by Amgen of this Licence Agreement; or (iii) for which Amgen is obligated to Indemnify the Celltech Indemnitees pursuant to Article 10.2 of this Licence Agreement.

10.2 **Indemnification by Amgen.** Amgen hereby agrees to Indemnify Celltech and its Affiliates, agents, directors, officers and employees (the "**Celltech Indemnitees**") from and against any and all Third Party claims, suits, actions or demands and all out-of-pocket liabilities, damages, costs, settlements, expenses and/or losses paid to any Third Party bringing any such Third Party claim, as well as reasonable legal expenses and attorney and expert fees incurred in defending and/or compromising the same ("**Celltech Loss(es)**") arising out of any of (a) any material breach or material default by Amgen of its material covenants and material obligations under this Licence Agreement; (b) Amgen's

negligence or intentional misconduct in carrying out its activities set forth in this Licence Agreement; and (c) the exercise of any rights by Amgen, its Affiliates, Sublicensees or any of their agents or distributors pursuant to this Licence Agreement (including any product liability claim). Celltech shall provide Amgen with prompt written notice of any claim (with a description of the claim and the nature and amount, if determinable, of any such Celltech Loss) giving rise to the indemnification obligation pursuant to this Article 10.2 and the exclusive ability to defend such Third Party claim; *provided however*, that Amgen shall be relieved of its obligations only to the extent the failure to be provided prompt written notice shall have been prejudicial to its ability to defend such action. Celltech shall co-operate as reasonably requested in the defence of the claim; *provided however*, that Celltech shall have the right to retain its own counsel, at its own expense, if representation of the counsel of Amgen would be inappropriate due to actual or potential differing interests between the Parties. Celltech shall not settle any claim for Celltech Losses for which any Celltech Indemnitee is seeking to be Indemnified by Amgen, without Amgen's prior written consent. Amgen's obligation to Indemnify the Celltech Indemnitees pursuant to this Article 10.2 shall not apply to the extent any Celltech Losses (i) arise from the negligence or intentional misconduct of any Celltech Indemnitee; (ii) arise from any material breach by Celltech of this Licence Agreement; or (iii) for which Celltech is obligated to Indemnify the Amgen Indemnitees pursuant to Article 10.1 of this Licence Agreement.

10.3 **Insurance.** Amgen shall maintain (through a captive insurer or Third Party insurer) appropriate product liability insurance with respect to Licensed Antibody Products and appropriate comprehensive general liability insurance to cover its obligations hereunder and which is/are consistent with normal business practices of prudent companies similarly situated. Amgen shall use reasonable endeavours to ensure that any insurance policy required by, and procured under, this Article 10.3 shall name Celltech as an additional insured. Such insurance shall not be construed to create a limit of the insuring Party's liability with respect to its indemnification obligations under this Article 10. Amgen shall furnish Celltech with a certificate(s) or other evidence from an insurance carrier showing all such insurance. Amgen shall diligently pursue recovery of insurance proceeds when a claim arises. The Parties acknowledge that it is the normal business practice of prudent companies similarly situated to have a reasonable level of uninsured loss.

10.4 **Pre-Effective Date Losses.** In accordance with Article 14.10 of the Collaboration Agreement, each Party shall retain its obligations for any liabilities, damages, expenses and/or losses accrued under the Collaboration Agreement prior to the Effective Date of Termination of the Collaboration Agreement ("**Pre-Effective Date Losses**"), and this Licence Agreement shall not release, waive, alter or otherwise modify the Parties' respective obligations thereunder. Other than with respect to

its obligation for any Pre-Effective Date Losses under and prior to the termination of the Collaboration Agreement, neither Party shall assume or be liable for (pursuant to this Licence Agreement) any liabilities, damages, expenses and/or losses resulting from or arising in connection with activities of the other Party which occurred on or prior to the Licence Agreement Effective Date.

10.5 **Limitation of Liability.** Without prejudice to either Party's obligations, as specified in this Licence Agreement, a Party shall have no liability with respect to (a) the results obtained in the Research, Development and Commercialisation of Licensed Antibody Product or (b) the results obtained in the prosecution, enforcement or defence of any intellectual property in accordance with Article 5.

ARTICLE 11

TERM AND TERMINATION

11.1 **Term.** This Licence Agreement shall become effective on the Licence Agreement Effective Date and shall remain in full force and effect, unless earlier terminated pursuant to this Article 11, on a country-by-country basis until there is no remaining payment obligation in any country. Upon the fulfilment of Amgen's obligation to pay Royalties under this Licence Agreement for a given Licensed Antibody Product in a country, Amgen's licence under the [*]Know-How, [*]Know-How and [*] Know-How to make, have made, use, sell, have sold, offer to sell or resell, import, export, distribute or otherwise transfer physical possession of or otherwise transfer title in or to such given Licensed Antibody Product in such country shall become fully paid and compensation free, provided that Amgen shall continue to be responsible for any Third Party Payments in accordance with Article 4.4 of this Licence Agreement.

11.2 **Termination for Convenience.**

(a) Amgen may terminate this Licence Agreement in its entirety at any time by providing [*] prior written notice of termination to Celltech. Termination shall be effective upon expiry of the [*] notice period.

(b) Celltech may terminate this Licence Agreement by providing [*] prior written notice of termination to Amgen if Amgen indicates in a document it provides in accordance with Article 3.4(d) of the Collaboration Agreement that any of the written representations and warranties of Amgen set out in Articles 16.1 and 16.2 of the Collaboration Agreement are not true and correct as of the date of such document (as if referring to this Licence Agreement and not the Collaboration Agreement) and that this has a material and adverse effect on Celltech in relation

to this Licence Agreement. Termination shall be effective upon expiry of the [*] notice period.

(c) If Amgen fails to provide a document in accordance with Article 3.4(d) of the Collaboration Agreement in a timely manner as required by that Article 3.4(d), Celltech may (within [*] of the date on which Amgen was due to provide such document) request in writing that Amgen provide such document. If Amgen fails to provide such document within [*] of receipt of such request, Celltech may terminate this Licence Agreement by providing Amgen with written notice thereof within [*] after expiry of such [*] period. Termination shall be effective upon receipt of such notice by Amgen.

(d) Should Amgen provide a notice pursuant to Article 3.1.2 of this Licence Agreement Amgen shall be deemed to have served a termination notice pursuant to this Article 11.2(d). Termination shall be effective on Celltech's receipt of such notice.

11.3 Termination for Default.

(a) In the event any material representation or warranty made under the Collaboration Agreement by either Party shall have been untrue in any material respect and this has had a material and adverse effect on the other Party in relation to this Licence Agreement ("**Representation Default**") or upon any material breach or material default of a material obligation of this Licence Agreement by a Party ("**Performance Default**"), the Party not in default ("Non-Defaulting Party") must first give the other Party ("**Defaulting Party**") written notice thereof ("**Notice of Default**"), which notice must state the nature of the Representation Default or Performance Default in reasonable detail and must request the Defaulting Party cure such Representation Default or Performance Default within [*], or if such Default cannot be cured, take such action as will substantially mitigate the material adverse effect of such Default on the other Party. During any such [*] period after receipt or delivery of a Notice of Default under this Article 11.3(a) for which termination of this Licence Agreement is a remedy, all of each Party's respective rights and obligations under this Licence Agreement (to the extent applicable) shall remain in force and effect. If the Defaulting Party shall dispute the existence, extent or nature of any default set forth in a Notice of Default, the Parties shall use good faith efforts to resolve the dispute.

(b) In the event of a Representation Default or a Performance Default by Celltech that shall not have been cured or mitigated within the [*] period, as set forth in Article 11.3(a) above, Amgen,

at its option, may immediately terminate this License Agreement upon prior written notice to Celltech. Termination shall be effective upon the receipt of such notice by Celltech.

(c) In the event of a Representation Default or a Performance Default by Amgen that shall not have been cured or mitigated within the [*] period, all as set forth in Article 11.3(a) above, Celltech, at its option, may immediately terminate this Licence Agreement upon prior written notice to Amgen. Termination shall be effective upon the receipt of such notice by Amgen.

11.4 Bankruptcy.

(a) All rights and licences granted under or pursuant to this Licence Agreement by Celltech are, and shall otherwise be deemed to be licences of rights to "**intellectual property**". The Parties agree that Amgen shall retain and may fully exercise all of its rights and elections under bankruptcy legislation in the Territory. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Celltech, Amgen shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property which at that date is known to be necessary or useful to a Licensed Antibody Product (then the subject of Research, Development or Commercialisation) and all embodiments of such intellectual property; and same, if not already in Amgen's possession, shall be promptly delivered to Amgen (i) upon any such commencement of a bankruptcy proceeding, upon Amgen's written request therefor (which request must identify the specific intellectual property), unless Celltech (or a trustee on behalf of Celltech) elects within [*] to continue to perform all of its obligations under this Licence Agreement or (ii) if not delivered under (i) above, upon the rejection of this Licence Agreement by or on behalf of Celltech, upon written request therefor by Amgen.

(b) Without prejudice to Article 11.4(a), this Licence Agreement may be terminated by Celltech upon written notice to Amgen in the event that (i) Amgen shall make an assignment for the benefit of its creditors, file a petition in bankruptcy, petition or apply to any tribunal for the appointment of a custodian, receiver or any trustee for it or a substantial part of its assets, or shall commence any proceeding under any bankruptcy, reorganisation, arrangement, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction (other than for the purposes of a solvent amalgamation or reconstruction) whether now or hereafter in effect; or (ii) if there shall have been filed against Amgen any such bona fide petition or application, or any such proceeding shall have been commenced against it in which an order for relief is entered or which remains undismissed for a period of ninety (90) days or more;

or (iii) if Amgen by any act or omission shall indicate its consent to, approval of or acquiescence in any such petition, application or proceeding or order for relief or the appointment of a custodian, receiver or trustee for it or any substantial part of its assets, and shall suffer any such custodianship, receivership or trusteeship to continue undischarged for a period of ninety (90) days or more. Termination shall be effective upon the date specified in such notice. Notwithstanding the foregoing, this Licence Agreement shall not be terminated pursuant to this Article 11.4(b) if, prior to the effective date of termination stated in the written notice from Celltech, Amgen demonstrates to Celltech that it is not insolvent.

11.5 Additional Termination Right of Celltech.

If in any suit or proceeding where Celltech or any of its Affiliates is a named party Amgen or any of its Affiliates asserts, or Amgen or any of its Affiliates provides Confidential Information, financial assistance or technical assistance in collusion with a Third Party to assist such Third Party in asserting that any claim within the [*] Patent Rights or any [*] Patent Rights is invalid, Celltech, at its option, may, within [*] of such assertion, terminate this Agreement in its entirety upon [*] prior written notice to Amgen (with termination being effective upon expiry of the [*] notice period); *provided however*, that nothing contained herein shall prohibit Amgen or any of its Affiliates from asserting the invalidity of any claim within the [*] Patent Rights or any [*] Patent Rights, where such assertion is raised as a defence against an assertion of such [*] Patent Rights or [*] Patent Rights in such suit or proceeding brought against Amgen or any of its Affiliates or any of its licensees (provided such suit or proceeding relates to the licensed subject matter) or its intellectual property rights. If the inclusion of this Article 11.5 would make invalid or unenforceable any other provision of this Agreement, or any of the Patent Rights licensed pursuant to this Agreement, this Article 11.5 shall be automatically and without notice severed from this Agreement and the remaining provisions of this Agreement shall remain in force.

11.6 Termination Date. The effective date of termination of this Agreement, as set forth in each instance in Articles 11.2 through 11.5, is hereby referred to as the "**Termination Date**".

11.7 Effects of Termination. In addition to any other remedies which may be available at law or equity upon termination of this Licence Agreement, the rights and obligations of the Parties shall be as set forth in this Article 11.7.

(a) Upon termination of this License Agreement, howsoever caused, the following rights and obligations shall apply:

(i) The following provisions shall remain in full force and effect after the expiration or termination of this Licence Agreement if Amgen is obliged to transfer to Celltech the Research, Development and Commercialisation responsibilities in accordance with Article 11.7(b) below: Article 1, Articles 4 and 6 (in case of any payments relating to the period prior to the Termination Date), Article 5.1, Article 8 (in relation to the other Party's Confidential Information only), Article 9.3, Article 10, this Article 11.7, Article 11.9 and Article 13, and all ancillary provisions necessary for the implementation of this Article 11.7.

(ii) The following provisions shall remain in full force and effect after the expiration or termination of this Licence Agreement if Amgen is not obliged to transfer to Celltech the Research, Development and Commercialisation responsibilities in accordance with Article 11.7(b) below: Article 1, Articles 4 and 6 (in the case of any payments relating to the period prior to the Termination Date), Article 5.1, Article 8 (in relation to the other Party's Confidential Information only), Article 9.3, Article 10, this Article 11.7, Article 11.9, and Article 13, and all ancillary provisions necessary for the implementation of this Article 11.7.

(iii) All other rights and obligations under this Licence Agreement shall terminate.

(iv) By the [*] of the Termination Date, each Party (unless Amgen is obliged to transfer to Celltech the Research, Development and Commercialisation responsibilities in accordance with Article 11.7(b) below, in which case only Amgen) shall destroy, or at the other Party's request return, all of the other Party's Confidential Information (other than with respect to maintaining one (1) archival copy of Confidential Information related thereto for its legal files, for the sole purpose of determining its obligations under this Licence Agreement) and Materials. In each instance where a Party is required to destroy or return the other Party's Confidential Information under this Article 11.7(a)(iv), such Party shall provide the other Party with certification by an officer of such Party that all such Confidential Information and Materials have been destroyed or returned to the other Party, as appropriate.

(b) Subject to Article 11.8 below, where Amgen has terminated this Agreement pursuant to Article 11.2(a) or Article 11.2(d), or where Celltech has terminated this Agreement pursuant to Article 11.2 (b) or Article 11.2(c), Article 11.3, Article 11.4 or Article 11.5, the Parties shall promptly meet to devise a transition plan which provides for an orderly and cost-effective transition of,

and which sets forth the responsibilities and a timetable for transferring to Celltech the Research, Development and Commercialisation responsibilities ("**Transition Plan**"). Where the Parties cannot agree the timetable Celltech shall determine the same. Such transition shall be completed as soon as practicable and, in any event, shall be no later than the [*] of the Termination Date. Such Transition Plan shall provide for transferring to Celltech the Research, Development and Commercialisation responsibilities as expeditiously as possible in accordance with this Article 11 while maintaining a supply of Licensed Antibody Products to meet the Development and/or Commercialisation requirements (as appropriate), and minimizing interruption of Research, Development and/or Commercialisation of the Licensed Antibody Products, including the following:

(i) Until the [*] of the Termination Date Amgen shall make its personnel and other resources reasonably available to Celltech, as necessary, and shall by the [*] of the Termination Date transfer copies of all relevant information, files or data containing Information and transfer all Materials to Celltech.

(ii) By the [*] of the Termination Date, Amgen shall transfer to Celltech all Regulatory Filings and Regulatory Approvals then in its name for all Licensed Antibody Products and shall notify the appropriate Regulatory Authorities and take any other action reasonably necessary to effect such transfer.

(iii) By the [*] of the Termination Date, Amgen shall assign its rights or grant sufficient sublicence rights to Celltech under Amgen's right, title and interest in the Product Trademarks (but otherwise not any of Amgen's Trademarks). Celltech shall also have the right, for a reasonable period not to exceed [*] from the Termination Date, to use Amgen's Trademarks solely in the selling of any existing inventory of Licensed Antibody Products (and to use Promotional Materials it then has on hand), with no obligation of accounting to Amgen.

(iv) By the [*] of the Termination Date, Amgen shall, at the request of Celltech, assign its rights or grant sufficient sublicence rights to Celltech, under all of Amgen's rights (but only to the extent permitted by its terms and subject to the obligations) under any [*] to the extent the same relates to Researching, Developing, Commercialising, making, having made, using, selling, having sold, offering to sell or resell, importing, exporting, distributing or otherwise transferring physical possession of or otherwise transferring title in or to Licensed Antibody Products and shall not (until receiving notice of whether

or not Celltech desires such an assignment or sublicence) terminate or amend any such [*].

(v) Amgen shall be responsible for supplying to Celltech the amounts of Licensed Antibody Product that it was supplying at the time of such termination for a reasonable period of time not to exceed [*] from the Termination Date, to allow Celltech to obtain an alternate source of supply, if necessary. Amgen shall also assign its rights or grant sufficient sublicence rights (but only to the extent permitted by its terms and only to the extent the same relates to Licensed Antibody Product) under all Third Party manufacturing agreements relating to Licensed Antibody Product to Celltech, if requested to do so by Celltech. Amgen shall no longer be responsible for supplying Licensed Antibody Product from the date of such assignment or sublicence or the rejection of a written offer of such assignment (such rejection to be deemed to be given if not accepted within [*] of receipt by Celltech of such written offer from Amgen) in writing by Celltech. In the event Amgen is obligated to continue to supply Licensed Antibody Products to the extent covered by such agreements, Celltech shall use Commercially Reasonable Efforts to identify one or more viable Third Party manufacturers in order to transfer manufacturing operations as soon as commercially reasonable.

(vi) By the [*] of the Termination Date, Amgen shall itself transfer any Information Controlled by it and, to the extent it is using a Third Party manufacturer(s), shall either use Commercially Reasonable Efforts to enforce or assign to Celltech the right to enforce the terms and conditions of each Third Party supply agreement entered into by it including (but only to the extent permitted by each such supply agreement with the Third Party) the provision to Celltech of any Information and assistance reasonably required by Celltech from such Third Party pertaining to the manufacture and analysis of Licensed Antibody Product, with the objective of Celltech being enabled to implement the [*] of [*], including Information contained in the [*] of any applicable Regulatory Filings and the results of any stability studies performed by or on behalf of Celltech.

(vii) Amgen shall continue to use Commercially Reasonably Efforts to promote, detail and otherwise Commercialise the Licensed Antibody Product and shall, if required to do so, complete [*], as modified by the Transition Plan, to enable Celltech to assume the

Commercialisation responsibilities previously carried out by Amgen with a minimum of disruption.

(viii) By the [*] of the Termination Date, Amgen shall (1) assign its rights or grant sufficient sublicense rights under all other Third Party agreements (but only to the extent permitted by their terms and subject to the obligations) to the extent the same relate to the Licensed Antibody Products and as requested to do so by Celltech; and (2) shall provide reasonable assistance to Celltech in assuming management of such agreements.

(ix) Amgen shall grant to Celltech a [*] licence under any [*] Technology ([*]) to Research, Develop, Commercialise, make, have made, use, sell, have sold, offer to sell or resell, import, export, distribute or otherwise transfer physical possession of or otherwise transfer title in or to Licensed Antibody Products.

Such [*] licence shall be [*] (but with Amgen as licensor and Celltech as licensee) *provided that* such licence shall not [*]:

(1) [*];

(2) [*]:

A. [*]; and

B. [*]; and

C. [*].

[*].

(c) Each Party shall assist in the transition as set forth in the Transition Plan in a timely, reasonable and businesslike manner. After completion of the responsibilities set forth in the Transition Plan, the Parties shall have no further obligation to assist in such transition.

(d) During any period after receipt or delivery of a notice of termination to the Termination Date, the Parties' respective rights and obligations under this Agreement shall (to the extent applicable) remain in full force and effect.

(e) If this Licence Agreement is terminated by [*] pursuant to Article 11.4, [*]. If this Licence Agreement is terminated by [*] pursuant to Articles 11.2(b), 11.2(c), 11.3 or 11.5, [*]. Where this Licence Agreement is terminated pursuant to Article 11.2(a) or 11.2(d), the Parties' reasonable out-of-pocket costs in implementing the transition provisions Article 11.7(b) shall be [*] (subject to each Party providing the other Party with reasonable supporting evidence of such costs).

11.8 No Transition. Articles 11.7(b), (c) and (e) shall not apply where this Licence Agreement has come into force as a result of termination of the Collaboration Agreement by Amgen pursuant to Article 14.4(b) (Default of Celltech) or Article 14.5(b) (Bankruptcy of Celltech) or by Celltech pursuant to Article 14.2.2(b) (No Parking) of the Collaboration Agreement.

11.9 Accrued Rights. Termination, relinquishment or expiration of any licences under this Licence Agreement or of this Licence Agreement for any reason in accordance with this Article 11 shall be without prejudice to any rights which shall have accrued to the benefit of either Party or any liability incurred by either Party prior to such termination, relinquishment or expiration.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Disputes. The Parties recognise that disputes as to certain matters may from time to time arise during the term of this Licence Agreement which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising from, concerning or in any way relating to this Licence Agreement in an expedient manner by mutual co-operation and without resort to litigation. In the event of a dispute, it shall be referred to the [*] of Celltech and the [*] of Amgen, or their respective officer designees (all such individuals being referred to herein as the "[*]"), as soon as practicable but in any event no later than [*] after a written request from either Party to the other Party for such a referral. If delegated by the [*] to other [*] and such other [*] are unable to resolve the matter within said [*], it shall be referred back to the [*] as soon as practicable but in any event no later than [*] after a written request from either Party to the other Party for such referral. Each [*] shall have the right to engage the services of any number of independent experts in the field in question (such independent expert(s) to be engaged under obligations of confidentiality and the expense of the Party so engaging such expert(s)) to assist the [*] in making a determination on the unresolved matter, and each [*] shall consider in good faith the analyses and opinions of any such independent experts engaged by either of them in making a

determination. In the event that following discussions between the [*], the [*] are unable to resolve such dispute within such [*] of the matter being referred to them, then either Party may at any time thereafter pursue any legal or equitable remedy available to it. Notwithstanding the above, either Party shall be entitled at all times and without delay to seek equitable relief.

ARTICLE 13

GENERAL

13.1 **Amendments.** This Licence Agreement may not be modified or supplemented by any purchase order, change order, acknowledgement, order acceptance, standard terms of sale, invoice or the like. Any amendment or modification to this Licence Agreement shall be made in a writing expressly stated for such purpose and signed by an authorised officer of each Party.

13.2 **Notices.** Any consent or notice required or permitted to be given or made under this Licence Agreement by one of the Parties to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery or courier), by a next business day delivery service of a nationally recognised overnight courier service or by courier, postage prepaid (where applicable), addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor in accordance with this Article 13.2 and shall be effective upon receipt by the addressee.

If to Celltech: Celltech R&D Limited
208 Bath Road
Slough SL1 3WE
Berkshire, England
Attention: Company Secretary
Facsimile: (XXX) (XX) XXXX XXXXXX

If to Amgen: Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799 U.S.A.
Attention: Vice President, Licensing
Marked to be copied to: Corporate Secretary
Facsimile: (XXX) (XXX) XXX-XXXX

13.3 **Force Majeure.** Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Licence Agreement for failure or delay in fulfilling or performing any term of this Licence Agreement to the extent such failure or delay is caused by or results from Force Majeure; *provided however,* that the Party so affected shall use Commercially Reasonable Efforts to avoid, remove or mitigate such causes of non-performance and shall continue performance with reasonable dispatch wherever such causes are removed. Each Party shall provide the other Party with prompt written notice of any delay or failure to perform that occurs by reason of Force Majeure. Such excuse shall be continued so long as the condition constituting Force Majeure continues. The Parties shall mutually seek in good faith a resolution of the delay or failure to perform.

13.4 **Use of Names, Logos or Symbols.** Subject to Article 2.2, Article 8.6 and Article 11.7(b)(iii), no Party hereto shall use and no rights are granted to the Trademarks (including the names "[*]" and "[*]"), physical likeness, employee names or owner symbol of the other Party for any purpose (including private or public securities placements) without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed so long as use of such name is limited to objective statement of fact rather than for endorsement purposes. Neither Party shall use any Trademark or domain name in connection with the subject matter of this Licence Agreement which either substantially resembles or is confusingly similar to, misleading or deceptive with respect to, or which dilutes any of the other Party's Trademarks or domain names, other than its own Product Trademark or domain names actually used in connection with a Licensed Antibody Product.

13.5 **No Strict Construction.** This Licence Agreement has been prepared Jointly and shall not be strictly construed against either Party.

13.6 **Assignment.**

(a) This Licence Agreement may not be assigned or otherwise transferred by any Party without the consent of the other Party, not to be unnecessarily withheld or delayed; *provided however,* that either Celltech or Amgen may, without such consent, assign its rights and obligations under this Licence Agreement (i) to any Affiliate, *provided* such interest shall be retransferred to the relevant Party if such entity ceases to be an Affiliate of such Party, and *provided further* that the assigning Party shall remain responsible for the acts and omissions in the performance of this Licence Agreement, by its Affiliate or (ii) in connection with a merger, consolidation or sale of substantially all of the business to which this Licence Agreement relates to an unrelated Third Party of [*].

(b) Except as aforesaid, any permitted assignee shall assume all rights and obligations of its assignor under this Licence Agreement; accordingly, all references to the assigning Party shall be deemed references to the assignee to whom the Licence Agreement is so assigned. The assigning Party shall forward to the other Party a copy of those portions of each such fully executed assignment agreement which relate to the assumption of the rights and responsibilities of the assigning Party, within [*] of the execution of such assignment agreements.

(c) Any assignment or attempted assignment by either Party in violation of the terms of this Article 13.6 shall be null and void and of no legal effect.

13.7 Severability. If any provision hereof should be held invalid, illegal or unenforceable from which no appeal can be or is taken, in any respect in any jurisdiction, the invalidity, illegality or unenforceability of one or several provisions of this Licence Agreement shall not affect the validity of this Licence Agreement as a whole. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the objectives contemplated by the Parties as evidenced by the terms and conditions of this Licence Agreement when entering into such invalid or unenforceable one.

13.8 Interpretation and Schedules.

(a) The captions or headings of the Articles or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof.

(b) Unless otherwise specified, (i) references in this Licence Agreement to any Article, or Schedule shall mean references to such Article or Schedule of this Licence Agreement; and (ii) references to any agreement, instrument or other document in this Licence Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto.

(c) Any statute defined or referred to herein or in any agreement or instrument that is referred to herein means such statute as from time to time amended, modified or supplemented, including by succession of comparable successor statutes and references to all attachments thereto and

instruments incorporated therein. References to a person are also to its permitted successors and assigns.

(d) All Schedules annexed hereto or referred to herein are hereby incorporated in and made a part of this Licence Agreement as if set forth in full herein. Any capitalised terms used in any Schedule but not otherwise defined therein, shall have the meaning as defined in this Licence Agreement.

(e) Whenever the words "**include**", "**includes**" or "**including**" are used in this Licence Agreement, they shall be deemed to be followed by the words "without limitation".

13.9 No Consequential Damages. NEITHER PARTY HERETO WILL BE LIABLE (WHETHER UNDER AN INDEMNITY OR OTHERWISE) FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR RELATING TO THIS LICENCE AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING WITHOUT LIMITATION LOST PROFITS, ANTICIPATED PROFITS, LOST GOODWILL, LOST REVENUE, LOST PRODUCTION, LOST CONTRACTS AND LOST OPPORTUNITY, ARISING FROM OR RELATING TO ANY BREACH OF THIS LICENCE AGREEMENT, WHETHER DENOMINATED IN OR ARISING IN CONTRACT, TORT OR OTHERWISE REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS ARTICLE 13.9 IS INTENDED TO LIMIT OR RESTRICT ANY PAYMENT OBLIGATION EXPLICITLY SET FORTH UNDER THIS LICENCE AGREEMENT.

13.10 Governing Law; Jurisdiction.

(a) This Licence Agreement shall be governed and interpreted in all respects under the substantive laws of the State of New York, United States, as applied to agreements executed and performed entirely in the State of New York by residents of the State of New York, without regard to conflicts of law rules and without regard to the United Nations Convention on International Contracts for the Sales of Goods.

(b) Each Party consents to the exclusive jurisdiction of the federal or state courts in the State of New York for any suit, action or other proceeding arising out of or relating to this Licence Agreement whether denominated or arising in contract, tort or otherwise, and further agrees that any process, notice of motion or other application to either such court or judge thereof may be served outside of New York City, New York by personal service, *provided that* a

reasonable time for appearance is allowed. Each Party hereby irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of or relating to this Licence Agreement whether denominated or arising in contract, tort or otherwise, in the federal or state courts in the State of New York. Each Party hereby irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any action, suit or proceeding brought in any such court has been brought in inconvenient forum. As between the Parties, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent Rights claiming the use or sale of any Antibody Product or of any Trademark rights relating to an Antibody Product shall be submitted to a court of competent jurisdiction in the Territory in which such Patent Rights or Trademark rights were granted or arose, which in the case of any United States Patent Rights or Trademark rights shall be a court of competent jurisdiction in the State of New York.

(c) Each Party hereby waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in respect to any litigation directly or indirectly arising out of or relating to this Licence Agreement.

13.11 General Provisions.

(a) The covenants and agreements set forth in this Licence Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and a person who is not a Party to this Licence Agreement may not enforce any of its terms.

(b) A waiver (whether express or implied) by one of the Parties of any of the provisions of this Licence Agreement or of any breach of or default by the other Party in performing any of those provisions must be in writing executed by a responsible officer of the Party providing the waiver and expressly waiving such provisions or breach or default by reference to this Licence Agreement, and any waiver shall not constitute a continuing waiver, and that waiver shall not prevent the waiving Party from subsequently enforcing any of the provisions of this Licence Agreement not waived or from acting on any subsequent breach of or default by the other Party under any of the provisions of this Licence Agreement.

(c) Each Party undertakes to execute all documents which may be reasonably necessary to give full effect to this Licence Agreement.

(d) Each Party shall pay its costs and expenses incurred by it in connection with negotiation and execution of this Licence Agreement.

(e) It is expressly agreed that for tax, legal or all other purposes (i) this Licence Agreement or any portion of this Licence Agreement shall not be considered to be a partnership agreement, and (ii) the relationship between the two Parties shall not constitute an employee-employer, partnership, Joint venture, agency or similar business relationship between the Parties. Neither Celltech nor Amgen shall have the authority to make any statements, representations, warranty, guarantee or commitments (express or implied) of any kind or to take any action which shall bind the other Party to a Third Party, without the prior consent of the other Party to do so. Each Party shall use its own discretion, shall have complete and authoritative control over its employees and the methods and means by which it performs its activities under this Licence Agreement (including the management of permitted subcontractors).

(f) This Licence Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

13.12 Whole Agreement. This Licence Agreement and the Schedules referred to in this Licence Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all previous understandings, arrangements and agreements with respect to the subject matter hereof, whether written or oral. Each Party acknowledges that in entering into this Licence Agreement it has not relied on any representation, warranty, collateral contract or other assurance (except those expressly set out in this Licence Agreement, together with its Schedules) made by or on behalf of any other Party. Each Party waives all rights and remedies which, but for this Article 13.12, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance. As of the Licence Agreement Effective Date, with respect to the subject matter licensed hereunder the terms and conditions of this Licence Agreement shall apply and the terms and conditions of the Collaboration Agreement (other than with respect to accrued or surviving obligations under the Collaboration Agreement) are hereby superseded.

SCHEDULE ONE

Defined Terms

"Affiliate" means any corporation, company, partnership, Joint venture and/or firm which controls, is controlled by, or is under common control with a Party. For purposes of this definition, "control" shall be presumed to exist if one 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 organised 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.

"[*] **Know-How"** means, other than [*] Know-How and [*]Know-How, all Information and Materials which are [*] for the [*] of Licensed Antibody Products to the extent the same are [*] as existing on the Licence Agreement Effective Date or during its Term.

"[*] **Patent Rights"** means, other than [*] Patent Rights and [*] Patent Rights, (i) all Patent Rights to the extent the same are [*] and which claim [*] Know-How and (ii) all Patent Rights [*] to the extent the same are [*]; and in each case which would be infringed by [*] Licensed Antibody Products.

"[*] **Know-How"** means all Information and Materials characterised, conceived, developed, derived, discovered, generated or identified solely by employees of or consultants to [*] in the course of the [*] of Antibody Products [*] and, in each case, [*] of [*].

"[*] **Patent Rights"** means those Patent Rights of [*] which specifically disclose and claim [*] Know-How.

"[*] **Technology"** means, collectively, [*] Know-How, [*] Know-How, [*] Patent Rights, [*] Patent Rights, and [*]'s interest in [*] Know-How and [*]'s interest in [*] Patent Rights.

"Antibody" means a polyclonal or monoclonal antibody, whether multiple or single chain, recombinant or naturally-occurring or a combination of the foregoing, whole or fragment, monospecific or

multi-specific, and any analogs, constructs, conjugates, fusions or chemical or other modifications and/or attachments thereof.

"Antibody Raw Material" means the bulk Licensed Antibody Product (including, if appropriate, [*] suitable for use in the manufacture of Licensed Antibody Product in Finished Form.

"BEER" means any protein or a portion thereof comprising the polypeptide sequence of [*] and any polypeptide sequence having [*] ([*]%) [*] and any [*].

"Business Day" means a day on which banking institutions in both New York, New York, USA, and London, England are open for business.

"Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on either March 31, June 30, September 30, or December 31 for so long as this Licence Agreement is in effect.

"Calendar Year" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

"[*] **Patent Rights"** means the patent applications and patents set forth in Part A of *Schedule Two* and all Patent Rights that issue from or claim priority from those Patent Rights and foreign counterparts thereof.

"[*] **Patent Rights"** means the Patent Rights set forth in Part B of *Schedule Two (*and all Patent Rights that issue from or claim priority from those Patent Rights and foreign counterparts thereof); *provided that* if Amgen has exercised rights under Section 3.2.1(e) of the Collaboration Agreement, unless otherwise agreed in writing the [*] Patent Rights shall be excluded from this Licence Agreement. For the avoidance of doubt, [*] Patent Rights shall not include [*] Patent Rights.

"[*] **Know-How"** means, other than [*] Know-How and [*] Know-How, all Information and Materials relating to Antibodies, which are [*] for the [*] of Licensed Antibody Products to the extent the same are [*] as in each case [*]; *provided that* if Amgen has exercised rights under Section 3.2.1(e) of the Collaboration Agreement, unless otherwise agreed in writing the [*] Know-How shall not include any Information or Materials [*] any invention claimed by any of the [*] Patent Rights.

"[*] **Patent Rights"** means, other than [*] Patent Rights, [*] Patent Rights and [*] Patent Rights, (i) all Patent Rights to the extent the same are [*] and which claim [*] Know-How and (ii) all Patent Rights of a [*] to the extent the same are [*]; and in each case which if not licensed herein would be infringed by [*]

Antibody Products. [*] Patent Rights include [*] Patent Rights; *provided that* if Amgen has exercised rights under Section 3.2.1(e) of the Collaboration Agreement, unless otherwise agreed in writing, the [*] Patent Rights shall be excluded from this Licence Agreement.

"[*] **Know-How"** means all Information and Materials characterised, conceived, developed, derived, discovered, generated or identified solely by employees of or consultants to [*] in the course of the [*] of Antibody Products [*] and, in each case, [*] of [*].

"[*] **Patent Rights"** means those Patent Rights of [*] which specifically disclose and claim [*] Know-How.

"[*] **Technology"** means, collectively, [*]Know-How, [*] Know-How, [*] Patent Rights, [*] Patent Rights, [*] Patent Rights, and [*] Know-How and [*] Patent Rights.

"[*] **Trademarks"** means the Trademarks including house marks and house dress [*] from time to time [*] and used on or in connection with Licensed Antibody Products, but excluding the [*] Trademarks.

"Collaboration Agreement" means that certain Collaboration and Licence Agreement by and between the Parties, dated May ____, 2002.

"Commercialisation" or **"Commercialise"** means any and all activities (whether before or after Regulatory Approval) directed to the marketing, detailing and promotion of a Licensed Antibody Product after Regulatory Approval for commercial sale has been obtained and shall include pre-launch and post-launch marketing, manufacturing for commercial sale, promoting, detailing, distributing, offering to sell and selling a Licensed Antibody Product, importing a Licensed Antibody Product for sale, conducting marketing clinical studies (but not Development clinical studies) and interacting with Regulatory Authorities regarding the foregoing. When used as a verb, "**Commercialising**" means to engage in Commercialisation and "**Commercialised**" shall have a corresponding meaning.

"Commercially Reasonable Efforts" means efforts and resources commonly associated with good business practice and standards in the research-based pharmaceutical industry to research, develop or commercialise (as appropriate) a product of similar market potential at a similar stage in its product life, taking into account efficacy, the competitiveness of alternative products and product candidates in the marketplace (excluding other products owned or controlled or marketed by a Party or any of its Affiliates), the patent and other proprietary position of the product, the likelihood of regulatory approval given the regulatory structure involved, the profitability of the product including the royalties payable to licensors of patent rights, alternative Third Party products and product candidates and other relevant factors.

Commercially Reasonable Efforts where appropriate shall be determined on a market-by-market basis for a particular product, and the level of effort may change over time, reflecting changes in the status of the product and the market involved.

"Competitive Product" means any [*] product, other than a Licensed Antibody Product, that contains [*] in either bulk or final finished form.

"Confidential Information" means all Information disclosed in good faith for the purposes of this Licence Agreement which is designated as confidential in writing by the disclosing Party, whether by letter or by the use of an appropriate stamp or legend, prior to or at the time any such Information is disclosed by the disclosing Party to the other Party. Notwithstanding anything in the foregoing to the contrary, Information which is disclosed in good faith for the purposes of this Licence Agreement, whether orally, electronically, visually or in writing without an appropriate letter, stamp or legend, shall constitute Confidential Information of a Party (a) if the disclosing Party within thirty (30) days after such disclosure, delivers to the other Party a written document or documents describing the Information and referencing the place and date of such oral, visual, electronic or written disclosure and the names of the persons to whom such disclosure was made or (b) if such Information is of the type that is customarily considered to be confidential information by persons engaged in activities that are substantially similar to the activities being engaged in by the Parties. The terms of this Licence Agreement shall be considered Confidential Information of each Party.

"Control" or "Controlled" or "Controlling" means with respect to any (a) Material or Information or (b) intellectual property right, in each case the possession (whether by ownership, licence or other right, other than pursuant to this Licence Agreement) by a Party or its Affiliates of the ability to grant to the other Party access and/or a licence (or sublicence) as provided herein under such item or right without violating the terms of any agreement or other arrangement with any Third Party existing on the Licence Agreement Effective Date or during the Term of this Licence Agreement and existing as of the date such Party obtains such ownership, licence or other right in such Material, Information or intellectual property.

"Development" or **"Develop"** means all clinical and other activities undertaken to obtain Regulatory Approval of a Licensed Antibody Product after the filing of an IND for a Licensed Antibody Product and up to and including the obtaining of Regulatory Approval for commercial sale of such Licensed Antibody Product in the Field in the Territory. For the avoidance of doubt, these activities shall include clinical drug development activities, including, among other things: test method development and stability testing, toxicology, formulation, process development, manufacturing, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, product

approval and registration, and regulatory affairs related to the foregoing. When used as a verb, "**Developing**" means to engage in Development and "**Developed**" shall have a corresponding meaning.

"Dollar" means a United States dollar, and **"$"** shall be interpreted accordingly.

"Drug Approval Application" means an application for any Regulatory Approval required before commercial sale or use of a Licensed Antibody Product as a drug or to treat a particular indication in a regulatory jurisdiction, including: (a) (i) a Biologics Licence Application (BLA) pursuant to 21 C.F.R. 601.2 (or any successor application or procedure) submitted to the FDA and (ii) any counterpart of a U.S. BLA in any other country in the Territory; and (b) all supplements and amendments that may be filed with respect to the foregoing.

"Effective Date of Termination of the Collaboration Agreement" means the Termination Date of the Collaboration Agreement as set forth in Article 14.8 of the Collaboration Agreement.

"FAMC" means the Fully Absorbed Manufacturing Cost as defined in Schedule E of the Collaboration Agreement.

"FDA" means the United States Food and Drug Administration or a successor agency thereto.

"Field" means [*].

"First Commercial Sale" means in relation to any Licensed Antibody Product the first shipment of such Licensed Antibody Product sold on arm's-length terms to a non-sublicensee Third Party by Amgen, its Affiliates or its Sublicensees, in a country in the Territory after the first Regulatory Approval for Commercialisation has been achieved for such Licensed Antibody Product in such country in any indication. Sales for test marketing, sampling and promotional uses, clinical trial purposes or compassionate or similar use shall not constitute a First Commercial Sale.

"Force Majeure" means any occurrence beyond the reasonable control of a Party that prevents or substantially interferes with the performance by a Party of any of its obligations hereunder.

"GAAP" means United States generally accepted accounting principles.

"IND" means (a) (i) an Investigational New Drug Application (as defined in the U.S. Federal Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder) that is required to be filed with the FDA before beginning clinical testing of a Licensed Antibody Product in human subjects, or any successor application or procedure and (ii) any counterpart of a U.S. Investigational New

Drug Application in any other country in the Territory; and (b) all supplements and amendments that may be filed with respect to the foregoing.

"Information" means tangible or intangible know-how, trade secrets, inventions (i.e., conceived or reduced to practice, constructively or actually), methods, knowledge, conclusions, skill, experience, test data and results (including but not limited to, chemical, biological, biochemical, pharmaceutical, pharmacological, toxicological and research, pre-clinical and clinical data, assay, control and manufacturing processes, test data and results), analytical and quality control methods and data, results or descriptions, software and algorithms or other information (whether or not patentable) regarding technology, techniques, practices, products, business information or objectives.

"[*] **Know-How"** means all Information or Materials that are conceived or developed [*] and, in each case, [*] of [*].

"[*] **Patent Rights"** means Patent Rights in any country within the Territory which claim [*] Know-How and which identify employees or contractors of [*] as inventors.

"Licensed Antibody Product(s)" means (i) any Antibody Product and Subsequent Products (as each is defined in the Collaboration Agreement) for which Celltech elected to opt out in accordance with Article 3.4 of the Collaboration Agreement, or (ii) where (i) does not apply, all Antibody or Antibodies in whatever form that [*], and any product incorporating any such Antibody or Antibodies.

"Materials" means biological and chemical materials including, Antibodies, Licensed Antibody Products, screens, animal models, cell lines, cells, vectors, nucleic acids, receptors and reagents.

"Net Sales" means with respect to any Licensed Antibody Product, all revenues recognised in accordance with GAAP, consistently applied as between the Parties, from sales of a Licensed Antibody Product by Amgen, its Affiliates and Sublicensees, to Third Parties (but not including sales relating to transactions between a Party, its Affiliates, and their respective Sublicensees), less the total of the following:

a) Normal or customary trade, cash, prompt payment and/or quantity discounts actually allowed and taken;

b) Returns, allowances, free goods, rebates, chargebacks, other allowances or payments to government agencies actually allowed and taken;

c) Retroactive price reductions applicable to sales of such product actually allowed and taken;

d) Credits or allowances (actively paid or allowed) for wastage replacement, whether cash or trade;

e) Non-recoverable sales taxes, excise taxes, tariffs and duties (excluding taxes when assessed on income derived from sales); and

f) [*] ([*]%) of the amount invoiced to cover bad debt, freight or other transportation charges, insurance charges, additional special packaging, and other governmental charges.

In the case of any sale of a Licensed Antibody Product between or among Amgen and its Affiliates or Sublicensees for resale, Net Sales shall be calculated as above only on the first arm's-length sale by any such Party, Affiliate or Sublicensee to a Third Party.

Upon any sale or other disposal of any Licensed Antibody Product for any consideration other than an exclusively monetary consideration on bona fide arm's-length terms then for the purposes of calculating the Net Sales under this Licence Agreement, such Licensed Antibody Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for such Licensed Antibody Product in the country in which such sale or other disposal occurred when such Licensed Antibody Product is sold alone and not with other products.

Where a Licensed Antibody Product is sold together with other pharmaceutical products for a single price (whether sold together in the same package, or merely price bundled), then for the purposes of calculating the Net Sales payable under this Licence Agreement such Licensed Antibody Product shall be deemed sold for an amount equal to the following:

(X divided by Y) multiplied by Z

where X is the average sales price during the applicable reporting period generally achieved for such Licensed Antibody Product in the country in which such sale or other disposal occurred when such Licensed Antibody Product is sold alone and not with other pharmaceutical products; Y is the sum of the average sales price during the applicable reporting period generally achieved in that country when sold alone by each product (including the Licensed Antibody Product) included in the bundle of pharmaceutical products that is sold for the single price; and Z equals the single price at which the bundle of pharmaceutical products represented in Y was actually sold. In the event one or more of the products in the bundled product are not sold separately, the Parties shall confer in good faith to determine a fair market price for the value of the Licensed Antibody Product(s) within the bundled product.

“Party” means Amgen or Celltech; **“Parties”** means Amgen and Celltech.

“Patent Rights” means all (a) existing issued, unexpired patents (with the term “patent” being deemed to encompass an inventor's certificate), including any reissue, re-examination, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent and (b) existing patent applications and patent applications hereafter filed, including any continuations, continuations-in-part, divisionals, provisionals, converted provisional, continued prosecution application, or any substitute applications, any patent issued with respect to any such patent applications, any reissue, re-examination, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent; and all foreign counterparts of any of the foregoing.

“[*] **Antibody”** means an Antibody which is [*] of any [*] and claimed by any of the [*] Patent Rights.

“Phase II Study” means a clinical trial that is designed to establish the safety and preliminary efficacy of a drug for its intended use, and to define warnings, precautions and adverse reactions that are associated with the drug in the dosage range to be prescribed and that satisfy the requirements of 21 CFR 312.21(b) (or its successor regulation), or its equivalent in any other jurisdiction.

“Pivotal Study” means a clinical trial that, if the defined end-points are met, is designed (and agreed to in advance by a Regulatory Authority(ies) having jurisdiction in the country(ies) in which the trial is to be conducted, based upon existing data in the same patient population as of the start of such clinical trial) to definitively establish that a Licensed Antibody Product drug is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with the Licensed Antibody Product in the dosage range to be prescribed, and provide pivotal data supporting Regulatory Approval of such Licensed Antibody Product and that satisfies the requirements of 21 CFR 321.21(c) (or its successor regulation), or its equivalent in any other jurisdiction.

“Product Trademark” means any trademarks and trade names (and trademark applications (whether or not registered), and any renewals, extensions or modifications thereto in the Territory) together with all goodwill associated therewith, trade dress and packaging which (a) are Controlled by either Party and (b) are applied to a Licensed Antibody Product or any Promotional Materials and (c) distinguishes that Licensed Antibody Product; but excluding any house marks or house dress or any reserve trademarks and trade names (and trademark applications (and any resulting trademarks) which are Controlled by a Party and are filed with a trademark office for use with a Licensed Antibody Product but which shall not have been applied to a Licensed Antibody Product.

“Promotional Materials” means all sales representative training materials and all written, printed, graphic, electronic, audio or video matter including, but not limited to, journal advertisements, sales visual aids, direct mail, direct-to-consumer advertising, Internet postings, product inserts, broadcast advertisements, and sales reminder aids (e.g., scratch pads, pens and other such items) intended for use or used by a Party in connection with any promotion or detailing of a Licensed Antibody Product.

“Regulatory Approval” means any and all approvals (including any applicable supplements, amendments, pre- and post-approvals, governmental price and reimbursement approvals and approvals of applications for regulatory exclusivity), licences, registrations, or authorisations of any federal, national, multinational, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity necessary for the manufacture, distribution, use, storage, import, export, transport, promotion, marketing and sale of a Licensed Antibody Product in a country or jurisdiction.

“Regulatory Authority” means any governmental or regulatory authority involved in granting Regulatory Approvals of any Licensed Antibody Product including in the United States the FDA.

“Regulatory Filings” means, collectively, INDs, Drug Approval Applications, establishment licence applications (ELAs) and drug master files (DMFs) or any other similar filings (including any equivalents in other jurisdictions and further including any related correspondence and discussions) and applications for regulatory exclusivity, and all data contained therein, as may be required by the FDA or equivalent Regulatory Authorities in other jurisdictions, for the Development or Commercialisation of a Licensed Antibody Product.

“Research” means all research and pre-clinical activities including the filing of any IND for a Licensed Antibody Product. When used as a verb “**Research**” means to engage in Research, and “**Researched**” and “**Researching**” shall have a corresponding meaning.

“Royalty” or “Royalties” means those amounts payable as royalties by Amgen to Celltech pursuant to Article 4.2 of this Licence Agreement.

“Sublicensee” means a Third Party to whom Amgen shall have granted a licence or sublicense under Amgen's rights pursuant to Article 2.3 to Research, Develop, Commercialise, make, have made, use, sell, have sold, offer to sell or resell, import, export, distribute or otherwise transfer physical possession of or otherwise transfer title in or to a Licensed Antibody Product in one or more countries in the Territory. Solely for the purpose of any compensation payable to Celltech hereunder, “Sublicensee” shall include a Third Party to whom Amgen or another Sublicensee shall have granted the right to distribute one or more Licensed Antibody Product(s) but, notwithstanding the foregoing, shall not include (i) [*]; or (ii) [*].

“Term” shall have the meaning set forth in Article 11.1.

“Territory” means all the countries of the world.

“Third Party” means any person, partnership, Joint venture, corporation, trust, estate, unincorporated organisation, government or any department or agency thereof, or any entity other than a Party or any of its Affiliates.

“Third Party Payment” means all fees, milestones, royalties and any other payments paid to Third Parties under patent or technology licences that are necessary in order to Research, Develop, Commercialise, make, have made, use, sell, have sold, offer to sell or resell, import, export, distribute or otherwise transfer physical possession of or otherwise transfer title in or to the Licensed Antibody Products.

“Trademark” means any and all corporate names, service marks, logos or trademarks and trademark applications (whether or not registered) together with all good will associated therewith, and any renewals, extensions or modifications thereto either filed or used.

“Transition Date” shall have the meaning set forth in Article 5.2.8.

“Valid Claim” means a claim of any issued, unexpired Patent Right which has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

Each of the following definitions are found in the body of this Licence Agreement as indicated:

Defined Terms	**Page/Article**
"Amgen"	Page 1, 1st paragraph
"Amgen Indemnitees"	Article 10.1
"Amgen Loss(es)"	Article 10.1
"Celltech"	Page 1, 1st paragraph
"Celltech Indemnitees"	Article 10.2
"Celltech Loss(es)"	Article 10.2
"Consultation Rights"	Article 5.2.2(b)
"Defaulting Party"	Article 11.3(a)
"include", "includes", and "including"	Article 13.8(e)
"Indemnify"	Article 10.1
"intellectual property"	Article 11.4(a)
"Licence Agreement"	Page 1, 1st paragraph
"Licence Agreement Effective Date"	Page 1, 1st paragraph
"[*] Patent Rights"	Article 5.2.2(a)
"Milestone Events"	Article 4.1(a)
"Milestone Payments"	Article 4.1(a)
"Non-Defaulting Party"	Article 11.3(a)
"Notice of Default"	Article 11.3(a)
"[*]"	Article 12.1
"patent"	Page S1-10 (part of "Patent Rights" def)
"Performance Default"	Article 11.3(a)
"Pre-Effective Date Losses"	Article 10.4
"Representation Default"	Article 11.3(a)
"Termination Date"	Article 11.6
"Transition Date"	Article 5.2.7
"Transition Plan"	Article 11.7(b)

SCHEDULE TWO

PART A

[*] PATENT RIGHTS

a) [*]

[*] Ref. No. [*]

Subject Matter: [*]

Title: [*]

Inventors: [*]
[*]
[*]
[*]
[*]
[*]
[*]

Priority Application Date: [*]
Earliest Publication Date/No. [*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]			
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		

*[*]

SCHEDULE TWO

PART B

[*] PATENT RIGHTS

b) [*]

[*] Ref. No:	[*]
Subject Matter:	[*]
Title:	[*]
Inventors:	[*] [*]
Priority Application Date:	[*]
Earliest Publication Date/No:	[*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]

*[*]

SCHEDULE TWO

PART B

[*] PATENT RIGHTS

b) [*]

[*] Ref. No:	[*]
Subject Matter:	[*]
Title:	[*]
Inventors:	[*]
	[*]
Priority Application Date:	[*]
Earliest Publication Date/No:	[*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]

*[*]

SCHEDULE TWO

PART B

[*] PATENT RIGHTS

c) [*]

[*] Ref. No.	[*]
Subject Matter:	[*]
Title:	[*]
Inventors:	[*]
	[*]
Priority Application Date:	[*]
Earliest Publication Date/No.	[*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]		

*[*]

SCHEDULE TWO

PART B

[*] PATENT RIGHTS

c) [*]

[*] Ref. No.	[*]
Subject Matter:	[*]
Title:	[*]
Inventors:	[*] [*]
Priority Application Date:	[*]
Earliest Publication Date/No.	[*]

Territory	Application Date	Application No.	Patent No.	Expiry Date
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		

*[*]

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

Amgen
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
805.447.1000

Via facsimile (XXX) (XX) XXXX XXXXXX and DHL Courier

Celltech R&D Limited
208 Bath Road
Slough SL1 3WE
Berkshire, England
Attention: Company Secretary

Re: Amendment No. 1 to Collaboration and Licence Agreement
Between Amgen Inc. and Celltech R&D Limited
Amgen Ref. No. XXXXXXXXX (the "Agreement")

To Whom It May Concern:

Celltech R&D Limited ("Celltech") and Amgen Inc. ("Amgen") entered into the captioned Agreement effective May 10th, 2002. The Parties agree that the Agreement is hereby amended as set forth below ("Amendment"), and that the Amendment shall have an effective date of June 9th, 2003 (the "Amendment Effective Date"). Unless specified herein, each capitalized term shall have the meaning assigned to it in the Agreement.

Section 3.2.1(d) and Section 3.2.1(e) of the Agreement are hereby amended in their entirety as follows:

3.2.1 *Research*

(d) If (i) Celltech has not achieved Milestone 1 as set out in Schedule A by [*]; or (ii) if Celltech achieves Milestone 1 but subsequently fails to achieve Milestone 3 as set out in Schedule A within [*] of Amgen notifying Celltech in writing (pursuant to Article 3.2.1(g) below) of [*] as determined by the [*] study results; the Parties (upon the written request of [*]) shall for a period of [*] of [*] with respect to unachieved Milestone 1 or unachieved Milestone 3 (as applicable) discuss the possibility of extending such time period for an additional, mutually agreed period. Each Party acknowledges that it shall be at its sole discretion as to whether or not to agree to such an extension of any such time period.

(e) Within [*] of expiry of the [*] period referred to in Article 3.2.1(d) or any extension to such date agreed to by the Parties, Amgen shall notify Celltech in writing that Amgen will either:

(i) assume the right and obligation to Research, Develop, and supply either itself or through agreement with a Third Party the [*] referred to in Milestone 1 and/or (as appropriate) the [*] referred to above in Article 3.2.1(d); or

(ii) terminate this Agreement.

If Amgen does not serve such a notice it will be deemed to have exercised the option set out in Article 3.2.1(e)(i).

Section 3.6.3 of the Agreement is amended in its entirety as follows:

3.6.3 *Late Stage Development Costs*

All Research and Development Costs cumulatively incurred (whether FTE Cost incurred directly by Amgen or Celltech or amounts payable to Third Parties engaged by Celltech or Amgen) for Late Stage Development of Antibody Products shall be shared as follows:

(a) up to [*] Dollars ($[*]) of such cumulative Research and Development Costs, on the basis of [*]:[*] Amgen:Celltech;

(b) over [*] Dollars ($[*]) of such cumulative Research and Development Costs, on the basis of [*]:[*] Amgen:Celltech.

The costs of manufacture, including scale-up and validation of Antibody Raw Material and Antibody Product in Finished Form, shall be deemed Research and Development Costs of Late Stage Development to the extent only that Antibody Raw Material and Antibody Product in Finished Form so produced is not used for Commercialisation and otherwise shall be a Cost of Goods.

Amgen and Celltech warrant and represent that they have the right to enter into this Amendment and that the terms of this Amendment are not inconsistent with other contractual obligations (express or implied) which they may have. No amendment, modification or supplement of any provision of this Amendment shall be valid or effective unless made in writing and signed by a duly authorized officer of each party. This Amendment shall be governed by the laws of the State of New York.

July 10, 2003

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain in full force and effect. The Agreement as amended pursuant to this Amendment, constitutes the entire understanding of the parties and each reference to "Agreement" contained in the Collaboration and Licence Agreement shall from and after the date of the Amendment Effective Date refer to the Collaboration and Licence Agreement as modified hereby. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. If this Amendment is acceptable to you, please confirm by signing and returning the duplicate copy of this agreement to XXXXX X. XXXXXXXXX, M/S XX-X-X, at Amgen.

Yours sincerely,

/s/ David L. Lacey

David L. Lacey, M.D.
Vice President, Basic Research & Metabolic Disorders

Celltech R&D Limited

By: /s/ Melanie G. Lee

Title: R&D Director

Date: 24th July 2003

copy: Ian J. Nicholson
Senior V.P. Business Development, Celltech

XXX XXXXXXXX, Esq.
XXXXX XXXXXX

Exhibit 10.58

Amendment No. 1 to Collaboration Agreement

This amendment to the Collaboration Agreement (this "Amendment") is made and entered into as of the 24th day of January, 2012 (the "Execution Date"), by and between Amgen Inc., a Delaware corporation with a place of business at 1 Amgen Center Drive, Thousand Oaks, CA 91320 ("Amgen"), and Glaxo Group Limited, registered in England as company number 305979, doing business as "GlaxoSmithKline" and having its principal office at Glaxo Wellcome House, Berkley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom ("GSK").

WITNESSETH:

WHEREAS, GSK and Amgen entered into a Collaboration Agreement dated July 27, 2009 (the "Agreement"), governing GSK's rights to commercialize Ivory in the Collaboration Territory; and

WHEREAS, the Parties desire to amend the Agreement with respect to certain matters relating to Product Trademarks and brand security, among other things, pursuant to Section 16.19 of the Agreement, as set forth below.

NOW THEREFORE, in consideration of the covenants and obligations expressed herein, and intending to be legally bound, the Parties agree as follows:

1. Capitalized terms used but not defined herein have the meanings ascribed to them in the Agreement.

2. Section 10.2 is hereby deleted in its entirety and replaced with the following language:

"Brand Security and Anti-Counterfeiting. The Parties will establish contacts for communication regarding brand security issues and will each reasonably cooperate with the other with respect thereto. The Parties will develop and implement an anti-counterfeiting strategy with respect to Ivory in the Collaboration Territory, including the following elements: (i) agreement on a counterfeit incident management process enabling the most effective response to incidents of suspected counterfeit Ivory and (ii) using a risk-based approach, identification of countries in the Collaboration Territory where Amgen will record its right to use the Product Trademark with the applicable governmental customs authorities and provide authority training. In the event that a Party becomes aware of suspected counterfeit Ivory in the Collaboration Territory, the Party with such knowledge shall promptly notify the other Party in writing using reasonable efforts to do so within five (5) business days, except in cases where local law requires a more prompt response (*e.g.*, with respect to an inquiry from a local customs authority wherein response times may be very short), in which case the Parties shall endeavor to give written notice more promptly. After such written notice, the Parties shall confer and endeavor to reach consensus as to a mutually acceptable response to the counterfeit Ivory in accordance with the counterfeit incident management process agreed to by the Parties. Such response may include further investigation, referral to drug regulatory authorities and/or law enforcement, cooperation with customs authorities, test purchases, obtaining of legal advice, sending a cease and desist letter and/or a decision not to take any action. In the event that the Parties cannot reach consensus as to the response to the counterfeit Ivory within sixty (60) days after written notice, or sooner if specifically required to preserve the right to act under Applicable Law, the Parties agree as follows: (i) Amgen will have the first right to take action with respect to such counterfeit Ivory, but only based on Product Trademarks and Amgen Housemarks, and shall not assert or otherwise rely on GSK Housemarks without GSK's prior written consent; and (ii) GSK will have the second right to take action with respect to such counterfeit Ivory where Amgen decides not to act, but only based on GSK Housemarks, and shall not assert or otherwise rely on Product Trademarks and/or Amgen Housemarks without Amgen's prior written consent; provided, that, in each case, the other Party will take reasonable steps, if and as directed by the Party wanting to take action and at such Party's sole expense, with respect to such suspected counterfeit Ivory. For the sake of clarity, nothing in this Section 10.2 shall in any way limit, nor is intended to so limit, the rights of Amgen with respect to any portion of the Ivory Intellectual Property as provided in other provisions of this Agreement, unless expressly agreed by the Parties in writing."

3. Section 9.11.3.2 of the Agreement is hereby amended to read in its entirety as follows:

"**To Amgen.** GSK hereby grants to Amgen a non-exclusive, royalty-free license to use the GSK Housemarks (i) as set forth in the Promotional Materials (including monographs) solely to Detail Ivory in the Collaboration Scope in accordance with the Brand Plan, Country Plans and this Agreement, and (ii) to the extent permissible in accordance with Applicable Law, on the labeling, packaging and package inserts for Ivory in the Collaboration Scope. Amgen's right to use the GSK Housemarks will terminate, on a country-by-country basis, when GSK's rights to promote Ivory in such country are

terminated or expire; provided, that the license set forth in this Section 9.11.3.2 (To Amgen) will continue for a period of six (6) months thereafter to permit Amgen to use and distribute its inventory of labeling, packaging, package inserts and Promotional Materials (including monographs) containing GSK Housemarks in such country (or, where the on-hand inventory as of such termination or expiration of such labeling, packaging, package inserts or Promotional Materials (including monographs) cannot practically be used within such six (6) month period, such longer period as reasonably necessary to exhaust such inventory, but in no event longer than twelve (12) months), in connection with Amgen's Detailing of Ivory. Amgen will take all such steps as GSK may reasonably request to give effect to the termination of the license to the GSK Housemarks in the applicable country and to record any documents that may be required to evidence the termination of such license."

4. The last sentence of Section 14.9.2 is amended to read in its entirety as follows:

   "Amgen's right to use the GSK Housemarks pursuant to Section 9.11.3.2 will survive expiration or termination of the Agreement as set forth in Section 9.11.3.2."

5. The Parties agree to add Gibraltar to the list of countries set forth on the Collaboration Territory Schedule.

6. All other terms, conditions and provisions of the Agreement shall remain in full force and effect except as otherwise provided herein. All references to the "Agreement" therein shall mean the Agreement as amended by this Amendment.

7. This Amendment may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall constitute a single instrument.

8. This Amendment will be governed by, and enforced and construed in accordance with, the laws of the State of New York without regard to its conflicts of law provisions. The United Nations Convention for the International Sale of Goods will not apply to the transactions contemplated herein.

[Remainder of page intentionally left blank - signature page to follow]

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized officers or representatives.

AMGEN INC.

By: /s/ Rolf K. Hoffmann

Name: Rolf K. Hoffmann

Title: Senior Vice President
International Commercial Ops

GLAXO GROUP LIMITED

By: /s/ Paul Williamson

Name: Paul Williamson

Title: Corporate Director

Exhibit 10.61

Amendment No. 2 to Expansion Agreement

This amendment to the Expansion Agreement (this "Amendment") is made and entered into as of the 24th day of January, 2012 (the "Execution Date"), by and between Amgen Inc., a Delaware corporation with a place of business at 1 Amgen Center Drive, Thousand Oaks, CA 91320 ("Amgen"), and Glaxo Group Limited, registered in England as company number 305979, doing business as "GlaxoSmithKline" and having its principal office at Glaxo Wellcome House, Berkley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom ("GSK").

WITNESSETH:

WHEREAS, GSK and Amgen entered into an Expansion Agreement dated July 27, 2009 (the "Agreement"), governing GSK's rights to develop and commercialize Ivory in the Expansion Territory; and

WHEREAS, the Parties desire to amend the Agreement with respect to certain matters relating to Product Trademarks and brand security, among other things, pursuant to Section 13.19 of the Agreement, as set forth below.

NOW THEREFORE, in consideration of the covenants and obligations expressed herein, and intending to be legally bound, the Parties agree as follows:

1. Capitalized terms used but not defined herein have the meanings ascribed to them in the Agreement.

2. Section 4.7 is hereby deleted in its entirety and replaced with the following language:

"Brand Security and Anti-Counterfeiting. The Parties will establish contacts for communication regarding brand security issues and will each reasonably cooperate with the other with respect thereto. The Parties will develop and implement an anti-counterfeiting strategy with respect to Ivory in the Expansion Territory, including the following elements: (i) agreement on a counterfeit incident management process enabling the most effective response to incidents of suspected counterfeit Ivory and (ii) using a risk-based approach, identification of countries in the Expansion Territory where GSK will record its right to use the Product Trademark with the applicable governmental customs authority and provide authority training. Notwithstanding the foregoing, if GSK is not legally permitted to record its right to use the Product Trademark with the applicable Governmental Authority in a particular country, then GSK will take such steps as reasonably necessary to enable Amgen to file such customs recordals using a law firm mutually acceptable to the Parties, and in such case, Amgen will authorize such law firm to notify both GSK and Amgen of suspected counterfeit Ivory in the applicable country. The Parties will share the costs of customs recordals and training to the extent the Parties agree on where to register the Product Trademarks. In the event the Parties cannot reach consensus, either Party may record the Product Trademark and conduct training at its sole expense. In the event that a Party becomes aware of suspected counterfeit Ivory in the Expansion Territory, the Party with such knowledge shall promptly notify the other Party in writing using reasonable efforts to do so within five (5) business days, except in cases where local law requires a more prompt response (*e.g.*, with respect to an inquiry from a local customs authority wherein response times may be very short), in which case the Parties shall endeavor to give written notice more promptly. After such written notice, the Parties shall confer and endeavor to reach consensus as to a mutually acceptable response to the counterfeit Ivory in accordance with the counterfeit incident management process agreed to by the Parties. Such response may include further investigation, referral to drug regulatory authorities and/or law enforcement, cooperation with customs authorities, test purchases, obtaining of legal advice, sending a cease and desist letter and/or a decision not to take any action. To the extent the Parties agree on a course of action, the Parties will share the costs of any action taken in response to such counterfeit Ivory. In the event that the Parties cannot reach consensus as to the response to the counterfeit Ivory within sixty (60) days after written notice, or sooner if specifically required to preserve the right to act under Applicable Law, the Parties agree as follows: (i) GSK will have the first right to take action at GSK's sole expense with respect to such counterfeit Ivory, but only based on the GSK Housemarks and Product Trademarks, and shall not assert or otherwise rely on the Amgen Trademarks without Amgen's prior written consent; and (ii) Amgen will have the second right to take action at Amgen's sole expense with respect to such counterfeit Ivory where GSK decides not to act, but only based on the Product Trademarks and Amgen Housemarks, and shall not assert or otherwise rely on the GSK Housemarks without GSK's prior written consent; provided, that, in each case, the other Party will take reasonable steps, if and as directed by the Party wanting to take action and at such Party's sole expense,, with respect to such suspected counterfeit Ivory. For the sake of clarity, nothing in this Section 4.7 shall in any way limit, nor is intended to so limit, the rights of Amgen with respect to any portion of the Ivory Intellectual Property as provided in other provisions of this Agreement, unless expressly agreed by the Parties in writing."

3. The first sentence of Section 8.8.3 (GSK Secondary Enforcement) is hereby amended to read as follows:

"In the event Amgen does not commence an Enforcement Action in accordance with Section 8.8.2 (Amgen Primary Enforcement), or otherwise take action to abate any alleged material infringement or misappropriation of any Ivory Intellectual Property within sixty (60) days (or, with respect to the Product Trademarks, such shorter time period under Applicable Law as is necessary to preserve the Parties' rights under this Agreement to bring such Enforcement Action, as reasonably demonstrated by GSK) after GSK requests Amgen to do so in writing (or, if later, within sixty (60) days (or, with respect to the Product Trademarks, such shorter time period referred to above) after such Enforcement Action can viably be brought by Applicable Law (as, for example, in the case of expiration of a clinical trial exemption to patent infringement)), GSK will be entitled to bring and prosecute such Enforcement Action in the Expansion Territory at GSK's sole cost and Amgen will cooperate with GSK at GSK's request (and GSK will reimburse all reasonable, documented, out-of-pocket expenses incurred by Amgen in connection therewith)."

4. The first sentence of Section 8.11.3.1 (Trademark Licenses) (To GSK) is hereby amended to read as follows:

"Amgen hereby grants to GSK a non-exclusive, royalty-free license to use the Product Trademarks and Amgen Housemarks (i) as set forth in the Promotional Materials and other materials provided to it by Amgen, solely to market and promote Ivory in the Expansion Scope in accordance with the Expansion Brand Plan, applicable Launch Plan and this Agreement, and (ii) to the extent permissible in accordance with Applicable Law, on the labeling, packaging and package inserts for Ivory solely with the concurrent use of the GSK Housemarks in the Expansion Scope; in each case, during the period that GSK has rights to promote Ivory hereunder."

5. Section 8.11.5 is hereby deleted in its entirety and replaced with the following language:

"*Infringement*. GSK and Amgen will monitor the Product Trademarks for infringing uses within the Expansion Scope consistent with its monitoring of product trademarks for its other products in the Expansion Territory. Each Party will give the other prompt notice of any infringement or threatened infringement of any of the Product Trademarks of which it becomes aware. Amgen will have the first right, but not the obligation, to bring an Enforcement Action in the Expansion Territory, at Amgen's sole cost with respect to the Product Trademarks as provided in Section 8.8.2. Notwithstanding anything to the contrary in Sections 8.8.2 or 8.8.3, if Amgen does not commence an Enforcement Action in relation to the Product Trademarks in accordance with Section 8.8.2, or otherwise take action to abate any alleged material infringement or misappropriation of any of the Product Trademarks within sixty (60) days or such shorter time period under Applicable Law as is necessary to preserve the Parties' rights under this Agreement to bring such Enforcement Action, as reasonably demonstrated by GSK, after GSK requests Amgen to do so in writing, GSK will be entitled to bring and prosecute such Enforcement Action in the Expansion Territory at GSK's sole cost and Amgen will cooperate with GSK at GSK's request (and GSK will reimburse all reasonable, documented, out-of-pocket expenses incurred by Amgen in connection therewith)."

6. A new Section 10.1.8 is hereby added to Section 10.1 (Mutual Representations and Warranties) of the Agreement as follows:

"Its so-called Detailed Description of Pharmacovigilance System ("DDPS") as provided to the other Party is an accurate representation of the providing Party's pharmacovigilance system as of the time the DDPS was provided."

7. The Parties agree to add Macau to the list of Initial Countries and Designated Countries.

8. Notwithstanding Section 3.3 (Launch Plans) of the Agreement, the Parties agree that GSK is not required to provide Launch Plans for the following countries: Albania, Afghanistan, Armenia, Azerbaijan, Georgia, Ghana, Iraq, Kyrgyzstan, Macau, Moldova, Namibia, Nigeria, Uzbekistan and Yemen (and any other countries within the Reserved Territory designated as such by the unanimous vote of the ESC (without the ability of GSK to make the decision in the event of a deadlock) from time to time) (the "Additional Countries") and to move the Additional Countries from the Reserved Territory into the Expansion Territory. For the purpose of Section A.1 (Fixed Amount) of the Supply Pricing Schedule of this Agreement and the Supply Agreement entered into by the Parties dated September 10, 2010, the "Per mg Price" for each of the Additional Countries, on a country-by-country basis, will be the price equal to the expected net selling price, as established in accordance with the terms and conditions of this Agreement, for commercial sale of Ivory in the applicable country, divided by the total milligrams of the Ivory SKU contemplated for such country. If more than one list price or more than one Ivory SKU are contemplated, the Parties will agree upon a single "Per mg Price" to apply to all Ivory SKUs supplied for such country. No clinical development activities are currently envisaged by the Parties as

necessary in order to commercialize Ivory in any such Additional Country; however, the Parties acknowledge that if in the future GSK believes development activities are required or advisable with respect to the commercialization of Ivory in any such Additional Country, it will have the right to propose such activities (together with a reasonably detailed description thereof) to the EDC in accordance with Section 5.1.1 (Development Activities) (Updates) of the Agreement.

9. The Parties agree to remove Gibraltar from the list of Initial Countries, as it will be added to the list of countries set forth on the Collaboration Territory Schedule by an amendment to the Collaboration Agreement of even date herewith.

10. The Parties agree that South Africa was deemed part of the Excluded Territory as of May 11, 2010.

11. All other terms, conditions and provisions of the Agreement shall remain in full force and effect except as otherwise provided herein. All references to the "Agreement" therein shall mean the Agreement as amended by this Amendment.

12. This Amendment may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall constitute a single instrument.

13. This Amendment will be governed by, and enforced and construed in accordance with, the laws of the State of New York without regard to its conflicts of law provisions. The United Nations Convention for the International Sale of Goods will not apply to the transactions contemplated herein.

[Remainder of page intentionally left blank - signature page to follow]

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized officers or representatives.

AMGEN INC.

By: /s/ Rolf K. Hoffmann

Name: Rolf K. Hoffmann

Title: Senior Vice President
International Commercial Ops

GLAXO GROUP LIMITED

By: /s/ Paul Williamson

Name: Paul Williamson

Title: Corporate Director

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

AMENDMENT NO. 1 TO SOURCING AND SUPPLY AGREEMENT
BETWEEN AMGEN USA INC. AND DAVITA HEALTHCARE PARTNERS INC.

This Amendment No. 1 ("Amendment No. 1") to Sourcing and Supply Agreement (the "Agreement") is being made by and between Amgen USA Inc. ("**Amgen**") and DaVita Healthcare Partners Inc. f/k/a DaVita Inc. ("**Dialysis Center**") and effective as of January 1, 2013 (the "Amendment No. 1 Effective Date").

WHEREAS, Amgen and Dialysis Center have entered into that Agreement, effective on January 1, 2012; and

WHEREAS, Amgen and Dialysis Center mutually desire to amend the Agreement as stated below.

NOW, THEREFORE, in consideration of the premises and of the mutual covenants, representations and warranties set forth herein, the parties agree as follows:

SECTION 1. Definitions; References. Unless otherwise specifically defined herein, each term used herein which is defined in the Agreement shall have the meaning assigned to such term in the Agreement. Except as amended and supplemented hereby, all of the terms of the Agreement are incorporated herein by reference, shall remain and continue in full force and effect and are hereby ratified and confirmed in all respects.

SECTION 2. Amendment of the Agreement. As of the Amendment No. 1 Effective Date, all references to DaVita Inc. in the Agreement shall hereby be changed to DaVita Healthcare Partners Inc.

SECTION 3. Amendment of Section 1.9 of Exhibit A. As of the Amendment No. 1 Effective Date, Section 1.9 of Exhibit A of the Agreement entitled "[*]" shall be amended and restated, as follows:

1.9 "[*]" shall mean for each [*] of EPOGEN purchased by a Dialysis Center Purchaser under this Agreement in any Quarter, the [*] in effect on the date of purchase less for such Quarter (i) the Discounts that Dialysis Center is eligible to earn under this Agreement during the applicable Quarter, including the [*] Rebate, the [*] Rebate and the [*] Rebate as applicable, but excluding the [*] Rebate, (ii) any [*] Rebate earned, and (iii) any other discount, rebate or other price adjustment received by a Dialysis Center Purchaser per [*] of EPOGEN which is included in the "Best Price" reported in Amgen's Best Price Submission under Title XIX of the Social Security Act in respect of such EPOGEN purchase.

SECTION 4. Amendment of Section 1 of Exhibit A. As of the Amendment No. 1 Effective Date, Section 1 of Exhibit A of the Agreement entitled "Definitions" shall be amended to add the following "[*] Rebate Definitions": Section 1.24 "[*] Rebate", Section 1.25 "[*] Rebate Eligibility", and Section 1.26 "[*] Rebate Period", as follows:

Additional Rebate Definitions

1.24 "[*] Rebate" shall mean, a rebate equal to [*] percent ([*]%) of the Qualified Gross Purchases of EPOGEN during the applicable Quarter.

1.25 "[*] Rebate Eligibility" shall mean, an Amgen ESA Share of Sales during the applicable Quarter that is equal to or greater than [*] percent ([*]%).

1.26 "[*] Rebate Period" shall mean, the period from January 1, 2013 through December 31, 2013.

SECTION 5. Amendment of Section 1.20 of Exhibit A. As of the Amendment No. 1 Effective Date, the row corresponding to 2013 set forth in the [*] Table set forth in Section 1.20 of Exhibit A of the Agreement entitled "[*]" shall be revised to be, as follows:

[*] Table	
Calendar Year	**[*]**
2013	$[*] in the event Dialysis Center earns the [*] Rebate in accordance with the terms and conditions of Section 3.6 of this Exhibit A, otherwise the [*] shall be $[*].

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

AMENDMENT NO. 1 TO SOURCING AND SUPPLY AGREEMENT
BETWEEN AMGEN USA INC. AND DAVITA HEALTHCARE PARTNERS INC.

SECTION 6. Amendment of Section 3 of Exhibit A. As of the Amendment No. 1 Effective Date, Section 3 of Exhibit A of the Agreement shall be amended to add Section 3.6 entitled "[*] Rebate", as follows:

3.6 [*] Rebate. During the [*] Rebate Period, Dialysis Center shall earn the [*] Rebate for each Quarter provided that Dialysis Center shall have met the [*] Rebate Eligibility during such Quarter.

3.6.1 Payment of [*] Rebate. Amgen will pay the [*] Rebate within [*] ([*]) days after the end of the corresponding Quarter, provided Amgen is in receipt of all Relevant Information in a form reasonably acceptable to Amgen.

3.6.2 Vesting of [*] Rebate. The [*] Rebate for a given Quarter shall vest on the last day of such Quarter.

SECTION 7. Amendment of Section 4 of Exhibit A. As of the Amendment No. 1 Effective Date, the column corresponding to 2013 of the Summary of Discounts Table set forth in Section 4 of Exhibit A of the Agreement shall be revised to be, as follows:

Summary of Discounts Table	
	2013
Base Invoice Discount	[*]%
Base Rate Rebate	[*]%
[*] Rebate	[*]%
[*] Rebate	[*]%
Total Discount Opportunity	**[*]%**

AMENDMENT NO. 1 TO SOURCING AND SUPPLY AGREEMENT
BETWEEN AMGEN USA INC. AND DAVITA HEALTHCARE PARTNERS INC.

The Parties have executed this Amendment No. 1 by their designated representatives set forth below effective as of the Amendment No. 1 Effective Date.

Amgen USA Inc.

By: /s/ Mark Bubany

Name (print): Mark Bubany

Its: Ex Director, Contracts & Pricing

Date: 12/11/12

DAVITA HEALTHCARE PARTNERS INC. F/K/A DAVITA INC.

By: /s/ Dennis L. Kogod

Name (print): Dennis L. Kogod

Its: Chief Operating Officer

Date: 12/10/12

AMGEN INC.

SUBSIDIARY (Name under which subsidiary does business)	STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION
Immunex Corporation	Washington
Amgen Manufacturing, Limited	Bermuda
Amgen USA Inc.	Delaware

Exhibit 31

CERTIFICATIONS

I, Robert A. Bradway, Chairman of the Board, President and Chief Executive Officer of Amgen Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Amgen Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer(s) 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 annual report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and 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 annual report based on such evaluation; and

   (d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's 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(s) 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 27, 2013

/s/ Robert A. Bradway

Robert A. Bradway

Chairman of the Board, President and Chief Executive Officer

CERTIFICATIONS

I, Jonathan M. Peacock, Executive Vice President and Chief Financial Officer of Amgen Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Amgen Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer(s) 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 annual report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and 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 annual report based on such evaluation; and

   (d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's 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(s) 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 27, 2013

/s/ JONATHAN M. PEACOCK

Jonathan M. Peacock

Executive Vice President and Chief Financial Officer

Exhibit 32

Certification of Chief Executive Officer

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Amgen Inc. (the "Company") hereby certifies that:

(i) the accompanying Annual Report on Form 10-K of the Company for the period ended December 31, 2012 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2013

/s/ Robert A. Bradway

Robert A. Bradway

Chairman of the Board, President and Chief Executive Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Amgen Inc. and will be retained by Amgen Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Certification of Chief Financial Officer

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Amgen Inc. (the "Company") hereby certifies that:

(i) the accompanying Annual Report on Form 10-K of the Company for the period ended December 31, 2012 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2013

/s/ JONATHAN M. PEACOCK

Jonathan M. Peacock

Executive Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Amgen Inc. and will be retained by Amgen Inc. and furnished to the Securities and Exchange Commission or its staff upon request.