AMGEN INC
Form 10-K
February 29, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2011

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, Thousand Oaks, California	**91320-1799**
(Address of principal executive offices)	(Zip Code)

(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 x 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 x

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 x 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 x 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 x

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $53,861,879,805 as of June 30, 2011(A)

(A) Excludes 966,638 shares of common stock held by directors and executive officers at June 30, 2011. 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.

791,432,134

(Number of shares of common stock outstanding as of February 10, 2012)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant s Proxy Statement with respect to the 2012 Annual Meeting of stockholders to be held May 23, 2012, are incorporated by reference into Part III of this annual report.

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PART I

Item 1. BUSINESS

Overview

Amgen Inc. (including its subsidiaries, referred to as Amgen, the Company, we, our or us) is the world s largest independent biotechn medicines company. We discover, develop, manufacture and market medicines for grievous illnesses. We focus solely on human therapeutics and concentrate on innovating novel medicines based on advances in cellular and molecular biology. Our mission is to serve patients.

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.

As of December 31, 2011, we had 17,800 staff members worldwide. Approximately 6,500 of our staff members work in our research and development (R&D) function, approximately 4,900 work in manufacturing, approximately 4,400 work in our commercial operations and the rest are in general and administrative functions.

Currently, we market primarily recombinant protein therapeutics in supportive cancer care, inflammation and nephrology. 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 selectively 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 the body s response to inflammatory diseases; and Aranesp® (darbepoetin alfa) and EPOGEN® (epoetin alfa), erythropoiesis-stimulating agents (ESAs) that stimulate the production of red blood cells. Our principal products represented 87%, 91% and 93% of our sales in 2011, 2010 and 2009, respectively. Our other marketed products include 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); Nplate® (romiplostim), a thrombopoietin (TPO) receptor agonist that mimics endogenous TPO, the primary driver of platelet production; and Prolia® (denosumab) and XGEVA® (denosumab), which both contain the same active ingredient but are approved for different indications, patient populations, doses and frequencies of administration. Denosumab is a fully human monoclonal antibody that specifically targets RANKL, an essential regulator of osteoclasts (the cells that break down bone).

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. 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 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 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 facilities are located in the United States, Puerto Rico and the Netherlands. (See Item 2. Properties.)

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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 2011 and early 2012 affecting our business. A more detailed discussion of each development follows in the appropriate section.

ESAs

The Centers for Medicare & Medicaid Services (CMS) Final Rule on Bundling in Dialysis became effective on January 1, 2011, and provides a single payment for all dialysis services, including drugs that were previously reimbursed separately.

On June 24, 2011, we announced that the FDA approved changes to the labels for the use of ESAs, including Aranesp® and EPOGEN®, in patients with chronic kidney disease (CKD) (June 2011 ESA label changes).

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 hemoglobin (Hb) level below 10 grams per deciliter (g/dL).

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.

XGEVA®

On July 15, 2011, we announced that the European Commission (EC) granted marketing authorization for XGEVA® for the prevention of skeletal-related events (SREs) in adults with bone metastases from solid tumors.

Vectibix®

On November 10, 2011, the EC approved a variation to the marketing authorization for the use of Vectibix® in first- and second-line treatment of metastatic colorectal cancer (mCRC) in patients whose tumors contain wild-type *KRAS* genes.

We announced on July 29, 2011, that we received Complete Response Letters from the FDA on the first- and second-line mCRC supplemental Biologics License Applications (sBLA) for Vectibix® that we filed in late 2010. We are currently working to address their requests.

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Motesanib

We along with our partner Takeda Pharmaceutical Company Limited (Takeda) announced that the motesanib pivotal phase 3 trial (MONET1) did not meet its primary objective of demonstrating an improvement in overall survival in patients with advanced non-squamous non small cell lung cancer (NSCLC).

Business combinations

On March 4, 2011, we acquired BioVex Group, Inc. (BioVex), a privately held biotechnology company developing treatments for cancers and for the prevention of infectious disease, including talimogene laherparepvec (formerly referred to as OncoVEX^{GM-CSF}), a novel oncolytic vaccine in phase 3 clinical development for the treatment of malignant melanoma.

On April 7, 2011, we acquired Laboratório Químico Farmacêutico Bérgamo Ltda (Bergamo), a privately held Brazilian pharmaceutical company that is a leading supplier of medicines to the hospital sector in Brazil with capabilities in oncology medicines.

On January 26, 2012, we announced that we entered into an agreement to acquire 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. The acquisition, which is subject to customary closing conditions, is expected to close in the first quarter of 2012.

Return of capital to shareholders

In the third quarter of 2011, we began paying quarterly cash dividends of $0.28 per share of common stock, aggregating $500 million paid in 2011. In December 2011, we increased our quarterly declared dividend by 29% to $0.36 per share of common stock, payable in March 2012.

During 2011, we repurchased approximately 15% of our stock outstanding as of December 31, 2010, for a total cost of $8.3 billion.

Proposed legal settlement

We recorded a $780 million charge (the legal settlement charge) in connection with an agreement in principle to settle allegations relating to our sales and marketing practices.

Marketed Products

We market our principal products, Neulasta®, NEUPOGEN®, ENBREL, Aranesp® and EPOGEN®, in supportive cancer care, inflammation and nephrology. Certain of our marketed products face, and our product candidates, if approved, are also expected to face, substantial competition, including from products marketed by large pharmaceutical corporations, which may have greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than we do. Our products competitive position among other biological and pharmaceutical products may be based on, among other things, safety, efficacy, reliability, availability, patient convenience/delivery devices, price, reimbursement and patent position and expirations.

Over the next several years, many of the existing patents on our principal products will expire, and we expect to face increasing competition thereafter, including from biosimilar products. A biosimilar product is a follow-on version of another 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 product 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 biosimilar products under a new, abbreviated pathway. On February 9, 2012, the FDA released three draft guidance documents that provide insight into the FDA s current thinking on the development of biosimilar products 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 product to gain approval (see Government Regulation). In the European Union

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(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, including from manufacturers with biosimilar products approved in Europe that may seek to quickly obtain U.S. approval. Upon patent expiration for small molecule products, there is typically intense competition from generics manufacturers, which generally leads to significant and rapid declines in sales of the branded product. Given that our principal products are biologics, we do not believe the impact of biosimilar competition will be as significant as with small molecule products in part because successful competitors must have a broad range of specialized skills and capabilities unique to biologics, including significant regulatory, clinical and manufacturing expertise, and since the products are similar, but not identical, the biosimilars will have to compete against a product with an established efficacy and safety record. 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, e.g., 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. For example, in 2008 the FDA began requiring 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, Australia and New Zealand under a licensing agreement with Kirin-Amgen, Inc.

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(K-A), a joint venture between Kirin Holdings Company, Limited (Kirin) and Amgen (see Business Relationships Kirin-Amgen, Inc.) (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. Treatments for various diseases and 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. Because pegfilgrastim is eliminated through binding to its receptor on neutrophils and neutrophil precursor cells, pegfilgrastim remains in the circulation 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. Filgrastim is also marketed under the brand name GRANULOKINE® in Italy. 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; 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).

Worldwide Neulasta®/NEUPOGEN® sales for the years ended December 31, 2011, 2010 and 2009, were $5.2 billion, $4.8 billion and $4.6 billion, respectively. U.S. Neulasta®/NEUPOGEN® sales for the years ended December 31, 2011, 2010 and 2009, were $4.0 billion, $3.6 billion and $3.4 billion, respectively. International Neulasta®/NEUPOGEN® sales for each of the three years ended December 31, 2011, 2010 and 2009, were $1.2 billion.

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) In some cases, this European patent may also be entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary by country.

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

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Our principal European patent relating 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.

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. Further, NEUPOGEN® competes with Neulasta® in the United States and Europe, and NEUPOGEN® sales have been adversely impacted by conversion to Neulasta®. However, we believe the conversion in the United States is substantially complete and that a significant amount of the conversion in Europe has already occurred.

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.

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, the following companies have long-acting filgrastim product candidates in phase 3 clinical development:

Teva Pharmaceutical (Neugranin and XM-22)

Sandoz (Peg G-CSF).

In February 2010, Teva Pharmaceutical announced that the FDA had accepted for review its Biologics License Applications (BLA) seeking U.S. approval to market XM02 (its filgrastim product currently sold under the brand name Tevagrastim® in several European countries) to stimulate

the production of neutrophils under the brand name Neutroval . On September 30, 2010, the FDA issued a Complete Response Letter requesting additional information from Teva Pharmaceutical to complete the review of its applications for approval of

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Neutroval . If approved in the United States, this drug would compete with NEUPOGEN® and Neulasta® subject to the terms of the injunction and settlement agreement discussed below.

On November 30, 2009, Teva Pharmaceutical filed a declaratory judgment action against us alleging that certain of our NEUPOGEN® patents are invalid and not infringed by Neutroval , and on January 15, 2010, we filed an answer and counterclaims seeking a declaratory judgment that our patents are valid and infringed. On July 15, 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 Neutroval in the United States, subject to receiving FDA approval for human therapeutic use. Teva also agreed not to sell Neugranin in the United States before November 10, 2013, unless it first obtains a final court decision that our patents are not infringed by Neugranin . 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.

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.

We acquired the rights to ENBREL in July 2002 with our acquisition of Immunex Corporation (Immunex). ENBREL was launched in the United States in November 1998 and in Canada in March 2001 for the treatment of rheumatoid arthritis (RA). In addition, ENBREL is now 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.

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

ENBREL sales for the years ended December 31, 2011, 2010 and 2009, were $3.7 billion, $3.5 billion and $3.5 billion, respectively.

In November 2011, we announced the issuance of U.S. Patent No. 8,063,182 related to ENBREL, which is owned by F. Hoffmann-La Roche Ltd. (Roche) and exclusively licensed to Amgen. This patent, which has a term of 17 years from issuance, is reflected in the following table along with our other outstanding material patents for etanercept.

Territory	General Subject Matter	Expiration
U.S.	TNFR DNA vectors, cells and processes for making proteins	10/23/2012
U.S.	Aqueous Formulation[(1)]	2/27/2023
U.S.	Fusion protein, and pharmaceutical compositions	11/22/2028

(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

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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)
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®	Roche
U.S.	Rheumatology	Actemra®	Roche
U.S. & Canada	Dermatology	Stelara®	Janssen [1]

[1] A subsidiary of Johnson & Johnson (J&J) formerly known as Centocor Ortho Biotech Products, L.P.

In December 2011, the FDA accepted a new drug application (NDA) from Pfizer for approval of tofacitinib in RA. In addition, several competitors have product candidates in phase 3 clinical development that may compete with ENBREL in the future:

- Celgene (apremilast), in both psoriasis and psoriatic arthritis.
- AstraZeneca PLC and Rigel Pharmaceuticals Inc. (fostamatinib) in RA.
- Eli Lilly and Company (Eli Lilly) (LY 2439821) 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 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 resulting in changes in the way ESAs are used in clinical practice, including by decreasing the number of treated patients, average dose and duration of ESA therapy.

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Further, the following developments occurred with respect to ESAs in 2011:

CMS s Final Rule on Bundling in Dialysis became effective on January 1, 2011, and provides a single payment for all dialysis services, including drugs that were previously reimbursed separately (except for oral drugs without intravenous equivalents, such as Sensipar®, which will be included in the bundle beginning in 2014). Substantially all dialysis providers in the United States opted into the bundled payment system in its entirety on January 1, 2011.

On June 24, 2011, we announced that the FDA had approved the June 2011 ESA label changes. While the previous label language specified a Hb target range of 10-12 g/dL for chronic renal failure (CRF) patients on dialysis as well as those not on dialysis, the modified labeling provides separate treatment guidance for these two populations. For patients on dialysis, who constitute the majority of CKD (or CRF) patients 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 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. (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.)

On November 1, 2011, 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 the QIP s measure that tracks the percent of a provider s Medicare patients with a Hb level below 10 g/dL. CMS indicated that removal of this measure from the QIP was being done in response to the June 2011 ESA label changes.

On June 16, 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, on June 16, 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, and that it would instead monitor the use of ESAs through its bundled payment system and its other policy avenues. In the absence of an NCD, Local Coverage Determinations (LCDs) may be made by 11 regional contractors called Medicare Administrative Contractors (MACs), which CMS contracts with to process Medicare claims. LCDs are binding on providers within their respective jurisdictions. Since CMS issued their FDM, one MAC has issued a final LCD relating to anemia in patients with CKD not on dialysis, and two more MACs have issued draft LCDs, all of which would restrict reimbursement to use in accordance with the revised label. Nonetheless, physician behavior may change at any time to be consistent with the label even before formal LCDs are implemented.

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, 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. Effective January 1, 2012, we also entered into a three-year non-exclusive supply agreement to supply EPOGEN® to Fresenius Medical Care North America, a subsidiary of Fresenius Medical Care AG & Co. KGaA (Fresenius Medical Care), following the 2011 expiration of our five-year ESA supply agreement with them.

We have an ongoing oncology pharmacovigilance program in place for Aranesp®. Of the clinical trials included in the program, five explore the use of ESAs in settings different from those outlined in the FDA approved label and are designated by the FDA as PMCs. Of the five studies, one was sponsored by Amgen while the other four were investigator-sponsored. Results of certain of those studies contributed to safety-related product labeling changes for our ESAs and changes in reimbursement, as noted above. Of the five studies, four are complete with final results of the remaining study expected in 2012. 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.

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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 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 are in ongoing discussions with the FDA regarding additional PMRs to explore alternative ESA dosing strategies in CKD patients on dialysis and not on dialysis.

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

Worldwide Aranesp® sales for the years ended December 31, 2011, 2010 and 2009, were $2.3 billion, $2.5 billion and $2.7 billion, respectively. For the years ended December 31, 2011, 2010 and 2009, U.S. Aranesp® sales were $1.0 billion, $1.1 billion and $1.3 billion, respectively, and international Aranesp® sales were $1.3 billion, $1.4 billion and $1.4 billion, respectively.

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) In some cases, this European patent may also be entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary by country.

Our principal European patent relating 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.

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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 marketed products and 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 CRF.

(5) A subsidiary of Teva Pharmaceutical.

In addition to competition from these marketed products, Affymax, Inc. (Affymax) and Takeda are co-developing peginesatide, a synthetic, PEGylated peptidic compound that binds to and stimulates the erythropoietin receptor and thus acts as an ESA, for the treatment of anemia in CRF patients on dialysis and have submitted an NDA to the FDA. On December 7, 2011, Affymax and Takeda announced that the Oncology Drug Advisory Committee (ODAC) panel voted 15 to 1, with 1 abstention, that peginesatide demonstrated a favorable risk-benefit profile for use in the treatment of dialysis patients with anemia due to CKD. The FDA has targeted a Prescription Drug User Fee Act (PDUFA) action date of March 27, 2012.

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 launched EPOGEN® in the United States in 1989 for the treatment of anemia associated with CRF in patients who are on dialysis. We market EPOGEN® in the United States for the treatment of anemic adult and pediatric patients with CRF who are on dialysis. EPOGEN® is indicated for elevating or maintaining the red blood cell level (as determined by hematocrit or Hb measurements) and decreasing the need for blood transfusions in these patients.

EPOGEN® sales in the United States for the years ended December 31, 2011, 2010 and 2009, were $2.0 billion, $2.5 billion and $2.6 billion, respectively.

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

Territory	General Subject Matter	Expiration
U.S.	Process of making erythropoietin	8/15/2012
U.S.	Product claims to erythropoietin	8/20/2013
U.S.	Pharmaceutical compositions of erythropoietin	8/20/2013
U.S.	Cells that make certain levels of erythropoietin	5/26/2015

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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 addition, EPOGEN® could face additional competition from those products noted in the Aranesp® section above that may be used in dialysis in the United States.

Other Marketed Products

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

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 2014 when they will be reimbursed under the bundled payment system. Inclusion in the bundled payment system may reduce utilization of these oral drugs and have a material adverse impact on Sensipar® sales. (See Reimbursement.)

The phase 3 EValuation Of Cinacalcet HCl Therapy to Lower CardioVascular Events (E.V.O.L.V.E) trial, initiated in 2006, is a large (3,800 patient), multi-center, international, randomized, double-blind study to assess the effects of Sensipar®/Mimpara® on mortality and cardiovascular morbidity in patients with CKD undergoing maintenance dialysis. The E.V.O.L.V.E study completed enrollment in January 2008 and we anticipate data from the study in 2012.

Worldwide Sensipar®/Mimpara® sales for the years ended December 31, 2011, 2010 and 2009, were $808 million, $714 million and $651 million, respectively.

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) In some cases, this European patent may also be entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary by country.

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.

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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. 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.	Hectorol®	Genzyme Corporation (Genzyme)
U.S.	Rocaltrol®	Roche
U.S.	Calcijex®	Abbott
U.S.	Calcium Acetate®	Roxane Laboratories/Sandoz
U.S. & Europe	Zemplar®	Abbott
U.S. & Europe	Renagel®	Genzyme
U.S. & Europe	Renvela®	Genzyme
U.S. & Europe	PhosLo®/Rephoren®	Fresenius Medical Care
U.S. & Europe	OsvaRen®	Fresenius Medical Care
U.S. & Europe	Fosrenol®	Shire Pharmaceuticals Group Plc

On July 25, 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 filed by Teva and Barr that sought approval to market generic versions of Sensipar®. Following trial, on January 7, 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 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. We acquired full ownership of Vectibix® with our acquisition of Abgenix, Inc. (Abgenix) in April 2006. 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.

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On February 8, 2011, we and four other sponsor companies met with the FDA and the ODAC to discuss the status of our respective PMCs for product indications that had been granted accelerated approval by the FDA prior to 2009, including Vectibix®. At that meeting, we updated the Committee on the completion and submission of the main PMC for Vectibix® and on the confirmatory 181 study; and we participated in an open discussion with the ODAC on the accelerated approval process.

On July 29, 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., which identifies a patient s *KRAS* gene status. We are currently working on addressing the FDA s requests in the Complete Response Letters.

On November 10, 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.

Worldwide Vectibix® sales for the years ended December 31, 2011, 2010 and 2009, were $322 million, $288 million and $233 million, respectively.

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) In some cases, this European patent may also be entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary by country.

Any products or technologies that are directly or indirectly successful in treating mCRC after disease progression on, or following fluoropyrimidine-, oxaliplatin- and irinotecan- containing chemotherapy regimens could negatively impact Vectibix® sales. The following table reflects the companies that currently market Erbitux®, which competes with Vectibix® in the United States and Europe. The table below and the following discussion of products in development may not be exhaustive.

Territory	Competitor Marketed Product	Competitor
U.S.	Erbitux®	Eli Lilly/BMS
Europe	Erbitux®	Merck KGaA

In addition to competition from Erbitux®, the following products in development could compete with Vectibix® in the future:

Sanofi filed a BLA with the FDA for approval of ZALTRAP for second-line mCRC in early 2012.

Bayer announced results from its phase 3 trial for regorafenib in patients with mCRC. Bayer is in discussions with health authorities worldwide regarding next steps in filing for approval.

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

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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.

Worldwide Nplate® sales for the years ended December 31, 2011, 2010 and 2009, were $297 million, $229 million and $110 million, respectively.

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) In some cases, this European patent may also be entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary by country.

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®	GlaxoSmithKline plc (GSK)
Europe	Revolade®	GSK

Prolia®/XGEVA® (denosumab)

In 2010, we launched Prolia® and XGEVA®, 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 GSK, for the commercialization of denosumab in certain countries. (See Business Relationships Glaxo Group Limited.)

Prolia®

On June 1, 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. On September 19, 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.

We estimate that the large majority of Prolia® usage to date in the United States has been under Medicare Part B. Additionally, most potential U.S. Prolia® patients now also have coverage for Prolia® under Medicare Part D. Future U.S. product sales for Prolia® will depend primarily on postmenopausal osteoporosis disease state awareness, the willingness of primary care physicians to prescribe the product and the availability of reimbursement for and patient acceptance of the product.

On May 25, 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. Since the first reimbursement authority was received in Germany in July 2010, reimbursement authority approval has been granted in most EU countries.

Worldwide Prolia® sales for the years ended December 31, 2011 and 2010, were $203 million and $33 million, respectively.

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Any products or technologies that are directly or indirectly successful in treating postmenopausal osteoporosis (PMO) in women 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®/Bonviva®	Roche
U.S. & Europe	Evista®	Eli Lilly
U.S. & Europe	Forteo®/Forsteo	Eli Lilly
U.S. & Europe	Miacalcin®	Novartis AG (Novartis)
U.S. & Europe	Aclasta®/Reclast®	Novartis
Europe	Conbriza®	Pfizer
Europe	Fablyn®	Pfizer

(1) Merck s patent covering the use of FOSAMAX® to treat bone loss expired in the United States in February 2008. Following the patent expiry, generic alendronate, which competes with FOSAMAX® and Prolia®, became available.

We expect several additional marketed products noted above to lose patent protection over the next several years, including Boniva® in 2012, at which time we expect generic versions of these products would become commercially available and compete with Prolia®.

The following companies have product candidates in phase 3 clinical development that may compete with Prolia® in the future:

Merck (odanacatib), for PMO.

Radius Health, Inc. (BA058) for PMO.

XGEVA®

On November 18, 2010, the FDA approved XGEVA® for the prevention of SREs in patients with bone metastases from solid tumors. XGEVA® is not indicated for the prevention of SREs in patients with multiple myeloma.

On May 17, 2011, we announced results of a pivotal phase 3 trial (Study 147) in 1,432 men with castration-resistant prostate cancer that has not yet spread to bone. The trial demonstrated that XGEVA® significantly improved median bone metastasis-free survival by 4.2 months compared to placebo (primary endpoint) and significantly improved time to first occurrence of bone metastases (secondary endpoint). Overall survival was similar between the XGEVA® and placebo arms (secondary endpoint), and adverse events and serious adverse events were relatively similar. Hypocalcemia and osteonecrosis of the jaw (ONJ) were reported with increased frequencies in the XGEVA® treated patients compared to placebo. The yearly rate of ONJ in the XGEVA® arm was similar to prior XGEVA® trial results. Back pain was the most common adverse event reported in the XGEVA® arm of the trial. On June 27, 2011, we announced the submission of an sBLA to the FDA to expand the indication to treat men with castration-resistant prostate cancer to reduce the risk of developing bone metastases. On February 8, 2012, the FDA convened the ODAC to discuss the sBLA filing. The ODAC panel voted 12 to 1 that the overall magnitude of benefit demonstrated with early treatment with XGEVA® to delay bone metastases was not sufficient to conclude a positive risk-benefit ratio in the absence of additional measures impacting quality of life or other disease outcomes. The FDA often seeks the advice of an advisory committee such as ODAC when evaluating a potential new treatment. The FDA has targeted a PDUFA action date of April 26, 2012.

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On July 15, 2011, we announced that the EC granted marketing authorization for XGEVA® for the prevention of SREs (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumors. The timing of reimbursement authority approval of pricing in individual EU countries will vary by country, which could follow the EC approval by many months. For example, in August 2011, XGEVA® received reimbursement authority in Germany. 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.

U.S. XGEVA® sales for the years ended December 31, 2011 and 2010, were $351 million and $8 million, respectively.

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 marketed products may not be exhaustive.

Territory	Competitor Marketed Product	Competitor
U.S. & Europe	Zometa®(1)	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 and 2012 in other major markets. At such time, we expect that generic forms of zoledronic acid may become commercially available and compete with Zometa® and XGEVA®.

(2) Novartis s patent covering the use of Aredia® to treat tumor-induced hypercalcemia, osteolysis from multiple myeloma and bone metastases from breast cancer expired in the United States in 2001. Following the patent expiry, generic pamidronate, which competes with Aredia® and XGEVA®, became available from other companies.

In addition, Bayer has a product candidate, alpharadin, in phase 3 clinical development for SREs in patients with prostate cancer, that may compete with XGEVA® in the future.

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

Territory	General Subject Matter	Expiration(1)
U.S.	RANKL antibodies; methods of interfering with RANK signaling	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 the same	11/11/2023
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.

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

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through direct-to-consumer print and television advertising, and also 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, as well as provide support to 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 the government regulation over 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.

We had product sales to three customers each accounting for more than 10% of total revenues for the years ended December 31, 2011, 2010 and 2009. For 2011, on a combined basis, these customers accounted for 72% and 90% 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, 2011, 2010 and 2009, was as follows (dollar amounts in millions):

	2011	2010	2009
AmerisourceBergen Corporation:			
Gross product sales	$ 7,574	$ 7,678	$ 7,179
% of total gross revenues	36%	38%	37%
% of U.S. gross product sales	45%	47%	46%
McKesson Corporation:			
Gross product sales	$ 4,591	$ 3,913	$ 3,694
% of total gross revenues.	22%	19%	19%
% of U.S. gross product sales	27%	24%	24%
Cardinal Health, Inc:			
Gross product sales	$ 3,021	$ 2,813	$ 2,841
% of total gross revenues.	14%	14%	15%
% of U.S. gross product sales	18%	17%	18%

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, recent healthcare reform efforts 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 significant 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 for covered services and products they use by the government through Medicare, Medicaid and other government healthcare programs as well as through private payers. 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.

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Medicare and Other Forms of Public Health Insurance

Medicare is a federal program administered by the federal government that covers individuals age 65 and over 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 statements 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, whose LCD s 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 and Coverage Advisory Committee (MEDCAC) was established to provide independent guidance and expert advice to CMS on specific clinical topics. The MEDCAC reviews and evaluates medical literature, 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 and ESRD. 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 is for 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). In addition, most patients with ESRD, regardless of age, are eligible for coverage of dialysis treatment through the ESRD Program under Medicare Part B. Because Medicare Part B is the primary payer for dialysis treatment, 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 has been reimbursed by Medicare under a bundled payment system described in more detail below. (See Dialysis Reimbursement.)

Medicare Part D. Medicare Part D provides a voluntary prescription drug benefit for Medicare eligible beneficiaries. The coverage is available through various 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.

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 federal government through taxes. Medicaid offers a broad set of benefits, including prescription drugs. Medicaid includes the Drug Rebate Program which requires manufacturers to provide rebates to 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

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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 for all healthcare costs incurred by employees directly through a plan administered by a third party). 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.

Reimbursement of Our Principal Products

Neulasta®, NEUPOGEN® and Aranesp®. 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® and Aranesp® (as well as certain of our other products including Vectibix®, Nplate®, Prolia® and XGEVA®) under Part B, when administered in the physician clinic setting and the hospital outpatient settings. Healthcare providers are reimbursed for these products under a buy and bill process where providers purchase the product in advance of treatment and then submit a reimbursement claim to Medicare following administration of the product. Medicare reimburses providers 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 upon 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 and 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 EPOGEN® and 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.)

Since 2005, products provided in the physician office setting under Medicare Part B have been reimbursed at 106% of their ASP (sometimes referred to as ASP+6%), and in 2012 will continue to be reimbursed at this rate pursuant to the 2012 Medicare Physician Fee Schedule Final Rule. In the hospital outpatient setting, from 2006 to 2010 Medicare reimbursement rates fell incrementally from ASP+6% to ASP+4%, then rose in 2011 to ASP+5%. Pursuant to the 2012 Hospital Outpatient Prospective Payment Final Rule, the rate will fall again to ASP+4% in 2012. CMS has the regulatory authority to further adjust formulas in future years. The extent to which commercial payers adopt the use of ASP as a payment methodology is often based on the contractual relationship between the provider and the insurer.

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%, 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 which provides a single payment for all dialysis services including drugs, supplies and non-routine laboratory tests that were previously 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

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drugs without intravenous equivalents, including Sensipar® and phosphate binders, will remain under the Medicare Part D benefit until 2014 when they will be reimbursed under the bundled payment system.

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 will be subject to a payment penalty of up to 2% of amounts reimbursed for failure to meet or exceed CMS quality performance standards, including performance standards related to anemia management and dialysis adequacy. Under the QIP as originally implemented, a provider s penalty in 2012 will be based on the provider s composite score for the following performance measures achieved during 2010:

- the percent of Medicare patients with Hb levels below 10 g/dL constitutes 50% of the weighting;
- the percent of Medicare patients with Hb levels above 12 g/dL represents 25% of the weighting; and
- the percent of Medicare patients with an average Urea Reduction Ratio of greater than or equal to 65% constitutes 25% of the weighting.

On November 1, 2011, CMS finalized a rule to update the QIP, eliminating 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. Beginning in payment year 2013, the remaining two metrics will each constitute 50% of the weighting. CMS indicated that removal of this measure from the QIP was being done in response to the June 2011 ESA label changes.

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.

Medicaid Reimbursement

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. As more fully described below, the healthcare reform law enacted in the United States in March 2010 made certain changes in how those rebates are calculated and to whom they must be extended. (See U.S. Healthcare Reform.) 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. As described below, 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 a variety of 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. As more fully described below, the list of entities to which we are required to extend these discounts also expanded as a result of the U.S. healthcare reform law.

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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 (the 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 (the 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 new healthcare reform law that are affecting and will affect the reimbursement of our products.

The U.S. healthcare reform law increased the rebates we pay to the states for our products that are covered and reimbursed by state Medicaid programs. The healthcare reform law increased the minimum base Medicaid rebate rate payable on our products reimbursed by Medicaid from 15.1% to 23.1% of the AMP of the product, or if it is greater, the difference between the AMP and the best price available from us to any non-government customer. The change in the minimum rebate percentage was effective on January 1, 2010. The healthcare reform law also extended the Medicaid drug rebate program to patients in Medicaid managed care insurance plans for whom rebates were not previously required. The extension of rebates to patients in Medicaid managed care plans was effective on March 23, 2010.

As mentioned above, the U.S. healthcare reform law also expanded the list of provider institutions to which we must extend discounts under the PHS 340B drug pricing program. The U.S. healthcare reform law added certain cancer centers, children s hospitals, critical access hospitals and rural referral centers to the list of entities to which these discounts must be extended. This change to the list of eligible entities was effective on January 1, 2010. 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 or biologicals licensed under section 351(a) of the Public Health Service Act. Beginning in 2011, the U.S. healthcare reform law sets an aggregate annual fee, to be paid by these manufacturers and importers, totaling $28 billion over 10 years, of which $2.5 billion was payable 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 became effective January 1, 2011, and is not deductible for U.S. federal income tax purposes. Manufacturers and importers of generic or biosimilar drugs are not subject to the fee.

Since the Medicare Part D drug benefit took effect in 2006, beneficiaries enrolled in Part D plans have been required to pay 100% of their prescription drug costs after their total drug spending exceeds an initial coverage limit until they qualify for catastrophic coverage. This coverage gap is sometimes referred to as the Part D

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doughnut hole. The U.S. healthcare reform law reduces the doughnut hole by requiring manufacturers like us to provide a 50% discount to Medicare Part D patients whose prescription expenses exceed the Part D prescription drug coverage limit but have not yet reached the catastrophic coverage threshold. This provision became effective January 1, 2011.

The U.S. healthcare reform law also expands the 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 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, unless a subsequent deficit reduction law was passed before January 2012. As no additional deficit reduction law was enacted by January 2012, the payment reduction (or sequestration) will likely start in January 2013 and continue until December 2021, subject to administrative implementation of the Budget Control Act or future statutory revision. A reduction in the availability or extent of reimbursement from U.S. government programs as a result of the sequestration 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.

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, including as a result of the proliferation of Health Technology Assessment (HTA) organizations (e.g., National Institute for Health and Clinical Excellence (NICE) in the UK) that make 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. 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 the 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 to 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 government-mandated price cuts. In addition, healthcare reform in France, Germany and Spain, as well as austerity plans in a number of countries, including Greece, Italy and Portugal, have targeted the pharmaceutical sector with multiple mechanisms to reduce government healthcare expenditures. Other countries may follow and/or take similar or more extensive actions to reduce expenditures on drugs and biologics, including implementing mandatory price reductions, initiating clawbacks of payments made to companies when national hospital drug spending thresholds are exceeded, establishing preferences for biosimilar products, or reducing the amount of reimbursement. 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.

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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 successfully listed 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 maintain access to innovative therapies while increasing their budget certainty. Requirements for such payment mechanisms can impact Amgen s business through increased net price concessions and added administrative burden.

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 a stable form. 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 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. (See Item 2. Properties.) We perform commercial bulk manufacturing for our proteins except Vectibix®, which is performed by a third-party contract manufacturer. We also supplement commercial bulk manufacturing for ENBREL, Prolia® and XGEVA® 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

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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 certain 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. (See Item 2. Properties.) Clinical bulk and fill manufacturing activities for our clinical product candidate, talimogene laherparepvec, are performed at our Woburn, Massachusetts facility. Certain finish activities for our clinical products are also performed in the Netherlands. In addition, we also utilize third-party contract manufacturers for certain of our 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 and California, and in 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:

- Construction of a new formulation and fill facility at our Puerto Rico site;
- Expansion of our bulk protein facilities at our Puerto Rico site;
- Modification and expansion of our recently acquired formulation, fill and finish site in Ireland; and
- Expansion of our Colorado and Rhode Island facilities to enable manufacturing of certain clinical products as well as to provide alternative bulk manufacturing sources for certain marketed 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 source for such materials. Also,

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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 source. 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, 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. (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 Federal Food, Drug and Cosmetic Act (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 takes a number of years and involves 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

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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 is substantial and may vary by product. For example, the clinical trials for the BLA for Prolia®/XGEVA® were large and required substantial time and resources to recruit patients and significant expense to execute. Historically, our products have required smaller, shorter trials. 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. The 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 different doses or schedules of administration that were 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, under the Food and Drug Administration Amendments Act of 2007 (the FDAAA), 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 FDAAA also gave the FDA authority to require companies to implement a REMS for a product to ensure that the benefits of the drugs outweigh the risks. While risk management activities and programs are not new, with FDAAA the FDA gained new authority to implement specific risk management requirements and new enforcement power to ensure that the goals of the REMS are being met. The FDA began to implement REMS in 2008. 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 including:

- estimated size of the population likely to use the product;
- seriousness of the condition treated and expected benefits of the product;

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duration of treatment with the product;

seriousness of known or potential adverse events associated with the product; and

whether the product is a new molecular entity.

All REMS are required to have a timetable for assessment and may have one or more of the following:

distribution of a medication guide or a patient package insert to patients;

communication plan for the healthcare provider or institution, such as a Dear Healthcare Professional Letter;

elements to assure safe use including, but not limited to:

- specific training, experience or certification for prescribers;
- certification of medication dispensing sites and dispensing in limited settings;
- monitoring of specific patients; and
- enrollment of patients in a registry.

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®. As REMS are relatively new, 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.

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, 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 ODAC, 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 Biosimilar Products. The U.S. healthcare reform law authorizes the FDA to approve biosimilar products under a separate, abbreviated pathway. The new 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 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. On February 9, 2012, the FDA released three draft guidance documents as part of the implementation of the abbreviated approval pathway for biosimilar products. While FDA guidance documents are not legally binding on the public or on the FDA, they indicate the FDA s views on a subject. The draft guidance documents provide insight to the FDA s current thinking on the development of biosimilar products and address 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 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

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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, including criteria for interchangeability (which FDA indicated would be higher standard than biosimilarity). The FDA will accept public comments on the guidance documents for 60 days, following which it may issue final guidance. The FDA has also stated publicly that it intends to hold a follow-up public meeting in the near future to obtain feedback on what additional clarification on the biosimilars approval process is needed.

FDA Regulation of Product Marketing and Promotion. The FDA closely reviews and regulates the marketing and promotion of products. We are required to obtain 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 a product. 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.

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 European Medicines Agency (EMA) who 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, biosimilar products have been approved under a sub-pathway of the centralized procedure since 2006. The pathway allows sponsors of a biosimilar product to seek and obtain regulatory approval based in part on the clinical trial data of an originator product to which the biosimilar product has been demonstrated to be similar. In many cases, this allows biosimilar products 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 responsibilities for the detection, assessment and prevention of adverse effects and other medicine-related problems in a process known as pharmacovigilance. Healthcare professionals and patients are also encouraged to

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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.

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 wherever 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), 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). If the government were to allege against or convict us of violating those laws or if we entered into a settlement with the government, there could be a material adverse effect on our business, including our stock price. 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

Our vision is to deliver therapeutics that can make a meaningful difference in patients lives. Therefore, 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 that is, we identify targets, and then choose the modality best suited to address a specific target. As such, our discovery research programs may yield targets that lead to the development of human therapeutics delivered as large molecules (such as proteins, antibodies and peptibodies) or small molecules.

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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. 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 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 upon the timing of entry into the market. Early entry may have important advantages in gaining product acceptance, 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 is expected to 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. These 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 governmental agencies conduct a significant amount of R&D in the biotechnology industry. We face competition in pursuing R&D arrangements and licensing or acquisition activities from other pharmaceutical and biotechnology companies that also seek to license or acquire technologies, product candidates or marketed products from these 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 the government regulation over clinical development.

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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 10, 2012, unless otherwise indicated. Each target indication for 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.)

Molecule	Disease/Condition	Therapeutic Area
Phase 3 Programs		
AMG 386	Ovarian cancer	Hematology/Oncology
Aranesp® (darbepoetin alfa)	Myelodysplastic syndromes	Hematology/Oncology
Aranesp® (darbepoetin alfa)	Anemia in heart failure	Nephrology
Ganitumab	Pancreatic cancer	Hematology/Oncology
Motesanib	First-line non-small cell lung cancer	Hematology/Oncology
Prolia® (denosumab)	Male osteoporosis	Bone Health
Sensipar®/Mimpara® (cinacalcet)	Cardiovascular disease in patients with secondary hyperparathyroidism and chronic kidney disease undergoing maintenance dialysis	Nephrology
Sensipar®/Mimpara® (cinacalcet)	Post renal transplant	Nephrology
Talimogene laherparepvec	Malignant melanoma	Hematology/ Oncology
Vectibix® (panitumumab) US Only	First- and second-line colorectal cancer	Hematology/Oncology
XGEVA® (denosumab)	Delay or prevention of bone metastases in prostate cancer	Hematology/Oncology
XGEVA® (denosumab)	Delay or prevention of bone metastases in breast cancer	Hematology/Oncology
Phase 2 Programs		
AMG 145	Hypercholesterolemia	Cardiovascular
AMG 151	Type 2 diabetes	General Medicine
AMG 386	Various cancer types	Hematology/Oncology
AMG 785	Bone-related conditions, including postmenopausal osteoporosis and fracture healing	Bone Health
AMG 827	Inflammatory diseases	Inflammation
AMG 888	Various cancer types	Hematology/Oncology
Prolia® (denosumab)	Rheumatoid arthritis	Inflammation
Ganitumab	Various cancer types	Hematology/Oncology
Nplate® (romiplostim)	Chemotherapy-induced thrombocytopenia	Hematology/Oncology
Omecamtiv mecarbil	Heart failure	Cardiovascular
Rilotumumab	Various cancer types	Hematology/Oncology
Vectibix® (panitumumab)	Locally advanced head and neck cancer	Hematology/Oncology
XGEVA® (denosumab)	Giant cell tumor of the bone	Hematology/Oncology
Phase 1 Programs		
AMG 139	Inflammatory diseases	Inflammation
AMG 157	Asthma	Inflammation
AMG 167	Bone-related conditions	Bone Health
AMG 181	Inflammatory diseases	Inflammation
AMG 208	Various cancer types	Hematology/Oncology
AMG 319	Hematologic malignancies	Hematology/Oncology
AMG 337	Various cancer types	Hematology/Oncology
AMG 557	Systemic lupus erythematosus	Inflammation
AMG 579	Neuroscience	General Medicine
AMG 729	Autoimmune diseases	Inflammation
AMG 745	Muscle-wasting disorders	General Medicine
AMG 747	Neuroscience	General Medicine
AMG 761	Asthma	Inflammation
AMG 780	Various cancer types	Hematology/Oncology
AMG 811	Systemic lupus erythematosus	Inflammation
AMG 820	Various cancer types	Hematology/Oncology
AMG 876	Type 2 diabetes	General Medicine
AMG 900	Various cancer types	Hematology/Oncology

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.

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

AMG 386

AMG 386 is a peptibody that inhibits the interaction between the endothelial cell-selective Tie2 receptor and its ligands Ang1and Ang2. It is being investigated as a cancer treatment.

In 2011, we announced that enrollment was suspended in the phase 3 study in recurrent ovarian cancer due to DOXIL® (doxorubicin HCl liposome injection) supply issues. We initiated a second phase 3 study in recurrent ovarian cancer in 2011. We initiated a phase 3 study for the treatment of first-line ovarian cancer and plan to initiate other phase 2 studies for the treatment of NSCLC and breast cancer in 2012. Phase 2 studies of AMG 386 for treatment of renal cell carcicoma and hepatocellular carcinoma are ongoing.

Aranesp® (darbepoetin alfa)

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

The RED-HF® trial phase 3 study, initiated in 2006, is a large (2,600 subjects planned), global, randomized, double-blind, placebo-controlled study to evaluate the effect of treatment of anemia with darbepoetin alfa on morbidity and mortality in patients with symptomatic left ventricular heart failure. The RED-HF® trial continues to enroll subjects and we anticipate data from the study in 2013. In 2011, we initiated a phase 3 study of Aranesp® for the treatment of low risk myelodysplastic syndromes.

Ganitumab (AMG 479)

Ganitumab is a fully human monoclonal antibody antagonist of IGF-1 receptor. It is being investigated as a cancer treatment.

In 2011, we initiated a phase 3 study for the treatment of first-line metastatic pancreatic cancer.

A phase 2 study for the treatment of small cell lung cancer is ongoing.

Motesanib

Motesanib is an orally-administered small molecule antagonist of vascular endothelial growth factor receptors 1, 2 and 3, platelet-derived growth factor receptors and stem cell factor receptor. It is being investigated as a cancer treatment. We are developing this product in collaboration with Takeda and Millennium Pharmaceuticals: The Takeda Oncology Company (Millennium).

In March 2011, we along with Takeda and Millennium announced top-line results from the MONET1 pivotal phase 3 trial evaluating motesanib administered in combination with paclitaxel and carboplatin in 1,090 patients with advanced non-squamous NSCLC. The trial did not meet its primary objective of demonstrating an improvement in overall survival (hazard ratio 0.90, 95% confidence interval 0.78 1.04, p=0.14). Detailed results were also presented at a medical meeting in May 2011. The parties continue to further analyze the data to explore potential opportunities for additional development in first-line NSCLC.

Denosumab

Denosumab is a fully 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. Denosumab is being studied across a range of conditions including osteoporosis, treatment-induced bone loss, rheumatoid arthritis and numerous tumor types across the spectrum of cancer-related bone diseases.

Prolia® (denosumab)

The phase 3 study evaluating Prolia® patients with male osteoporosis was completed and based on the results we announced on November 21, 2011, an sBLA was filed with the FDA for the indication to increase

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bone mass in men with osteoporosis at high risk for fracture. We also plan to initiate a phase 3 study of Prolia® for the treatment of Glucocorticoid-Induced Osteoporosis in 2012.

XGEVA® (denosumab)

In April 2011, we announced that we plan to file for the treatment of giant cell tumor of the bone. On June 27, 2011, we announced the submission of an sBLA to the FDA to expand the indication for XGEVA® to treat men with castration-resistant prostate cancer to reduce the risk of developing bone metastases. On February 8, 2012, the FDA convened the ODAC to discuss the sBLA filing. The ODAC panel voted 12 to 1 that the overall magnitude of benefit demonstrated with early treatment with XGEVA® to delay bone metastases was not sufficient to conclude a positive risk-benefit ratio in the absence of additional measures impacting quality of life or other disease outcomes. The FDA has targeted a PDUFA action date of April 26, 2012. A phase 3 study for the delay or prevention of bone metastases in patients with adjuvant breast cancer is ongoing. We are planning an additional phase 3 SRE study in patients with multiple myeloma.

Sensipar®/Mimpara® (cinacalcet)

Sensipar®/Mimpara® is an orally-administered small molecule that lowers PTH levels in blood by signaling through the calcium-sensing receptor in parathyroid tissue to inhibit PTH secretion. It also lowers blood calcium and phosphorous levels.

The phase 3 E.V.O.L.V.E trial, initiated in 2006, is a large (3,800 patient), multi-center, international, randomized, double-blind study to assess the effects of Sensipar®/Mimpara® on mortality and cardiovascular morbidity in patients with CKD undergoing maintenance dialysis. The E.V.O.L.V.E study completed enrollment in January 2008 and we anticipate data from the study in 2012.

Sensipar®/Mimpara ® is also being evaluated in post renal transplant patients.

Talimogene laherparepvec (formerly known as OncoVEX^{GM-CSF})

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

On March 4, 2011, we acquired BioVex, a privately held biotechnology company developing treatments for cancer and the prevention of infectious disease, including talimogene laherparepvec, then in phase 3 clinical development for the treatment of malignant melanoma and head and neck cancer. On July 29, 2011, we announced our decision to terminate the phase 3 trial in patients with head and neck cancer. The phase 3 study for the treatment of malignant melanoma is ongoing.

Vectibix® (panitumumab)

Vectibix® is a 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. A phase 2 study for the treatment of locally advanced head and neck cancer is ongoing.

AMG 145

AMG 145 is a fully human monoclonal antibody to Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9), a negative regulator of low-density lipoprotein receptor. AMG 145 is being investigated for the treatment of hypercholesterolemia.

Phase 1 single and multiple ascending dose studies have been completed. Results of the phase 1 single dose study were presented at a medical conference in November 2011. In 2011, phase 2 studies of AMG 145 for the treatment of hypercholesterolemia were initiated.

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AMG 151

AMG 151 is an orally-administered small molecule glucokinase activator. It reduces glucose levels via a dual mechanism of action working in both the pancreas and the liver. It is being investigated as a treatment of type 2 diabetes.

In 2011 we initiated a phase 2 study of AMG 151 for the treatment of type 2 diabetes.

AMG 785

AMG 785 is a humanized monoclonal antibody that targets sclerostin, a protein secreted by bone cells that inhibits bone formation. AMG 785 (also known as CDP7851) is being developed in collaboration with UCB for bone-related conditions, including postmenopausal osteoporosis and fracture healing.

In April 2011, we announced top-line results from the phase 2 clinical study comparing sclerostin-antibody AMG 785 to placebo in postmenopausal women with low bone mineral density BMD for the treatment of PMO. We plan to initiate phase 3 studies for the treatment of PMO in 2012. Phase 2 studies of AMG 785 for the treatment of fracture healing are ongoing.

AMG 827

AMG 827 is a human monoclonal antibody that binds to and blocks signaling via the interleukin-17 receptor. It is being investigated as a treatment for a variety of inflammatory diseases.

We reported the results from the phase 2 psoriasis study at a medical meeting in May 2011. Based on the study results, we plan to initiate phase 3 studies for the treatment of psoriasis in 2012. In 2011, we announced that following the review of the results, we have elected to discontinue our phase 2 studies for the treatment of RA and Crohn s disease. In October 2011, we initiated a phase 2 study for the treatment for psoriatic arthritis. A phase 2 study of AMG 827 for the treatment of asthma is ongoing.

AMG 888

AMG 888 is a fully human monoclonal antibody that inhibits human epidermal growth factor receptor 3 (HER3) oncogenic signaling. AMG 888 is being investigated as a cancer treatment. Amgen is developing this product in collaboration with Daiichi Sankyo.

Daiichi Sankyo initiated a phase 1b/2 study of AMG 888 (U3-1287) in advanced NSCLC in 2010, a phase 1b study in Japan in 2nd line NSCLC in 2011, and a phase 1b/2 study in metastatic breast cancer in 2012.

Nplate® (romiplostim)

Nplate® is a peptibody agonist of the TPO receptor.

Nplate® is being evaluated in chemotherapy-induced thrombocytopenia.

Omecamtiv mecarbil

Omecamtiv mecarbil is a small molecule activator of cardiac myosin. Omecamtiv mecarbil is being investigated to improve cardiac contractility in subjects with heart failure. We are developing this product in collaboration with Cytokinetics, Inc.

In 2011, we initiated a phase 2 study for the treatment of heart failure in patients with left ventricular systolic dysfunction who are hospitalized for acute heart failure.

Rilotumumab (AMG 102)

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

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Results from a phase 2 study in gastric cancer in combination with chemotherapy were reported at a meeting in September 2011. Phase 2 combination studies in the prostate and small cell lung cancer settings continue.

As of February 9, 2011, we had nine phase 3 programs. As of February 10, 2012, we had twelve phase 3 programs, as one was added as the result of our BioVex acquisition and two programs had advanced into phase 3 trials. These changes are set forth in the following table:

Molecule	Disease / Condition	Program Change
Talimogene laherparepvec	Malignant melanoma	Added through acquisition of BioVex
Sensipar®/ Mimpara® (cinacalcet)	Post Renal Transplant	Advanced to Phase 3
Aranesp® (darbepoetin alfa)	Myelodysplastic syndromes	Advanced to Phase 3

Phase 3 Product Candidate Patent Information

Our outstanding patents for each of our product candidates in phase 3 development that have yet to be approved for any indication are described in the following table. 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 386	U.S.	DNA, polypeptides and compositions	2025
	Europe	DNA, polypeptides, compositions and method of treatment	2019-2022
Ganitumab	U.S.	Antibodies and compositions	2029
Motesanib	U.S.	Motesanib and compositions	2022
	Europe	Motesanib, compositions and use for treatment of cancer	2022
Talimogene laherparepvec	U.S.	Modified HSV1 compounds and strains and methods of treatment using modified HSV1 strains	2021
	Europe	Modified HSV1 compounds and strains and methods of treatment using modified HSV1 strains	2021

* Patent expiration ranges for each region are based on one or more issued patents, some of which may be or become eligible for term adjustments, extensions or supplemental protection certificates not captured in this estimate. In addition, new patents may be issued in the future, and existing patents may be challenged, invalidated or circumvented by third parties.

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, regulatory and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. The activities under our collaboration agreements are performed with no guarantee of either technological or commercial success, and each is unique in nature.

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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 Kirin and Amgen.

K-A has given us exclusive licenses to manufacture and market: (i) G-CSF and pegfilgrastim in the United States, Europe, Canada, Australia and New Zealand, (ii) darbepoetin alfa, romiplostim and AMG 827 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. AMG 827 is currently in phase 2 development. 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 AMG 827 in Japan, China, Taiwan, South Korea and in certain other countries 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, darbepoetin alfa, romiplostim and recombinant human erythropoietin under the brand names GRAN®/Grasin®/Filgrastim®, NESP®, ROMIPLATE® and ESPO®, respectively. Kirin received approval for pegfilgrastim in Taiwan in September 2011 under the brand name Neulasta®. Kirin is currently in the process of seeking marketing approval for pegfilgrastim in South Korea. 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 of 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 agreement in the fourth quarter of 2013, we will be required to pay Pfizer 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.

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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. In the future, 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

We are in a collaboration with Takeda, which provides Takeda 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 for the worldwide development and commercialization of our product candidate, motesanib, in the oncology area. The Japanese market products include: (i) Vectibix®, which received regulatory approval in Japan, in 2010, for unresectable, advanced or recurrent colorectal cancer with wild-type *KRAS*, (ii) AMG 386, which is in a phase 3 trial for recurrent ovarian cancer, and (iii) ganitumab (AMG 479), which is in a phase 3 trial for first-line metastatic pancreatic cancer. Through collaboration committees, the parties jointly coordinate and oversee Takeda s development and commercialization of the Japanese market products in Japan. The parties share responsibility for the development of motesanib outside Japan and Takeda is responsible for development in Japan. Additionally, Amgen shall be responsible for commercialization of motesanib in North America and Takeda shall be responsible for commercialization outside of North America. Each party has the right to participate in the commercialization of motesanib in the other party s territory. In addition, under the collaboration Amgen will manufacture and supply Takeda motesanib and the Japanese market products for both clinical and commercial purposes. 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.

Daiichi Sankyo Company, Limited

We are in a collaboration with Daiichi Sankyo, which provides Daiichi Sankyo the exclusive rights to develop and commercialize denosumab in Japan for osteoporosis, oncology and certain other indications. As part of the agreement, Amgen received exclusive worldwide rights to certain Daiichi Sankyo intellectual property to the extent applicable to denosumab. Through collaboration committees, the parties jointly coordinate and oversee Daiichi Sankyo s development and commercialization of denosumab in Japan.

DaVita Inc.

In November 2011, we entered into a seven-year supply agreement with DaVita, commencing 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.

Fresenius Medical Care North America

In October 2011, the five-year supply agreement for ESAs with Fresenius Medical Care North America expired. Effective January 1, 2012, we entered into a three-year non-exclusive supply agreement with them to supply EPOGEN®.

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Human Resources

As of December 31, 2011, Amgen had approximately 17,800 staff members, which includes approximately 300 part-time staff members. There can be no assurance that we will be able to continue attracting and retaining qualified personnel in sufficient numbers to meet our needs. None of our staff members are covered by a collective bargaining agreement, and we have experienced no work stoppages. We consider our staff relations to be good.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require our staff members, material consultants and scientific advisors to execute confidentiality agreements upon commencement of employment or a consulting relationship with us. However, others could either develop independently the same or similar information or obtain access to our information.

Executive Officers of the Registrant

The executive officers of the Company as of February 13, 2012, are as follows:

Mr. Kevin W. Sharer, age 63, has served as a director of the Company since November 1992. Mr. Sharer has been the Company s Chief Executive Officer since May 2000 and has also been Chairman of the Board of Directors since January 2001. Effective as of May 23, 2012, Mr. Sharer will step down as CEO of the Company. Mr. Sharer will remain as Chairman of the Board of Directors until December 31, 2012, at which time he will retire from the Board and the Company. From May 2000 to May 2010, Mr. Sharer served as the Company s President and Chief Operating Officer. From October 1992 to May 2000, Mr. Sharer served as President and Chief Operating Officer of the Company. From April 1989 to October 1992, Mr. Sharer was President of the Business Markets Division of MCI Communications Corporation. From February 1984 to March 1989, Mr. Sharer held numerous executive capacities at General Electric Company (GE). Mr. Sharer is a director of Chevron Corporation and Northrop Grumman Corporation. He is Chairman of the Board of the Los Angeles County Museum of Natural History.

Mr. David W. Beier, age 63, became Senior Vice President, Global Government and Corporate Affairs in March 2008. He joined the Company in 2003 as Senior Vice President, Global Government Affairs. Previously, Mr. Beier was a partner with the law firm of Hogan and Hartson in Washington, D.C. From 1998 to early 2001, Mr. Beier served as Chief Domestic Policy Advisor to the Vice President of the United States. He also held positions as Vice President of Government Affairs and Public Policy for Genentech and staff counsel in the U.S. House of Representatives.

Dr. Fabrizio Bonanni, age 65, became Executive Vice President, Operations in August 2007. He served as Senior Vice President, Manufacturing of the Company from 2004 to August 2007. Dr. Bonanni joined the Company in 1999 as Senior Vice President, Quality and Compliance, and in June 2001, he also became the Corporate Compliance Officer. Previously, Dr. Bonanni held various management positions at Baxter International, Inc. from 1974 to 1999, including positions as Corporate Vice President, Regulatory and Clinical Affairs and Corporate Vice President, Quality System.

Mr. Robert A. Bradway, age 49, has served as a director of the Company since October 2011. Mr. Bradway has been the Company s President and Chief Operating Officer since May 2010 and will succeed to the role of Chief Executive Officer in May 2012. 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.

Dr. Sean E. Harper, age 49, 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

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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 57, 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 this, 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 55, 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.

Mr. Jonathan M. Peacock, age 53, became Executive Vice President and Chief Financial Officer in September 2010. Prior to joining Amgen, Mr. Peacock served as Chief Financial and Administration Officer of Novartis Pharmaceuticals AG, a healthcare company based in Switzerland, beginning in 2005. From 1998 to 2005, Mr. Peacock was a partner at McKinsey and Co., where he co-led the European Corporate Finance Practice. Mr. Peacock was also a partner at Price Waterhouse in London and New York from 1993 to 1998.

Ms. Anna S. Richo, age 51, became Senior Vice President and Chief Compliance Officer in June 2008. From December 2003 to June 2008, Ms. Richo served as Vice President, Law. Prior to Amgen, she spent 12 years at Baxter Healthcare Corporation in roles of increasing responsibility in law, including Vice President, Law, for Baxter s BioScience Division. Also, for more than five years, Ms. Richo served on the Board of Directors of Cytyc Corporation and was a member of the Audit and Finance Committees.

Mr. David J. Scott, age 59, 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, D.C. 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 1-800-SEC-0330.

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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 of our products. 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, signed into law in the United States in August 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, unless a subsequent deficit reduction law was passed before January 2012. As no additional deficit reduction law was enacted by January 2012, the payment sequestration will likely start in January 2013 and continue until December 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 from U.S. government 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

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reimbursement 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. We also face certain risks relating to the calculation of ASP. ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. However, the statute, regulations and CMS guidance do not define specific methodologies for all aspects of the calculation of ASP. For example, in the Medicare Physician Fee Schedule Final Rule for 2012, CMS did not address a proposed methodology for treatment of bundled price concessions. Consequently, the current CMS guidance is that manufacturers may make reasonable assumptions in their calculation of ASP consistent with the general requirements and the intent of the Medicare statute, federal regulations and their customary business practices. As a result, we are required to apply our judgment in certain aspects of calculating ASP which are disclosed to CMS and also are subject to further CMS review. If our calculation of ASP is incorrect, we could be subject to substantial fines and penalties which could have a material adverse impact on our business and results of operations. Additionally, we are required to pay rebates to the federal government on products reimbursed by Medicaid at a rate of 23.1% of the AMP of a product, or if it is greater, the difference between the AMP and the best price available to any non-government customer. The PPACA changed the definition of AMP, and in January 2012 CMS issued a proposed rule further defining the new AMP definition. Until that rule is final, we will be required to apply our reasonable judgment in certain aspects of the AMP calculation. Once this CMS rule has been finalized, we will have to determine whether our interpretation of AMP follows the rule or if our calculations will need to be amended and this 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 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, and that it would instead monitor the use of ESAs through the ESRD bundled payment system and its other policy avenues. In the absence of an NCD, Medicare determinations are made by the eleven regional MACs, one of which has already issued a final LCD relating to anemia in patients with CKD not on dialysis, and two more MACs have issued draft LCDs in this setting. All three final or draft LCDs would 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 propose an NCD and/or further review or change the reimbursement of ESAs in the nephrology setting at some point in the future. CMS has also previously identified a list of potential future NCDs that includes the category of thrombopoiesis stimulating agents (platelet growth factors), the category of drugs that includes Nplate®, and a discussion on bisphosphonates used to treat osteoporosis. CMS has not announced whether it will proceed with an NCA related to thrombopoiesis stimulating agents and, while

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Prolia® and XGEVA® are not bisphosphonates, there is the possibility that CMS might evaluate other agents, including RANK Ligand inhibitors such as Prolia® and XGEVA®.

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 a 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.

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 reductions continue to be a significant aspect of business for the pharmaceutical and biotechnology industries outside of the United States. Healthcare reform in France, Germany and Spain, as well as austerity plans in a number of countries, including Italy, Greece and Portugal, have targeted the pharmaceutical sector with multiple mechanisms to reduce government 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 national hospital drug spending thresholds are exceeded, preferences for biosimilar products, changes in international price referencing and transparency to achieve prices similar to that in lower-priced countries, and reductions in the amount of reimbursement. 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. The proliferation of HTA organizations (e.g., NICE in the UK) 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 of 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 operation.

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

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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, 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 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. Current policy discussions underway in the United States include debates about the implementation of the new, abbreviated pathway for biosimilars established under the healthcare reform law; renegotiation of the PDUFA, which governs the user fees pharmaceutical and biological companies pay to the FDA that provide a substantial portion of the FDA s operating budget, in anticipation of re-authorization before September 30, 2012; and reforms to the regulations that govern diagnostics and medical devices which are sometimes used in conjunction with our products. We are unable to predict when and whether any changes to laws or regulatory policies affecting our business could occur, and 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 and background adverse event rates to inform the methodology 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.

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, 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

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used endpoints other than overall survival, such as progression-free survival and bone-metastasis-free survival (BMFS), in the clinical trial data submitted for agency review or in clinical trials now being conducted. 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. On February 8, 2012, the FDA convened the ODAC to discuss our sBLA filing for XGEVA® to delay bone metastases in prostate cancer and the data from Study 147 submitted to support the filing. 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. Further, some of our products or product candidates may be used with a companion diagnostic product, such as a test kit, or companion device, such as an injector or other delivery system. These product candidates or expanded indications of our products may not be approved if the companion diagnostic product or companion device does not gain or maintain regulatory approval. These companion diagnostics and 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 in conducting the studies required for such approval by the applicable regulatory agencies. Delays in the studies or failure of the third-party company to obtain regulatory approval of the companion diagnostic or device could negatively impact the approval of our product candidate or the expanded indication of our product and we may incur increased development costs, delays in regulatory approval and/or associated delays in a product candidate reaching the market or the expansion of existing product labels for new indications.

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 pre-clinical 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. 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;

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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. (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, and/or;

increased timelines or delays in being approved by the FDA or other regulatory bodies; and

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

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. 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.

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Further, if new medical data or product quality issues suggest an unacceptable 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 other parties (including our independent clinical trial investigators or our licensees, such as J&J, Pfizer, Glaxo, Takeda and Daiichi Sankyo) 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 could materially and adversely affect the sales of our products, our business and results of operations.

Current 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 biosimilar products, higher hurdles for initial reimbursement approval for new products or other similar measures. (See We expect to face increasing competition from biosimilar products which could impact our profitability.) Additionally, as a result of the current 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 biosimilar products 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 downturn, 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

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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 like Greece, which is facing possible default of its sovereign debt obligations, and Spain, France and Italy, whose sovereign debt obligations were recently downgraded. 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. (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.

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, the FDA has reviewed and continues to review the benefit-risk profile of ESAs, which has resulted in and could result in future changes to ESA labeling and usage. For example, in August 2008, we revised the labeling for our ESAs as the FDA directed. In addition, in July 2007 CMS issued an NCD for non-renal ESAs that determined that ESA treatment was not reasonable and necessary for certain clinical conditions, and established Medicare coverage parameters for FDA-approved ESA use in oncology. Since these labeling and reimbursement changes, we experienced a substantial reduction in our ESA sales, in particular Aranesp sales in the U.S. supportive cancer care setting. U.S. regulators have also reviewed the use of ESAs in the nephrology setting. In October 2009, the results from TREAT, a phase 3 pivotal study of patients with CKD not on dialysis were published in the New England Journal of Medicine. The study failed to meet its primary objectives of demonstrating a reduction in all-cause mortality, cardiovascular morbidity, including heart failure, heart attack, stroke or hospitalization for myocardial ischemia, or time to ESRD. On December 16, 2009, based on the 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. And in June 2011, we announced that the FDA approved further changes to the labels for the use of ESAs, including Aranesp® and EPOGEN®, in patients with CKD. Over the past several years, CMS has also reviewed the use of ESAs and has considered and incorporated significant changes in the ways ESAs are reimbursed in the nephrology setting, including the implementation of the ESRD bundled payment system, subsequent changes to

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the QIP and consideration of a possible NCD to manage anemia in patients with CKD and dialysis-related anemia. Further restrictions are possible as the regional MACs implement LCDs to address Medicare coverage for ESAs in CKD not on dialysis within their respective geographic areas, and such restrictions could have a material adverse effect on the reimbursement, use and sales of Aranesp®. (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. We do not know what effect, if any, the June 2011 ESA label changes will have on the final version of the Kidney Disease: Improving Global Outcomes group (KDIGO) global anemia clinical practice guidelines which KDIGO has indicated could be available by early 2012. (See Guidelines and recommendations published by various organizations can reduce the use of our products.)

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 part of that pharmacovigilance program, four are complete, and the results of certain of those studies contributed to safety-related product labeling changes for our ESAs and changes in reimbursement, as noted above. The remaining study, the LNH03-6B Study, is being conducted by the Groupe d Etudes des Lymphomes de l Adulte, which presented second interim analysis results at the annual meeting of the American Society of Clinical Oncology in June 2011, and is currently estimated to be completed in 2012. 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 are in ongoing discussions with the FDA regarding additional PMRs to explore alternative ESA dosing strategies in CKD patients on dialysis and not 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. The product information for all ESAs was updated to advise that, in some clinical situations, blood transfusions should be the preferred treatment for the management of anemia in patients with cancer and that the decision to administer ESAs should be based on a benefit-risk assessment with the participation of the individual patient. 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, 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 is anticipated in 2012. Unfavorable results from these or similar trials or meta-analyses

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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. 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 research and development 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.

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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 have 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 biosimilar products.

We currently face competition in Europe from biosimilar products, 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 has already created 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.

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 final regulatory guidelines related to the development and approval of biosimilar products. The final guidelines included clinical trial guidance for certain biosimilar products, including erythropoietins and G-CSFs, recommending that applicants seeking approval of such biosimilar products conduct pharmacodynamic, toxicological and clinical safety studies as well as a pharmacovigilance program. In late 2011, the EMA

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announced plans to issue in the first half of 2012 final guidelines on the approval process for biosimilar monoclonal antibodies and draft guidelines on the approval process for other biosimilar drugs. 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 biosimilar products 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 biosimilar products compete with NEUPOGEN® and Neulasta®. Further, as in an effort to reduce costs, countries in the EU may in the future permit the automatic substitution by pharmacists of biosimilars for the corresponding innovator products or adopt other biosimilar uptake measures. We cannot predict to what extent the entry of biosimilar products 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.

On March 23, 2010, President Obama signed into law the PPACA which authorized the FDA to approve biosimilar products under a separate, abbreviated pathway. 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 biosimilar products 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 product will depend on a variety of factors, including the complexity of the protein, the sophistication of the manufacturing required 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 quickly 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 includes 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 recent guidelines will contribute to that impact, we expect in the future to face greater competition in the United States as a result of biosimilar products 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.

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;

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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;

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.

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 biosimilar products. These companies may have greater resources than we do. In addition, some of our competitors may have technical or competitive advantages over us for the development of technologies and processes. These resources 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, equivalent or superior performance, better safety profile, are easier to administer 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. In addition, 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

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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, in the notes to our consolidated financial statements in our annual report.) 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. Beginning in 2007, we received a number of subpoenas from various government entities, including the U.S. Attorney s Offices for the Eastern District of New York and the Western District of Washington, as well as the Attorneys General of New York and New Jersey. The federal subpoenas were issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (18 U.S.C. 3486), and by a federal grand jury, while the Attorneys General subpoenas were issued pursuant to state specific statutes relating to consumer fraud laws and state false claims acts. In general, the subpoenas requested documents relating to the sales and marketing of our products, and our collection and dissemination of information reflecting clinical research as to the safety and efficacy of our ESAs. Based on representations in a U.S. government filing that became public in May 2009 relating to the Massachusetts Qui Tam Action (as defined in Note 18, Contingencies and commitments in the notes to our consolidated financial statements) and subsequent conversations with government prosecutors, we learned that the subpoenas we received from the U.S. Attorney s Offices for the Eastern District of New York and the Western District of Washington relate to the Massachusetts Qui Tam Action and nine additional Qui Tam Actions (as defined in Note 18, Contingencies and commitments in the notes to our consolidated financial statements) pending against us in various federal jurisdictions. In October 2011 we announced that we had reached an agreement in principle to settle the allegations regarding our sales and marketing practices arising out of the 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 proposed settlement involves numerous state and federal agencies and remains subject to continuing discussions regarding the components of the agreement, and the completion and execution of all required documentation. Until the proposed settlement becomes final, there can be no guarantee that these matters will be resolved by the agreement in principle. If the proposed settlement is not finalized as proposed, we would have to continue to explain and defend our actions to government entities involved, which would be burdensome, expensive and time-consuming for us and could result in criminal charges, civil penalties or other enforcement actions. In addition, while the agreement in principle includes the dismissal of the claims of the government in the Qui Tam Actions, the individual relators in the Qui Tam Actions have the opportunity to join in the proposed settlement or, if they object, to have the settlement evaluated in a federal court fairness hearing to determine whether it is fair, adequate and reasonable under all the circumstances. If the court determines that the settlement is not fair, adequate and reasonable, then we would have the option to continue to defend our actions in court, or to seek to negotiate a new settlement. We have been made aware that we are also a defendant in several other civil qui tam actions that remain under seal in the U.S. federal courts where they were filed. Included with these actions are allegations that our promotional, contracting, sales and marketing activities relating to ENBREL and Aranesp® caused the submission of various false claims under the Federal Civil False Claims Act and various State False Claims Acts. Certain of the allegations in these other actions are not encompassed in the proposed settlement discussed above. In addition, as described in Note 18, Contingencies and commitments in the notes to our consolidated financial statements, this proposed settlement does not cover a number of other litigation matters that will continue to be pending against us.

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Throughout these investigations, the government entities are asserting that we violated various state and federal laws. These investigations are very burdensome, expensive and time-consuming for us to explain and defend to these entities. Although we cannot predict whether additional proceedings may be initiated against us, or predict when these matters may be resolved, it is not unusual for investigations such as these to continue for a considerable period of time and to require management s attention and significant legal expense. A determination that we are in violation of the various federal and state laws that govern the sales and marketing of our products could result in federal criminal liability and/or federal or state civil or administrative liability, and thus could result in substantial financial damages or criminal penalties and possible exclusion from future participation in the Medicare and Medicaid programs. In addition, 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

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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 manufacture 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 maintain supply and to satisfy anticipated future demand for denosumab, we are qualifying the expansion of our existing bulk protein facilities at our Puerto Rico site. In addition, in order 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 are modifying

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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® and the purification of bulk EPOGEN® material at this facility, and plan to perform substantially all of the bulk manufacturing for Prolia® and XGEVA® at the Puerto Rico facility once the facility has been approved by the FDA for that purpose. 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

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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 Food, Drug and Cosmetic Act 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 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, many 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,

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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, while we do not expect biosimilars competition on ENBREL in the United States for the foreseeable future, 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 will go into 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 not be able 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,

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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 2007, the National Kidney Foundation (NKF) distributed to the nephrology community final updated Kidney Disease Outcomes Quality Initiative (KDOQI) clinical practice guidelines and clinical practice recommendations for anemia in CKD. The NKF-KDOQI Anemia Work Group recommended in its 2007 Update to the NKF-KDOQI Anemia Management Guidelines that physicians target Hb in the range of 11 g/dL to 12 g/dL, and also stipulated that the target not be above 13 g/dL.

In December 2008, the KDIGO, a not-for-profit foundation managed by NKF, announced that it was developing a new global anemia guideline. The announcement stated that an updated anemia guideline is necessary in light of new study results, particularly the data from the TREAT trial, which had become available since the NKF-KDOQI s clinical practice guidelines and clinical practice recommendations for anemia in CKD were released. On September 30, 2011, the KDIGO released its draft global anemia clinical practice guidelines for public review and comment. KDIGO has indicated that final guidelines could be available by early 2012.

In February 2007, following the reported results from our Anemia of Cancer 103 Study, the U.S. Pharmacopoeia Dispensing Information Drug Reference Guides removed Aranesp® in the treatment of anemia of cancer.

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

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.) 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 or all potentially applicable foreign regulations and/or laws. If we or our agents fail to comply with any of those regulations and/or laws, 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. Additionally, while we have implemented numerous risk mitigation measures, we cannot guarantee

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that we will be able to effectively mitigate all operational risks. If we fail to effectively mitigate all operational risks, our product supply may be negatively impacted, which 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. 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 earnings 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 international income, 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 international income, could have a material and adverse effect on our business and results of operations.

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

On April 20, 2011, our Board of Directors adopted a dividend policy pursuant to which the Company would pay quarterly dividends on our common stock, and increased the total authorization for repurchases of our common stock to approximately $7.2 billion. On October 13, 2011, our Board of Directors increased the total authorization for repurchases of our common stock by approximately $6.1 billion to $10 billion, and in December 2011 we repurchased approximately $5 billion of our common stock in a modified Dutch auction tender offer, leaving approximately $5 billion remaining for future repurchases under our Board 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

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Item 2. PROPERTIES

The following table summarizes our significant properties and their primary functions as of December 31, 2011. For additional information regarding manufacturing initiatives, see Item 1. Business Manufacturing, Distribution and Raw Materials.

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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 in 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 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, 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.

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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 10, 2012, there were approximately 9,153 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, 2011	**High**	**Low**
Fourth quarter	$ 64.74	$ 53.90
Third quarter	58.28	48.27
Second quarter	61.17	53.08
First quarter	57.31	50.95
Year ended December 31, 2010		
Fourth quarter	$ 57.96	$ 52.69
Third quarter	56.32	50.93
Second quarter	61.14	50.36
First quarter	60.09	55.71

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Performance graph

The following graph shows the value of an investment of $100 on December 31, 2006, 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 paid by companies included in these indices 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, 2006

	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/31/2011
Amgen (AMGN)	$ 100.00	$ 67.98	$ 84.54	$ 82.81	$ 80.37	$ 94.98
Amex Biotech (BTK)	100.00	104.28	85.80	124.91	172.04	144.79
Amex Pharmaceutical (DRG)	100.00	101.01	84.76	99.15	101.64	114.77
S&P 500 (SPX)	100.00	105.48	66.93	84.28	96.78	98.81

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.

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During the three months and year ended December 31, 2011, we had one outstanding stock repurchase program. Our repurchase activity for the three months and year ended December 31, 2011, 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 $ value that may yet be purchased under the program[2]
October 1 - October 31	2,728,703	$ 53.99	2,728,703	$ 10,000,000,000
November 1 - November 30				10,000,000,000
December 1 - December 31	83,333,333	60.08	83,333,333	4,993,072,585
	86,062,036	59.89	86,062,036	
January 1 - December 31	144,331,565	$ 57.55	144,331,565	

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

(2) Following the repurchase of $147 million in additional shares in early October 2011, on October 13, 2011, our Board of Directors increased the authorization for repurchase of our common stock by $6.1 billion to an aggregate of $10 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. Additionally, on December 15, 2011, the Board of Directors declared a quarterly cash dividend of $0.36 per share of common stock, which will be paid on March 7, 2012, to all stockholders of record as of the close of business on February 15, 2012. 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.

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Item 6. SELECTED FINANCIAL DATA

	Years ended December 31,				
Consolidated Statement of Income Data:	**2011**	**2010**	**2009**	**2008**	**2007**
	(In millions, except per share data)				
Revenues:					
Product sales	$ 15,295	$ 14,660	$ 14,351	$ 14,687	$ 14,311
Other revenues	287	393	291	316	460
Total revenues	15,582	15,053	14,642	15,003	14,771
Operating expenses[1]:					
Cost of sales (excludes amortization of certain acquired intangible assets presented separately)	2,427	2,220	2,091	2,296	2,548
Research and development	3,167	2,894	2,864	3,030	3,266
Selling, general and administrative	4,486	3,983	3,820	3,789	3,361
Amortization of certain acquired intangible assets	294	294	294	294	298
Write-off of acquired in-process research and development[2]					590
Other[3]	896	117	67	380	728
Net income[4]	3,683	4,627	4,605	4,052	3,078
Diluted earnings per share[4]	4.04	4.79	4.51	3.77	2.74
Dividends paid per share	0.56				

	As of December 31,				
Consolidated Balance Sheet Data:	**2011**	**2010**	**2009**	**2008**	**2007**
			(In millions)		
Total assets	$ 48,871	$ 43,486	$ 39,629	$ 36,427	$ 34,618
Total debt[4][5][6]	21,428	13,362	10,601	9,352	10,114
Total stockholders equity[4][6]	19,029	23,944	22,667	20,885	18,512

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 common share.

(1) On August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure. Under this plan in 2009, 2008 and 2007, we incurred restructuring charges of $70 million ($44 million, net of tax), $148 million ($111 million, net of tax) and $739 million ($576 million, net of tax), respectively, related primarily to staff separation costs, asset impairment charges, accelerated depreciation (primarily in 2007) and loss accruals for leases on certain facilities that will not be used in our business.

(2) As part of the accounting for the business combinations of Alantos Pharmaceutical Holding, Inc. and Ilypsa, Inc. in 2007, under the then existing accounting rules we recorded charges to write-off acquired in-process R&D (IPR&D) of $270 million and $320 million, respectively. The charges represent the estimated fair values of the IPR&D that, as of the respective acquisition dates, had not reached technological feasibility and had no alternative future use.

(3) 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 relating 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. (Ortho Biotech) antitrust suit.

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(4) Effective January 1, 2009, we adopted a new accounting standard that changed the method of accounting for convertible debt that may be partially or wholly settled in cash. As required by this standard, we retrospectively applied this change in accounting to all prior periods for which we had applicable outstanding convertible debt. Under this method of accounting, the debt and equity components of our convertible notes are bifurcated and accounted for separately. The equity components of our convertible notes are included in Common stock and additional paid-in capital in the Consolidated Balance Sheets, with a corresponding reduction in the carrying values of these convertible notes as of the date of issuance or modification, as applicable. The reduced carrying values of our convertible notes are being accreted back to their principal amounts through the recognition of non-cash interest expense. This results in recognizing interest expense on these borrowings at effective rates approximating what we would have incurred had we issued nonconvertible debt with otherwise similar terms. Included in net income for 2011, 2010, 2009, 2008 and 2007 is the incremental non-cash interest expense of $143 million ($91 million, net of tax), $266 million ($168 million, net of tax), $250 million ($155 million, net of tax), $235 million ($144 million, net of tax) and $168 million ($88 million, net of tax), respectively, related to the adoption of the new accounting standard.

(5) See Note 14, Financing arrangements, to the Consolidated Financial Statements for discussion of our financing arrangements. In addition, in 2008 and 2007 we issued $1.0 billion and $4.0 billion, respectively, aggregate principal amount of notes. In 2008, we repaid our $2.0 billion of floating rate notes. In 2007, as a result of holders of substantially all of our outstanding zero-coupon 2032 Modified Convertible Notes exercising their put option, we repurchased the majority of the then outstanding convertible notes, at their then-accreted value of $1.7 billion.

(6) Throughout the five years ended December 31, 2011, we had a share repurchase program authorized by the Board of Directors through which we repurchased $8.3 billion, $3.8 billion, $3.2 billion, $2.3 billion and $5.1 billion, respectively, of Amgen common stock.

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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, 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 the world s largest independent biotechnology medicines company. We discover, develop, manufacture and market medicines for grievous illnesses. We concentrate on innovative novel medicines based on advances in cellular and molecular biology. Our mission is to serve patients. 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 and nephrology. Our principal products include Neulasta®, NEUPOGEN®, ENBREL, Aranesp® and EPOGEN®. For additional information about our products, their approved indications and where they are marketed, see Item 1. Business Marketed Products.

In 2011, we had several notable accomplishments, including achieving record U.S. and international product sales of $11.7 billion and $3.6 billion, respectively. We also paid our first ever dividends, aggregating $500 million paid in 2011. In December 2011, we declared a quarterly dividend of $0.36 per share of common stock payable in March 2012, representing a 29% increase over prior quarters. Additionally, in 2011, we repurchased approximately 15% of our stock outstanding as of December 31, 2010, for a total cost of $8.3 billion. Of this amount, $5 billion was purchased in a modified Dutch auction tender offer following an increase in our authorized stock repurchase program to $10 billion and our announcement that we intended to accelerate our repurchases, reflecting our confidence in the long-term value of the Company and the attractive interest rate environment. We issued $7.5 billion of debt, in part to fund the purchase of stock related to the tender offer. We expect to repurchase the remaining $5 billion of stock under our authorized stock repurchase program through open-market purchases.

We enter 2012 with various opportunities to continue growing our business. We believe the currently approved indications for XGEVA® and Prolia® represent significant commercial opportunities. In addition, receiving regulatory and/or reimbursement approvals in new geographic territories or for additional indications

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for these products may provide further opportunities for growth. Longer-term growth may also be achieved by expansion into emerging markets and Japan, by the successful development of our later stage pipeline and through strategic business development opportunities, such as our acquisitions of BioVex, Bergamo and our recently announced agreement to acquire Micromet. Our continued focus on increasing cost efficiencies, along with the significant savings that we will realize upon the expiration of our ENBREL co-promotion agreement with Pfizer in the fourth quarter of 2013, may 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 continue to face increasing competitive pressure, including in Europe as a result of biosimilars. In the United States, ENBREL will also continue to face increasing competition and our ESAs may begin facing competition in the near term. Additionally, over the next several years, many of the existing patents on our principal products will expire and, as a result, we expect to face increasing competition from biosimilars. We also believe our products and product candidates will continue to face regulatory and reimbursement challenges. In addition, the current global economic conditions continue to pose challenges to our business, including increased pressure to reduce healthcare expenditures.

Certain of the above challenges may have a material adverse impact on our sales, results of operations and liquidity. However, these effects may be offset by certain of the opportunities we have to grow our business, as discussed above.

Selected financial information

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

	2011	Change	2010
Product sales:			
U.S.	$ 11,725	4 %	$ 11,254
International	3,570	5 %	3,406
Total product sales	15,295	4 %	14,660
Other revenues	287	(27)%	393
Total revenues	$ 15,582	4 %	$ 15,053
Operating expenses	$ 11,270	19 %	$ 9,508
Operating income	$ 4,312	(22)%	$ 5,545
Net income	$ 3,683	(20)%	$ 4,627
Diluted EPS	$ 4.04	(16)%	$ 4.79
Diluted shares	912	(5)%	965

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 2011 reflects overall growth for all marketed products except ESAs, which declined 17%. Excluding sales of ESAs, U.S. product sales increased 14%, driven primarily by unit growth and, to a lesser extent, increases in average net sales prices. International product sales for 2011 were negatively impacted by a decline in sales of Aranesp® of 5%. Excluding Aranesp® sales, international product sales grew 11%.

The decrease in other revenues for 2011 was due principally to certain milestone payments earned in 2010.

The increase in operating expenses for 2011 was driven primarily by a legal settlement charge and higher SG&A expenses.

The decrease in diluted EPS for 2011 was due to the reduction in net income, attributable primarily to lower operating income. This decrease in diluted EPS was offset partially by the favorable impact of our stock repurchase program, which reduced the number of shares used to compute diluted EPS.

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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 the euro.

Our results of operations for 2011 were impacted by the Puerto Rico excise tax. Commencing January 1, 2011, Puerto Rico imposes a temporary excise tax on the acquisition of goods and services from a related manufacturer in Puerto Rico. This tax is currently scheduled to expire in 2016. 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, for 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, 2011, our cash, cash equivalents and marketable securities totaled $20.6 billion, and total debt outstanding was $21.4 billion. Of our total cash, cash equivalents and marketable securities balance as of December 31, 2011, approximately $16.9 billion was generated from operations in foreign tax jurisdictions and is intended to be invested indefinitely outside of 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):

	2011	Change	2010	Change	2009
Neulasta®/NEUPOGEN ®	$ 5,212	8 %	$ 4,844	4 %	$ 4,643
ENBREL	3,701	5 %	3,534	1 %	3,493
Aranesp®	2,303	(7)%	2,486	(6)%	2,652
EPOGEN®	2,040	(19)%	2,524	(2)%	2,569
Other products	2,039	60 %	1,272	28 %	994
Total product sales	$ 15,295	4 %	$ 14,660	2 %	$ 14,351
Total U.S.	$ 11,725	4 %	$ 11,254	1 %	$ 11,135
Total International	3,570	5 %	3,406	6 %	3,216
Total product sales	$ 15,295	4 %	$ 14,660	2 %	$ 14,351

Product sales are influenced by a number of factors, some of which may impact the sales of certain of our existing products more significantly than others, including, but not necessarily limited to:

our contracting and pricing strategies;

recent and future reimbursement changes resulting from:

- governmental or private organization regulations or guidelines relating to the use of our products;

- legislative reform in federal, state and foreign jurisdictions;

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- cost containment pressures; and

- the mix of reimbursement from governmental and private payers;

clinical trial outcomes, including adverse events or results from clinical trials, including sub-analyses, studies or meta-analyses performed by us or by others (including our licensees or independent investigators), which could impact product safety labeling and may negatively impact healthcare provider prescribing behavior, use of our products, regulatory or private healthcare organization medical guidelines and reimbursement practices;

competitive products, including biosimilars;

physician and patient compliance with product dosing regimens;

changes in clinical practice, including those resulting from the development of new protocols, tests and/or treatments;

adoption of and adherence to risk management activities, such as a REMS, undertaken by us or required by the FDA or other regulatory authorities;

product label changes;

patient population growth;

segment growth and penetration;

new product launches and indications;

expansion into new international markets;

patent expirations and our ability to obtain and defend our patent and other intellectual property rights;

fluctuations in foreign currency exchange rates;

adequacy of product supply and distribution;

effectiveness of our marketing efforts, including those conducted under collaboration agreements;

concentration of customer purchasing power; and

acquisitions and divestures.

Our U.S. product sales are also subject to certain other influences throughout the year, including wholesaler and end-user buying patterns (e.g., holiday-driven wholesaler and end-user stocking, contract-driven buying and patients purchasing products later in the year after satisfying their annual insurance deductibles). 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 reduction in demand and/or a drawdown in wholesaler inventories and a corresponding 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 have been slightly lower relative to the immediately preceding three-month period, which we believe to be due, in part, to certain of these factors. 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.

In addition, general economic conditions may affect, or in some cases amplify, certain of these factors with a corresponding impact on our product sales.

See Item 1. Business Marketed Products for a discussion of our principal products and their approved indications.

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Neulasta®/NEUPOGEN®

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

	2011	Change	2010	Change	2009
Neulasta® U.S.	$ 3,006	13 %	$ 2,654	5 %	$ 2,527
NEUPOGEN® U.S.	959	3 %	932	3 %	901
Total U.S. Neulasta®/NEUPOGEN®	3,965	11 %	3,586	5 %	3,428
Neulasta® International	946	5 %	904	9 %	828
NEUPOGEN® International	301	(15)%	354	(9)%	387
Total International Neulasta®/NEUPOGEN®	1,247	(1)%	1,258	4 %	1,215
Total Neulasta®/NEUPOGEN®	$ 5,212	8 %	$ 4,844	4 %	$ 4,643

The increase in U.S. sales of Neulasta®/NEUPOGEN® for 2011 was driven principally by an increase in the average net sales price and Neulasta® unit growth. The decrease in Neulasta®/NEUPOGEN® international sales was driven by a decline in NEUPOGEN® sales due, in part, to biosimilar competition, offset partially by an increase in Neulasta® sales due, in part, to continued conversion from NEUPOGEN®.

The increase in U.S. sales of Neulasta®/NEUPOGEN® for 2010 was driven principally by an increase in the average net sales price and, to a lesser extent, favorable changes in wholesaler inventories. The increase in international Neulasta®/NEUPOGEN® sales for 2010 reflects primarily growth in Neulasta®, principally from the continued conversion from NEUPOGEN®, offset partially by a decline in NEUPOGEN® sales due, in part, to biosimilar competition.

In addition to other factors mentioned in the Product sales section above, future Neulasta®/NEUPOGEN® sales will 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.

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

ENBREL

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

	2011	Change	2010	Change	2009
ENBREL U.S.	$ 3,458	5 %	$ 3,304	1 %	$ 3,283
ENBREL Canada	243	6 %	230	10 %	210
Total ENBREL	$ 3,701	5 %	$ 3,534	1 %	$ 3,493

The increase in ENBREL sales for 2011 reflects primarily an increase in the average net sales price.

The increase in ENBREL sales for 2010 reflects an increase in the average net sales price, offset partially by a low single-digit percentage point unit decline, resulting primarily from share declines in dermatology.

ENBREL continues to maintain a leading position in both the rheumatology and dermatology segments.

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

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Aranesp®

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

	2011	Change	2010	Change	2009
Aranesp® U.S.	$ 986	(11)%	$ 1,103	(12)%	$ 1,251
Aranesp® International	1,317	(5)%	1,383	(1)%	1,401
Total Aranesp®	$ 2,303	(7)%	$ 2,486	(6)%	$ 2,652

The decrease in U.S. Aranesp® sales for 2011 was due principally to a high-teens percentage point unit decline, offset partially by an increase in the average net sales price. The unit decline reflects segment contraction resulting from changes to reimbursement in 2011 and the June 2011 ESA label changes. The decrease in international Aranesp® sales for 2011 was due to a decrease in the average net sales price and a unit decline, reflecting segment contraction.

The decrease in U.S. Aranesp® sales for 2010 was due primarily to a unit decline, reflecting segment contraction. The decrease in international Aranesp® sales for 2010 was due primarily to a unit decline.

In addition to other factors mentioned in the Product sales section above, future Aranesp® sales will depend, in part, on such factors as:

- regulatory developments, including the June 2011 ESA label changes and any other product label changes;
- reimbursement developments, including LCDs;
- changes in dose utilization as healthcare providers continue to refine their treatment practices in accordance with approved labeling; and
- 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.

Certain of the above factors may have a material adverse impact on future sales of Aranesp®.

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

EPOGEN®

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

	2011	Change	2010	Change	2009
EPOGEN® U.S.	$ 2,040	(19)%	$ 2,524	(2)%	$ 2,569

The decrease in EPOGEN® sales for 2011 was due primarily to a decrease in dose utilization related to changes to reimbursement in 2011 and the June 2011 ESA label changes, offset partially by an increase in the average net sales price and patient population growth.

The decrease in EPOGEN® sales for 2010 was due primarily to a unit decline and certain changes in accounting estimates. The unit decline reflects a decrease in dose utilization, offset partially by patient population growth.

In addition to other factors mentioned in the Product sales section above, future EPOGEN® sales will depend, in part, on such factors as:

potential peginesatide launch;

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reimbursement developments, including those resulting from:

- CMS s 2011 Final Rule on Bundling in Dialysis; and
- other CMS activities, including recent changes related to the QIP;

regulatory developments, including the June 2011 ESA label changes and any other product label changes;

changes in dose utilization as healthcare providers continue to refine their treatment practices in accordance with approved labeling;

new contracts with dialysis centers; and

adoption of alternative therapies or development of new modalities to treat anemia associated with CRF.

Certain of the above factors may have a material adverse impact on future sales of EPOGEN®.

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

Other products

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

	2011	Change	2010	Change	2009
Sensipar®/Mimpara ® U.S.	$ 518	13 %	$ 459	7 %	$ 429
Sensipar®/Mimpara ® International	290	14 %	255	15 %	222
Vectibix® U.S.	122	6 %	115	19 %	97
Vectibix® International	200	16 %	173	27 %	136
Nplate® U.S.	163	26 %	129	65 %	78
Nplate® International	134	34 %	100		32
Prolia® U.S.	130		26		
Prolia® International	73		7		
XGEVA® U.S.	343		8		
XGEVA® International	8				
Other International	58				
Total other product sales	$ 2,039	60 %	$ 1,272	28 %	$ 994
Total U.S. other products	$ 1,276	73 %	$ 737	22 %	$ 604
Total International other products	763	43 %	535	37 %	390
Total other product sales	$ 2,039	60 %	$ 1,272	28 %	$ 994

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

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Operating expenses

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

	2011	Change	2010	Change	2009
Operating expenses:					
Cost of sales (excludes amortization of certain acquired intangible assets presented separately)	$ 2,427	9%	$ 2,220	6%	$ 2,091
% of product sales	15.9%		15.1%		14.6%
Research and development	$ 3,167	9%	$ 2,894	1%	$ 2,864
% of product sales	20.7%		19.7%		20.0%
Selling, general and administrative	$ 4,486	13%	$ 3,983	4%	$ 3,820
% of product sales	29.3%		27.2%		26.6%
Amortization of certain acquired intangible assets	$ 294		$ 294		$ 294
Other	$ 896		$ 117		$ 67

Cost of sales

Cost of sales, which excludes the amortization of certain acquired intangible assets, 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. This decrease was driven by improved productivity, offset partially by certain expenses related to actions to improve cost efficiencies.

Cost of sales increased to 15.1% of product sales for 2010, driven primarily by higher bulk material costs and higher inventory write-offs due to voluntary EPOGEN®, PROCRIT® (epoetin alfa) and ENBREL recalls. These increases were offset partially by lower excess capacity charges and lower royalties, primarily for ENBREL.

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.

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

	2011	2010	2009
Discovery Research and Translational Sciences	$ 1,125	$ 1,154	$ 1,157
Later stage clinical programs	983	832	1,000
Marketed products	1,059	908	707
Total R&D expense.	$ 3,167	$ 2,894	$ 2,864

The increase in R&D expense for 2011 was driven primarily by an increase of $151 million in our marketed product support largely driven 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.

The increase in R&D expense for 2010 was driven primarily by an increase of $201 million in our marketed product support largely driven by our support for Prolia® and XGEVA® which, subsequent to their approvals during 2010, were categorized as marketed products rather than later stage clinical programs and, to a lesser extent, lower cost recoveries from ongoing collaborations. This increase was offset by a reduction of $168 million in our later stage clinical programs as a result of the aforementioned approvals of Prolia® and XGEVA®, as well as licensing fees paid in 2009, and lower expenses associated with our Discovery Research and Translational Sciences activities of $3 million.

Certain amounts for 2010 have been reclassified to better conform to the above descriptions of R&D activities.

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. 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 2011 was driven primarily by the U.S. healthcare reform 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.

The increase in SG&A expense for 2010 was due primarily to higher promotional costs for Prolia® and other marketed products of $148 million, higher staff-related costs of $46 million and higher litigation expenses of $45 million, offset partially by charges of $29 million in 2009 for certain cost savings initiatives related to our 2007 restructuring plan.

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For the years ended December 31, 2011, 2010 and 2009, the expenses associated with the ENBREL profit share were $1,288 million, $1,184 million and $1,163 million, respectively.

Other

In 2011, we recorded a $780 million legal settlement charge in connection with an agreement in principle to settle allegations relating to our sales and marketing practices. In addition in 2011, as part of our continuing efforts to improve cost efficiencies in our operations, we recorded certain charges, primarily severance related, of $109 million. In 2010, we recorded a $118 million asset impairment charge for our manufacturing operations located in Fremont, California, associated with our continuing efforts to optimize our network of manufacturing facilities and improve cost efficiencies. In 2009, we recorded loss accruals for settlements of certain legal proceedings aggregating $33 million.

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):

	2011	2010	2009
Interest expense, net	$ 610	$ 604	$ 578
Interest and other income, net	$ 448	$ 376	$ 276
Provisions for income taxes	$ 467	$ 690	$ 599
Effective tax rate	11.3%	13.0%	11.5%

Interest expense, net

Included in interest expense, net, for the years ended December 31, 2011, 2010 and 2009, is the impact of non-cash interest expense of $143 million, $266 million and $250 million, respectively, resulting from the change in the accounting for our convertible debt effective January 1, 2009. The reduction of non-cash interest expense in 2011 was offset by increased interest expense associated with recent borrowings.

Interest and other income, net

The increase in interest and other income, net, for 2011 was due primarily to higher net realized gains on sales of investments of $67 million.

The increase in interest and other income, net, for 2010 was due primarily to higher net realized gains on sales of investments of $48 million and higher interest income of $51 million, due principally to higher average cash, cash equivalents and marketable securities balances.

Income taxes

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 acquisition of goods and services from a related manufacturer in Puerto Rico. The excise tax is imposed over 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). 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 rate for 2011 would have been approximately 18% without the impact of the tax credits associated with the Puerto Rico excise tax.

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The increase in our effective tax rate for 2010 was due primarily to the incremental favorable impact resulting from the resolution of certain prior years matters with tax authorities in 2009 compared to 2010; the unfavorable tax impact of changes in revenue and expense mix in 2010; and the tax impact from adjustments to deferred taxes arising from changes in California tax law enacted in 2009 and effective for subsequent periods. The resolution of prior years tax matters recognized in 2010 and 2009 reduced the effective tax rate by 3.1% and 4.2%, respectively.

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 of the United States.

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

Recent accounting pronouncements

In June 2011, a new accounting standard was issued that changed the disclosure requirements for the presentation of other comprehensive income (OCI) in the financial statements, including the elimination of the option to present OCI in the statement of stockholders equity. OCI and its components will be required to be presented for both interim and annual periods either in a single financial statement, the statement of comprehensive income, or in two separate but consecutive financial statements, consisting of a statement of income followed by a separate statement presenting OCI. This standard is required to be applied retrospectively beginning January 1, 2012, except for certain provisions for which adoption was delayed.

Financial Condition, Liquidity and Capital Resources

Selected financial data was as follows as of December 31, 2011 and 2010 (in millions):

	2011	2010
Cash, cash equivalents and marketable securities	$ 20,641	$ 17,422
Total assets	48,871	43,486
Current portion of long-term debt	84	2,488
Long-term debt	21,344	10,874
Stockholders equity	19,029	23,944

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, as well as 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). In April 2011, the Board of Directors authorized us to repurchase up to an additional $5 billion of our common stock. Subsequently in October 2011, the Board of Directors increased the total authorization for stock repurchases by $6.1 billion to $10 billion. At that time, we announced our intent to accelerate our stock repurchase program, reflecting our confidence in the long-term value of the Company and the attractive interest rate environment. During 2011, we repurchased 144 million shares of our common stock at an aggregate cost of $8.3 billion, including $5 billion purchased in a modified Dutch auction tender offer. We expect to repurchase the remaining $5 billion of stock under our authorized stock repurchase program through open-market purchases. In April 2011, the Board of Directors also 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. Additionally in December 2011, the Board of Directors declared a 29% increase in our quarterly cash dividend to $0.36 per share of common stock, payable in March 2012.

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We believe 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 Current economic conditions may magnify certain risks that affect our business.

A significant portion of our operating cash flows is dependent upon the timing of payments from our customers located in the United States and, to a lesser extent, 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, upon the economic stability and creditworthiness of their applicable country. Deteriorating credit and economic conditions in parts of Southern Europe, particularly in Spain, Italy, Greece and Portugal, may continue to increase the average length of time it takes to collect payments, particularly in certain regions within these countries. However, the timing of payments from government healthcare providers has not nor is it expected to have a material adverse impact on our operating cash flows. To date we have not incurred any significant losses on collections of trade receivables from these government healthcare providers.

Over the next several years, many of the existing patents on our principal products will expire. As a result, we expect to face increasing competition from biosimilars that may have a material adverse impact on our product sales, results of operations and liquidity. Upon patent expiration for small molecule products, there is typically intense competition from generics manufacturers, which generally leads to significant and rapid declines in sales of the branded product. Given that our principal products are biologics, we do not believe the impact of biosimilar competition will be as significant as with small molecule products, in part because successful competitors must have a broad range of specialized skills and capabilities unique to biologics, including significant regulatory, clinical and manufacturing expertise, and since the products are similar, but not identical, the biosimilars will have to compete against a product with an established efficacy and safety record. As discussed above, 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, 2011, approximately $16.9 billion was generated from operations in foreign tax jurisdictions and is intended to be invested indefinitely outside of 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, 2011, were $84 million and $21.3 billion, respectively. The current and noncurrent portions of our long-term borrowings at December 31, 2010, were $2.5 billion and $10.9 billion, respectively.

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We issued debt securities in various offerings during the three years ended December 31, 2011, including:

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.

In 2009, we issued $2.0 billion aggregate principal amount of notes, comprised of the 5.70% 2019 Notes and the 6.40% 2039 Notes.

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, and we repaid $1.0 billion aggregate principal amount of notes with a fixed interest rate of 4.00% in 2009.

To achieve a desired mix of fixed and floating interest rate debt, we enter into interest rate swap contracts that effectively convert 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 qualify and are designated as fair value hedges. As of December 31, 2011 and 2010, we had interest rate swap contracts with an aggregate face value of $3.6 billion. See Note 14, Financing arrangements, and Note 17, Derivative instruments, to the Consolidated Financial Statements for further discussion of our interest rate swap contracts.

In order to hedge our exposure to foreign currency exchange rate risk associated with our pound sterling denominated long-term notes issued in 2011, we entered into cross currency swap contracts. These cross currency swap contracts qualify and are designated as cash flow hedges. Under the terms of these contracts, we receive interest payments in pounds sterling at a fixed rate of 5.5% on £475 million and pay interest in U.S. dollars at a fixed rate of 5.8% on $748 million, the aggregate notional amounts paid to/received from the counterparties upon exchange of currencies at the inception of these contracts. We will pay U.S. dollars to and receive pounds sterling from the counterparties at the maturity of the contracts for the 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 pounds sterling to U.S. dollars.

As of December 31, 2011, 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, 2011 and 2010, 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. We would be charged interest at LIBOR plus 0.9% for any amounts borrowed under this facility. As of December 31, 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 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.

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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, 2011 and 2010, 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, 2011.

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):

	2011	2010	2009
Net cash provided by operating activities	$ 5,119	$ 5,787	$ 6,336
Net cash used in investing activities	(786)	(4,152)	(3,202)
Net cash used in financing activities	(674)	(1,232)	(2,024)

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 decreased during the 2011 due primarily to: increased interest payments; working capital increases related to the launch of Prolia® and XGEVA®; and the prepayment of certain royalties. The reduction in net income during 2011 was driven primarily by the accrual of the legal settlement charge of $780 million, which will be paid in a subsequent period. Cash provided by operating activities during 2010 decreased due primarily to the timing and amount of payments to taxing authorities.

Investing

Capital expenditures totaled $567 million, $580 million and $530 million in 2011, 2010 and 2009, respectively. Capital expenditures in 2011, 2010 and 2009 were associated primarily with manufacturing capacity expansions in Puerto Rico and other site developments. We currently estimate 2012 spending on capital projects and equipment to be approximately $700 million.

Cash used in investing activities during the year ended December 31, 2011, also included the cost of acquiring certain businesses totaling $701 million.

Net proceeds from marketable securities were $437 million for 2011, compared to net purchases of marketable securities of $3.5 billion for 2010 and $2.7 billion for 2009.

Financing

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 the net proceeds from 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. Cash used in financing activities during 2009 was due to repurchases of our common stock of $3.2 billion and repayment of long-term debt of $1.0 billion, offset partially by the net proceeds from issuance of long-term debt of $2.0 billion.

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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, 2011, 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] [3]	$ 37,521	$ 888	$ 6,131	$ 3,396	$ 27,106
Operating lease obligations	774	116	189	141	328
Purchase obligations [4]	2,992	865	420	243	1,464
Unrecognized tax benefits [5]					
Total contractual obligations	$ 41,287	$ 1,869	$ 6,740	$ 3,780	$ 28,898

(1) The long-term debt obligation amounts also include future interest payments. Future interest payments are included on our financing arrangements at the fixed contractual coupon rates. To achieve a desired mix of fixed and floating interest rate debt, we enter into interest rate swap contracts that effectively convert a fixed rate interest coupon for certain of our debt issuances to a floating LIBOR-based coupon over the life of the respective note. We used an interest rate forward curve at December 31, 2011, in computing net amounts to be paid or received under our interest rate swap contracts which resulted in an aggregate net reduction in future interest payments of $366 million. See Note 14, Financing arrangements, to the Consolidated Financial Statements for further discussion of our interest swap contracts.

(2) In order to hedge our exposure to foreign currency exchange rate risk associated with our pound sterling denominated long-term debt issued in December 2011, we entered into cross currency swap contracts that effectively convert interest payments and principal repayment on this debt from pounds sterling 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 and principal payments and on this debt. See Note 14, Financing arrangements, to the Consolidated Financial Statements for further discussion of our cross currency swap contracts.

(3) The long-term debt obligations amounts include the repayment of principal on our euro denominated foreign currency debt at the foreign currency exchange rates in effect at December 31, 2011. See Note 14, Financing arrangements, to the Consolidated Financial Statements for further discussion of our long-term debt obligations.

(4) 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.

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(5) Liabilities for unrecognized tax benefits (UTBs) (net of foreign tax credits and federal tax benefit of state taxes) and related accrued interest and penalties totaling approximately $912 million at December 31, 2011, 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. 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, 2011, the maximum amount that may be payable in the future for agreements we have entered into with third parties is approximately $3.6 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, sales deductions and returns

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, 2009	$ 653	$ 84	$ 139	$ 876
Amounts charged against product sales	1,663	2,424	552	4,639
Payments	(1,609)	(2,380)	(556)	(4,545)
Balance as of December 31, 2009	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

For the years ended December 31, 2011, 2010 and 2009, total sales deductions were 25%, 25% and 24% 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 2% or less of the aggregate sales deductions charged against product sales for the three year ended December 31, 2011.

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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 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. We adjust the accrual 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 greater than one year for certain recent government programs. Rebates totaled $1.8 billion, $1.9 billion and $1.7 billion for the years ended December 31, 2011, 2010 and 2009, 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 have been less than 5% of the estimated rebate amounts charged against product sales for each of the three years ended December 31, 2011. A 5% change in our rebate estimate attributable to rebates recognized in 2011 would have had an impact of approximately $90 million, or approximately one-half of 1% of our 2011 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 the healthcare providers purchase our products through wholesalers at these reduced prices, the wholesaler charges 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 $2.6 billion, $2.6 billion and $2.4 billion for the years ended December 31, 2011, 2010 and 2009, 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 been insignificant, amounting to less than 1.5% of gross product sales. Furthermore, changes in estimates for prior year sales return provisions have historically also 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.

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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 upon settlement. 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. Such timing 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) a tax expense recognized in the financial statements for which payment has been deferred; or (ii) an expense for which the Company has already taken a deduction on the tax return, but has not yet recognized the expense in the financial statements.

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 pre-tax 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. 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 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.

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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.

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 the 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 historically low interest rates on corporate debt issuances during 2011. Short-term interest rates on U.S. Treasury instruments continued to decline 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, 2011 and 2010. 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, 2011 and 2010.

Interest rate sensitive financial instruments

Our portfolio of available-for-sale debt security investments at December 31, 2011 and 2010, was comprised of: U.S. Treasury securities and other government-related debt securities; corporate debt securities; mortgage- and

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asset-backed securities; money market mutual funds; and additionally at December 31, 2010, other short-term interest bearing securities, composed principally of commercial paper. The fair value of our investment portfolio of debt securities was $20.0 billion and $17.3 billion at December 31, 2011 and 2010, 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, 2011 and 2010, 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, 2011 and 2010, would not result in a material effect on the related income or cash flows in the respective ensuing year.

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. As of December 31, 2010, we had outstanding debt with a carrying value of $13.4 billion and a fair value of $14.5 billion. Our outstanding debt at December 31, 2011 and 2010, 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, 2011, would have resulted in an increase of approximately $2.1 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, 2010, would have resulted in an increase of approximately $1.0 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 and cross currency swap contracts.

To achieve a desired mix of fixed and floating interest rate debt, we have entered into interest rate swap contracts, which qualify and have been designated for accounting purposes as fair value hedges, for certain of our fixed rate debt with notional amounts totaling $3.6 billion at December 31, 2011 and 2010. These derivative contracts effectively convert a fixed rate interest coupon to a floating rate LIBOR-based coupon over the life of the respective note. A hypothetical 100 basis point increase in interest rates relative to interest rates at December 31, 2011 and 2010, would have resulted in a reduction fair value of approximately $200 million on our interest rate swap contracts on these dates 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, 2011, we had open cross currency swap contracts with an aggregate notional amount of $748 million that hedge the entire principal amount of our pound sterling denominated debt and related interest payments. These contracts effectively convert payments on this debt to U.S. dollars 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, 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 not have a material 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, predominately 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, 2011, we had outstanding debt with a carrying value and fair value of $1.5 billion that was denominated in pounds sterling and euros. 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

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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 and would not result in a material effect on the related cash flows in the ensuing year. The analysis for this debt does not consider the impact that hypothetical changes in foreign exchange would have on the related cross currency swap contracts.

With regard to our cross currency swap contracts that are designated as cash flow hedges of our pound sterling denominated debt, 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 the fair value of these contracts of approximately $210 million on this date and would not result in a material effect on the related cash flows in the ensuing year. The impact on income in the ensuing year of this hypothetical adverse movement in foreign currency exchange rates, which would equal the entire change in the carrying amount of the hedged debt, would be approximately $150 million.

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, 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, 2010, we had open foreign currency forward and options contracts, primarily euro-based, with notional amounts of $3.2 billion and $398 million, respectively. As of December 31, 2011 and 2010, 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, 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. With regard to contracts that were open at December 31, 2010, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2010, would have resulted in a reduction in fair value of these contracts of approximately $670 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, 2011 and 2010, we had open foreign currency forward contracts with notional amounts totaling $389 million and $670 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, 2011 and 2010. With regard to these foreign currency forward 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 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. With regard to these foreign currency forward contracts that were open at December 31, 2010, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2010, would have resulted in a reduction in fair value of these contracts on these dates of approximately $130 million and would not result in a material effect on the related income or cash flows in the 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, 2011 and 2010, 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, 2011 and 2010, 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

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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, 2011.

Management determined that, as of December 31, 2011, 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, 2011. 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, 2011, 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, 2011.

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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, 2011, 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, 2011, 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, 2011 and 2010, and the related Consolidated Statements of Income, Stockholders Equity, and Cash Flows for each of the three years in the period ended December 31, 2011 of Amgen Inc. and our report dated February 29, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California

February 29, 2012

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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 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2011 (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.

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

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table sets forth certain information as of December 31, 2011, concerning our common stock that may be issued under any form of award granted under all of our equity compensation plans approved by stockholders and equity compensation plans not approved by stockholders in effect as of December 31, 2011 (including upon the exercise of options, pursuant to purchases of stock or upon vesting of awards of restricted stock units (RSUs) or performance units).

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	(b) Weighted Average Exercise Price Outstanding Options and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by Amgen security holders:			
2009 Equity Incentive Plan[1]	25,145,740	$ 54.78	58,012,064
Amended and Restated 1991 Equity Incentive Plan [2]	10,937,360	$ 58.16	
Amended and Restated Employee Stock Purchase Plan[3]		$	5,961,514
Total Approved Plans	36,083,100	$ 56.25	63,973,578
Equity compensation plans not approved by Amgen security holders:			
Amended and Restated 1993 Equity Incentive Plan[4]	6,077	$ 52.60	
Amended and Restated 1999 Equity Incentive Plan[4]	5,752,222	$ 65.37	
Amended and Restated 1997 Equity Incentive Plan[5]	772,456	$ 51.71	
Amended and Restated 1997 Special Non-Officer Equity Incentive Plan[6]	3,136,770	$ 66.46	
Amended and Restated 1996 Incentive Stock Plan[7]	290,500	$ 68.86	
Amended and Restated 1999 Incentive Stock Plan[7]	1,271,686	$ 68.40	
Amended and Restated Assumed Avidia Equity Plan[8]	11,415	$ 1.96	
Amgen Profit Sharing Plan for Employees in Ireland[9]		$	192,180
Total Unapproved Plans	11,241,126	$ 65.06	192,180
Total All Plans	47,324,226	$ 59.11	64,165,758

(1) The number under column (a) with respect to this plan includes approximately 13.06 million shares issuable upon the exercise of outstanding options with a weighted-average exercise price of approximately $54.78, approximately 8.03 million shares issuable upon the vesting of outstanding RSUs and approximately 4.05 million shares issuable upon the vesting of outstanding performance units. The performance units awarded in 2010 and 2011 continue to be subject to performance goals and the maximum number of units that could be earned is 200% of the units awarded in 2010 and 150% of the units awarded in 2011. The number under column (c) with respect to this plan represents the maximum number of shares that remain available for future issuance under this plan. This number may fluctuate depending on the nature of the award granted. Shares that are subject to awards of options or stock appreciation rights granted under the 2009 Plan will be counted against the pool of available shares under the 2009 Plan as one (1) share for every one (1) share granted. Shares that are subject to awards granted under the 2009 Plan other than options or

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stock appreciation rights will be counted against the pool of available shares under the 2009 Plan as 1.9 shares for every one (1) share granted. Furthermore, if any shares subject to an award under the 2009 Plan are forfeited or expire or an award under the 2009 Plan is settled for cash, then any shares subject to such award may, to the extent of such forfeiture, expiration or cash settlement, be used again for new grants under the 2009 Plan and the shares subject to such awards will be added back to the pool of available shares under the 2009 Plan as (i) one (1) share if such shares were subject to an option or stock appreciation right granted under the 2009 Plan and (ii) as 1.9 shares if such shares were subject to awards other than options or stock appreciation rights granted under the 2009 Plan.

(2) This plan has terminated as to future grants. The number under column (a) with respect to this plan includes approximately 10.04 million shares issuable upon the exercise of outstanding options with a weighted-average exercise price of approximately $58.16 and approximately 0.89 million shares issuable upon the vesting of outstanding RSUs.

(3) The purchases occurred on June 15, 2011, and December 15, 2011 (the Purchase Dates), with a purchase of 204,758 shares of Common Stock at a purchase price of $55.00 per shares on June 15, 2011, and 149,728 shares of Common Stock at a purchase price of $55.69 per share on December 15, 2011. Such purchases reflect 95% of the closing price of the Common Stock on the applicable Purchase Date.

(4) These plans have terminated as to future grants. These Plans were originally assumed pursuant to the terms of the merger agreement between Amgen and Immunex which was approved by our stockholders in May 2002. Both plans were previously approved by Immunex s shareholders. The number under column (a) with respect to the Amended and Restated 1999 Equity Incentive Plan includes approximately 5.74 million shares issuable upon the exercise of outstanding options with a weighted-average exercise price of approximately $65.37 and approximately 12,000 shares issuable upon the vesting of outstanding RSUs.

(5) This plan has terminated as to future grants. This plan was originally assumed by Amgen in connection with the merger of Tularik with and into Amgen SF, LLC, a wholly owned subsidiary of Amgen, on August 13, 2004. This plan was previously approved by Tularik s shareholders.

(6) This plan has terminated as to future grants.

(7) These plans have terminated as to future grants. These plans were originally assumed by Amgen in connection with the merger of Abgenix with and into Amgen Fremont Inc., a wholly owned subsidiary of Amgen, on April 1, 2006. The Amended and Restated 1996 Incentive Stock Plan (1996 Plan) was previously approved by Abgenix s shareholders. The number under column (a) with respect to the 1996 Plan includes approximately 291,000 shares issuable upon the exercise of outstanding options with a weighted-average exercise price of approximately $68.86. The number under column (a) with respect to the Amended and Restated 1999 Incentive Stock Plan includes approximately 1.15 million shares issuable upon the exercise of outstanding options with a weighted-average exercise price of approximately $68.40 and approximately 119,000 shares issuable upon the vesting of outstanding RSUs.

(8) This plan has terminated as to future grants. This plan was originally assumed by Amgen in connection with the merger of Avidia, Inc. with and into Amgen Mountain View Inc., a wholly owned subsidiary of Amgen, on October 24, 2006.

(9) The Amgen Profit Sharing Plan for Employees in Ireland (the Profit Sharing Plan) was approved by the Board of Directors on July 28, 2011. The Profit Sharing Plan permits eligible employees of the Company s subsidiaries located in Ireland, which participate in the Profit Sharing Plan, to apply a portion of their qualifying bonus and salary to the purchase the Company s Common Stock on the open market at the market price by a third-party trustee as described in the Profit Sharing Plan. 7,820 shares were purchased on December 16, 2011.

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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 ACCOUNTING 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.

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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.

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(a)3. Exhibits

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of January 25, 2012, among Micromet, Inc., Amgen Inc., and Armstrong Acquisition Corp. (Filed as an exhibit to Form 8-K filed on January 26, 2012 and incorporated herein by reference.)
3.1	Restated Certificate of Incorporation (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 of the Restated Certificate of Incorporation (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 the Restated Certificate of Incorporation (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 Amendment of the Restated Certificate of Incorporation (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.)
3.6	Certificate of Correction of the Restated Certificate of Incorporation (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.)
3.7	Certificate of Correction of the Restated Certificate of Incorporation (As Corrected May 13, 2010). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2010 on August 9, 2010.)
3.8	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.)
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	Two Agreements of Resignation, Appointment and Acceptance in the same form as the previously filed Exhibit 4.3 hereto are omitted pursuant to instruction 2 to Item 601 of Regulation S-K. Each of these agreements, which are dated December 15, 2008, replaces the current trustee under the agreements listed as Exhibits 4.9 and 4.15, respectively, with Bank of New York Mellon. Amgen Inc. hereby agrees to furnish copies of these agreements to the Securities and Exchange Commission upon request.
4.5	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.6	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.)

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Exhibit No.	Description
4.7	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.)
4.8	Form of Liquid Yield Option Note due 2032. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.9	Indenture, dated as of March 1, 2002. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.10	First Supplemental Indenture, dated March 2, 2005. (Filed as an exhibit to Form 8-K filed on March 4, 2005 and incorporated herein by reference.)
4.11	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.)
4.12	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.)
4.13	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.)
4.14	Form of Zero Coupon Convertible Note due 2032. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
4.15	Indenture, dated as of May 6, 2005. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
4.16	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.)
4.17	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.)
4.18	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.)
4.19	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.)
4.20	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.)
4.21	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.)
4.22	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.)

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Exhibit No.	Description
4.23	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.)
4.24	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.)
4.25	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.)
10.1+	Amgen Inc. 2009 Equity Incentive Plan. (Filed as Appendix A to Amgen Inc. s Proxy Statement 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 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.)
10.3+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Equity Incentive Plan. (As Amended on 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.)
10.4+	Amgen Inc. 2009 Performance Award Program. (As Amended and Restated on December 4, 2009.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2009 on March 1, 2010 and incorporated herein by reference.)
10.5+	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on 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.)
10.6+	Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.7+	Form of Grant of Non-Qualified Stock Option Agreement and Restricted Stock Unit 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+	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.)
10.9+	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.)
10.10+*	Second Amendment to the Amgen Supplemental Retirement Plan, effective October 12, 2011.
10.11+*	Third Amendment to the Amgen Supplemental Retirement Plan, executed December 16, 2011.
10.12+	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.)
10.13+	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.)
10.14+	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.)

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Exhibit No.	Description
10.15+	First Amendment to the Amgen Inc. Executive Nonqualified Retirement Plan. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2010 on August 9, 2010 and incorporated herein by reference.)
10.16+	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.)
10.17+	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.)
10.18+*	Second Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 12, 2011.
10.19+	2002 Special Severance Pay Plan for Amgen Employees. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2002 on August 13, 2002 and incorporated herein by reference.)
10.20+	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.)
10.21+*	Agreement between Amgen Inc. and Mr. Anthony C. Hooper, dated October 12, 2011.
10.22+	Consulting Agreement, effective February 1, 2011, between Amgen Inc. and Mr. George Morrow. (Filed as an exhibit to Form 8-K on October 22, 2010 and incorporated herein by reference).
10.23	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.)
10.24	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.)
10.25	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.)
10.26	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.)
10.27	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.)
10.28	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.)

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Exhibit No.	Description
10.29	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.)
10.30	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.)
10.31	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.)
10.32	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.)
10.33	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.)
10.34	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.)
10.35	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.)
10.36	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.)
10.37	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 Form S-4/A on June 29, 2004 and incorporated herein by reference.)
10.38	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.)
10.39	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.)
10.40	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.)

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Exhibit No.	Description
10.41	Collaboration Agreement, dated July 11, 2007, between Amgen Inc. and Daiichi Sankyo Company (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2007 on November 9, 2007 and incorporated herein by reference.)
10.42	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.)
10.43	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.)
10.44	License Agreement for motesanib diphosphate 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.)
10.45	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.)
10.46	Sale and Purchase 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.)
10.47	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.)
10.48	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.)
10.49	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.)
10.50	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.)
10.51	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.)

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Exhibit No.	Description
10.52 *	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).
21*	Subsidiaries of the Company
23	Consent of the Independent Registered Public Accounting Firm. The consent is set forth on pages 105 and 106 of this Annual Report on Form 10-K.
24	Power of Attorney. The Power of Attorney is set forth on pages 107 and 108 of this Annual Report on Form 10-K.
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.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase.

(* = 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 or arrangement)

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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: 02/29/2012

By: /s/ JONATHAN M. PEACOCK
Jonathan M. Peacock
Executive Vice President
and Chief Financial Officer

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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;

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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; and

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.

Registration Statement (Form S-8 No. 333-176240) pertaining to the Amgen Profit Sharing Plan for Employees in Ireland;

of our reports dated February 29, 2012, 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) of Amgen Inc. for the year ended December 31, 2011.

/s/ Ernst & Young LLP

Los Angeles, California

February 29, 2012

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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/ Kevin W. Sharer **Kevin W. Sharer**	Chairman of the Board, Chief Executive Officer and Director (Principal Executive Officer)	02/29/2012
/s/ Jonathan M. Peacock **Jonathan M. Peacock**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	02/29/2012
/s/ Thomas J.w. Dittrich **Thomas J.W. Dittrich**	Vice President Finance and Chief Accounting Officer (Principal Accounting Officer)	02/27/2012
/s/ Robert A. Bradway **Robert A. Bradway**	President, Chief Operating Officer and Director	02/29/2012
/s/ David Baltimore **David Baltimore**	Director	02/29/2012
/s/ Frank J. Biondi, Jr. **Frank J. Biondi, Jr.**	Director	02/29/2012
/s/ Vance D. Coffman **Vance D. Coffman**	Director	02/29/2012
/s/ François De Carbonnel	Director	02/29/2012

François de Carbonnel		
/s/ Rebecca M. Henderson	Director	02/29/2012
Rebecca M. Henderson		
/s/ Frank C. Herringer	Director	02/23/2012
Frank C. Herringer		
/s/ Gilbert S. Omenn	Director	02/29/2012
Gilbert S. Omenn		

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Signature	Title	Date
/s/ Judith C. Pelham **Judith C. Pelham**	Director	02/29/2012
/s/ J. Paul Reason **J. Paul Reason**	Director	02/29/2012
/s/ Leonard D. Schaeffer **Leonard D. Schaeffer**	Director	02/29/2012
/s/ Ronald D. Sugar **Ronald D. Sugar**	Director	02/29/2012

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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, 2011 and 20010, and the related Consolidated Statements of Income, Stockholders Equity, and Cash Flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, 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 29, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California

February 29, 2012

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For the fiscal year ended December 31, 2011

AMGEN INC.

CONSOLIDATED STATEMENTS OF INCOME

Years ended December 31, 2011, 2010 and 2009

(In millions, except per share data)

	2011	2010	2009
Revenues:			
Product sales	$ 15,295	$ 14,660	$ 14,351
Other revenues	287	393	291
Total revenues	15,582	15,053	14,642
Operating expenses:			
Cost of sales (excludes amortization of certain acquired intangible assets presented separately)	2,427	2,220	2,091
Research and development	3,167	2,894	2,864
Selling, general and administrative	4,486	3,983	3,820
Amortization of certain acquired intangible assets	294	294	294
Other	896	117	67
Total operating expenses	11,270	9,508	9,136
Operating income	4,312	5,545	5,506
Interest expense, net	610	604	578
Interest and other income, net	448	376	276
Income before income taxes	4,150	5,317	5,204
Provision for income taxes	467	690	599
Net income	$ 3,683	$ 4,627	$ 4,605
Earnings per share:			
Basic	$ 4.07	$ 4.82	$ 4.53
Diluted	$ 4.04	$ 4.79	$ 4.51
Shares used in the calculation of earnings per share:			
Basic	905	960	1,016
Diluted	912	965	1,021

See accompanying notes.

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AMGEN INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2011 and 2010

(In millions, except per share data)

	2011	2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,946	$ 3,287
Marketable securities	13,695	14,135
Trade receivables, net	2,896	2,335
Inventories	2,484	2,022
Other current assets	1,572	1,350
Total current assets	27,593	23,129
Property, plant and equipment, net	5,420	5,522
Intangible assets, net	2,584	2,230
Goodwill	11,750	11,334
Other assets	1,524	1,271
Total assets	$ 48,871	$ 43,486
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 642	$ 716
Accrued liabilities	5,028	3,366
Current portion of long-term debt	84	2,488
Total current liabilities	5,754	6,570
Long-term debt	21,344	10,874
Other noncurrent liabilities	2,744	2,098
Contingencies and commitments		
Stockholders equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding 795.6 shares in 2011 and 932.1 shares in 2010	27,777	27,299
Accumulated deficit	(8,919)	(3,508)
Accumulated other comprehensive income	171	153
Total stockholders equity	19,029	23,944
Total liabilities and stockholders equity	$ 48,871	$ 43,486

See accompanying notes.

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AMGEN INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

Years ended December 31, 2011, 2010 and 2009

(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, 2008	1,047.5	$ 26,441	$ (5,673)	$ 117	$ 20,885
Comprehensive income:					
Net income			4,605		4,605
Other comprehensive loss, net of tax				(72)	(72)
Comprehensive income					4,533
Issuance of common stock in connection with the Company s equity award programs	6.3	190			190
Stock-based compensation		324			324
Tax impact related to employee stock options		(11)			(11)
Repurchases of common stock	(59.2)		(3,254)		(3,254)
Balance at December 31, 2009	994.6	26,944	(4,322)	45	22,667
Comprehensive income:					
Net income			4,627		4,627
Other comprehensive income, net of tax				108	108
Comprehensive income					4,735
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 options		(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
Comprehensive income:					
Net income			3,683		3,683
Other comprehensive income, net of tax				18	18
Comprehensive income					3,701
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 options		(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

See accompanying notes.

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AMGEN INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2011, 2010 and 2009

(In millions)

	2011	2010	2009
Cash flows from operating activities:			
Net income	$ 3,683	$ 4,627	$ 4,605
Depreciation and amortization	1,060	1,017	1,049
Stock-based compensation expense	341	353	284
Deferred income taxes	(399)	(167)	47
Property, plant and equipment impairments	6	118	21
Dividend received from equity investee			110
Other items, net	63	140	111
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	(557)	(210)	(36)
Inventories	(383)	153	(134)
Other assets	(133)	36	(3)
Accounts payable	(95)	142	71
Accrued income taxes	(20)	(656)	(142)
Legal reserve	780		
Other liabilities	773	234	353
Net cash provided by operating activities	5,119	5,787	6,336
Cash flows from investing activities:			
Purchases of property, plant and equipment	(567)	(580)	(530)
Cash paid for acquisitions, net of cash acquired	(701)		
Purchases of marketable securities	(21,183)	(14,602)	(12,418)
Proceeds from sales of marketable securities	20,871	10,485	8,252
Proceeds from maturities of marketable securities	749	642	1,443
Other	45	(97)	51
Net cash used in investing activities	(786)	(4,152)	(3,202)
Cash flows from financing activities:			
Repurchases of common stock	(8,315)	(3,786)	(3,208)
Repayment of debt	(2,500)		(1,000)
Repayments of commercial paper	(762)		
Dividends paid	(500)		
Net proceeds from issuance of debt	10,387	2,471	1,980
Net proceeds from issuance of commercial paper	762		
Other	254	83	204
Net cash used in financing activities	(674)	(1,232)	(2,024)
Increase in cash and cash equivalents	3,659	403	1,110
Cash and cash equivalents at beginning of period	3,287	2,884	1,774

Cash and cash equivalents at end of period	$ 6,946	$ 3,287	$ 2,884

See accompanying notes.

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2011

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 medicines company discovers, develops, manufactures and markets medicines for grievous illnesses. We concentrate on innovating novel medicines based on advances in cellular and molecular biology, and we operate in one business segment: human therapeutics.

Principles of consolidation

The consolidated financial statements include the accounts of Amgen as well as its wholly owned subsidiaries. We do not have any significant interests in any variable interest entities. 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

Product sales consist primarily of sales of Neulasta® (pegfilgrastim), NEUPOGEN® (Filgrastim), Enbrel® (etanercept), Aranesp® (darbepoetin alfa) and EPOGEN® (epoetin alfa). 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.

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 sell epoetin alfa under the brand name EPOGEN®. 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 the 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

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Muliple-deliverable revenue arrangements

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 or determinable is then allocated to each separate unit of accounting based on the relative selling price of 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.

For MDRAs entered into prior to January 1, 2011, (pre-2011 arrangements) 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 and where standalone value could not be determined under the previous guidance, 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.

The primary impact of adopting the new accounting standard is expected to be the earlier recognition of revenue associated with delivering rights to the underlying intellectual property. The adoption of this accounting standard did not have a material impact on our consolidated results of operations for the year ended December 31, 2011, or on our financial position as of December 31, 2011. Our consolidated results of operations for the year ended December 31, 2010, or our financial position as of December 31, 2010, also would not have been materially impacted if the accounting standard had been adopted on January 1, 2010. The impact of adopting this new accounting standard is dependent on the terms and conditions of any future arrangements that we may enter into that include multiple-deliverables and pre-2011 arrangements that are materially modified. Depending on the terms of any such arrangements, the adoption of this accounting standard may have a material impact on our consolidated results of operations or financial position.

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 K-A and third-party R&D arrangements, including upfront fees and milestones paid to third parties in connection with technologies which

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 the 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 stock options, restricted stock units (RSU) and performance units. The estimated fair values of stock option and RSU 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 on a straight-line basis 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 on 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 upon settlement. 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

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 on 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.

Intangible assets and goodwill

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, Intangible assets.

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 subject to impairment testing until completion or abandonment of the project. 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. 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.

Goodwill relates principally to our 2002 acquisition of Immunex Corporation (Immunex). We perform an impairment test of goodwill annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

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 0.125% 2011 Convertible Notes and 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.

Recent accounting pronouncements

In June 2011, a new accounting standard was issued that changed the disclosure requirements for the presentation of other comprehensive income (OCI) in the financial statements, including the elimination of the option to present OCI in the statement of stockholders equity. OCI and its components will be required to be presented for both interim and annual periods either in a single financial statement, the statement of comprehensive income, or in two separate but consecutive financial statements, consisting of a statement of income followed by a separate statement presenting OCI. This standard is required to be applied retrospectively beginning January 1, 2012, except for certain provisions for which adoption was delayed.

2. Business combinations

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 (formerly referred to as OncoVEX$^{GM\text{-}CSF}$), a novel oncolytic vaccine in phase 3 clinical development for the treatment of malignant melanoma. This 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.

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 with the U.S. Food and Drug Administration (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. 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):

Intangible assets IPR&D	$ 675
Goodwill	170
Deferred tax liabilities	(246)
Other assets (liabilities) acquired, net	(2)
Total consideration	$ 597

Intangible assets are composed of the estimated fair value of acquired IPR&D 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. The estimated net cash flows were discounted to present value using a discount rate of 11%, which is based on the estimated weighted-average cost of capital for companies with characteristics similar to those of BioVex. This is comparable to the estimated internal rate of return on BioVex operations and represents the rate that market participants would use to value the intangible assets. The projected cash flows from talimogene laherparepvec were based on certain key assumptions, including estimates of future revenue and expenses and taking into account the stage of development of talimogene laherparepvec at the acquisition date, the time and resources needed to complete development and the probabilities of obtaining marketing approval from the FDA and other regulatory agencies. IPR&D intangible assets acquired in a business combination are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts.

The estimated incremental R&D costs to be incurred to obtain necessary regulatory approvals for talimogene laherparepvec are not material. The major risks and uncertainties associated with the timely and successful completion of development and commercialization of this product candidate include our ability to confirm its 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

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 of the acquired IPR&D may vary from its estimated fair value at the date of acquisition.

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

During the year ended December 31, 2011, 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 an interim 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 relating 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. The purchase price allocation for the Bergamo transaction is preliminary and will be finalized upon collection of information regarding certain tax-related items. 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.

Pro forma supplemental consolidated results of operations for the years ended December 31, 2011 and 2010, that assumes the acquisitions of BioVex, Bergamo, Dun Laoghaire and Hypermarcas all occurred on January 1, 2010, are not provided because the impact would not be material to our consolidated results of operations either individually or in the aggregate.

In addition to the increase in goodwill for the acquisitions of the businesses discussed above, goodwill decreased by $19 million for the year ended December 31, 2011, due to changes in foreign currency exchange rates.

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Stock-based compensation

Our 2009 Equity Incentive Plan (the 2009 Plan) provides for the grant of equity-based awards, including stock options, RSUs 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. The 2009 Plan authorizes the issuance of 100 million shares of our common stock. 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, 2011, the 2009 Plan provides for future grants and/or issuances of up to approximately 58 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, 2011, 2010 and 2009 (in millions):

	2011	2010	2009
Stock options	$ 85	$ 124	$ 115
Restricted stock units	188	182	134
Performance units	68	47	35
Total stock-based compensation expense, pre-tax	341	353	284
Tax benefit from stock-based compensation expense	(124)	(120)	(97)
Total stock-based compensation expense, net of tax	$ 217	$ 233	$ 187

Employee stock options and restricted stock units

Eligible employees generally receive a grant of stock options and/or 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. Our stock option and RSU 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 retirement of employees who meet certain service and/or age requirements. Stock options and RSUs 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.

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.

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

We use an option valuation model to estimate the grant date fair value of our employee stock options. The weighted-average assumptions used in the option valuation model and the resulting weighted-average estimated grant date fair values of our employee stock options were as follows for the years ended December 31, 2011, 2010 and 2009:

	2011	2010	2009
Closing price of our common stock on grant date	$ 54.66	$ 58.32	$ 50.65
Expected volatility	23.5%	28.0%	39.6%
Expected life (in years)	5.9	6.6	4.6
Risk-free interest rate	2.5%	3.2%	2.1%
Expected dividend yield	2.0%	0%	0%
Fair value of stock options granted	$ 11.39	$ 20.97	$ 18.35

The expected volatility reflects the 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, 2011:

	Options (in millions)	Weighted-average exercise price	Weighted-average remaining contractual life (years)	Aggregate intrinsic value (in millions)
Balance unexercised at December 31, 2010	46.8	$ 58.66		
Granted	2.3	$ 54.66		
Exercised	(5.0)	$ 50.22		
Expired/forfeited	(9.9)	$ 60.43		
Balance unexercised at December 31, 2011	34.2	$ 59.11	3.8	$ 245
Vested or expected to vest at December 31, 2011	33.8	$ 59.15	3.7	$ 242
Exercisable at December 31, 2011	23.6	$ 61.49	2.3	$ 135

The total intrinsic value of options exercised during the three years ended December 31, 2011, 2010 and 2009, was $47 million, $15 million and $57 million, respectively.

Restricted stock units

The fair value of an RSU granted prior to April 25, 2011, is equal to the closing price of our common stock on the grant date. The fair values of RSUs granted on and after April 25, 2011, are based on the closing price of our common stock on the grant date reduced by the weighted average expected dividend yield of 1.9% over the weighted-average vesting period, discounted at a weighted-average risk-free interest rate of 1.0%. The weighted-

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average grant date fair values of RSUs granted in 2011, 2010 and 2009 were $51.83, $58.19 and $51.24, respectively. The following summarizes select information regarding our RSUs during the year ended December 31, 2011:

	Units (in millions)	Weighted-average grant date fair value
Balance nonvested at December 31, 2010	9.3	$ 52.67
Granted	4.0	$ 51.83
Vested	(3.4)	$ 52.06
Forfeited	(0.9)	$ 52.77
Balance nonvested at December 31, 2011	9.0	$ 52.64

The total fair values of shares associated with RSUs that vested during the year ended December 31, 2011, 2010 and 2009, were $176 million, $184 million and $139 million, respectively.

As of December 31, 2011, there was approximately $407 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 performance goals over the performance period, which is generally three years. The performance goals for the units granted in 2011, 2010 and 2009, which are accounted for as equity awards, are based upon Amgen s annual 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 and 2009, Amgen s standalone financial performance, which are considered performance conditions. The expense recognized for the awards granted in 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 and 2009 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.

We used payout simulation models to estimate the grant date fair value of performance units granted in 2011, 2010 and 2009. 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, 2011, 2010 and 2009:

	2011	2010	2009
Closing price of our common stock on grant date	$ 51.67	$ 56.90	$ 47.63

Volatility	32.8%	34.7%	34.3%
Risk-free interest rate	1.2%	1.3%	1.2%
Expected dividend yield	0.1%	0%	0%
Fair value of unit	$ 49.50	$ 62.06	$ 48.22

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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, 2011 and 2010, a total of 4.1 million and 2.7 million performance units were outstanding with weighted-average grant date fair values of $51.92 and $49.49 per unit, respectively. During the year ended December 31, 2011, 2.5 million performance units with a weighted average grant date fair value of $49.50 were granted, 0.4 million performance units with a grant date fair value of $48.22 vested and 0.2 million performance units with a weighted-average grant date fair value of $52.70 were forfeited.

The total fair values of performance units that vested during 2011, 2010 and 2009 were $25 million, $34 million and $29 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. Performance unit awards granted for performance periods that ended prior to 2009 were accounted for as liability awards and were paid in the year after the performance period ended. Performance unit liability awards paid in 2009 aggregated $30 million.

As of December 31, 2011, there was approximately $90 million of unrecognized compensation cost related to the 2011 and 2010 performance unit grants that is expected to be recognized over a weighted-average period of approximately 1.1 years.

4. Income taxes

The provision for income taxes includes the following for the years ended December 31, 2011, 2010 and 2009 (in millions):

	2011	2010	2009
Current provision:			
Federal	$ 618	$ 636	$ 325
State	58	52	85
Foreign	148	153	155
Total current provision	824	841	565
Deferred (benefit) provision:			
Federal	(340)	(196)	92
State	(16)	43	(59)
Foreign	(1)	2	1
Total deferred (benefit) provision	(357)	(151)	34
Total provision	$ 467	$ 690	$ 599

Deferred income taxes reflect the 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 carryforwards.

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Significant components of our deferred tax assets and liabilities are as follows as of December 31, 2011 and 2010 (in millions):

	2011	2010
Deferred income tax assets:		
Intercompany inventory related items	$ 387	$ 306
Expense accruals	751	626
Acquired net operating loss and credit carryforwards	192	147
Expenses capitalized for tax	167	188
Stock-based compensation	241	269
Deferred revenue	133	117
Other	72	72
Total deferred income tax assets	1,943	1,725
Valuation allowance	(126)	(80)
Net deferred income tax assets	1,817	1,645
Deferred income tax liabilities:		
Acquired intangibles	(832)	(739)
Fixed assets	(219)	(181)
Unremitted foreign earnings	(61)	(118)
Other	(110)	(142)
Total deferred income tax liabilities	(1,222)	(1,180)
Total deferred income taxes, net	$ 595	$ 465

The valuation allowance for deferred tax assets increased by $46 million in 2011, due primarily to valuation allowances established as part of the BioVex and Dun Laoghaire 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 the expiration of state investment credits. The valuation allowance for deferred tax assets decreased by $12 million in 2010, due primarily to the utilization and expiration of certain acquired net operating loss carryforwards. Valuation allowances are provided when we believe our deferred tax assets are not recoverable based on an assessment of estimated future taxable income that incorporates ongoing, prudent and feasible tax planning strategies.

At December 31, 2011, we had $44 million of tax credit carryforwards available to reduce future federal income taxes for which a full valuation allowance has been provided. In addition, we had $176 million of tax credit carryforwards available to reduce future state income taxes and have provided a valuation allowance for $67 million of those state tax credit carryforwards. The majority of the state tax credit carryforwards have no expiry; the remainder expires between 2012 and 2025.

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, 2011, 2010 and 2009, is as follows (in millions):

	2011	2010	2009
Balance at beginning of year	$ 920	$ 1,140	$ 1,113
Additions based on tax positions related to the current year	283	305	302
Reductions for tax positions of prior years	(7)	(110)	(215)
Settlements	(221)	(415)	(60)
Balance at end of year	$ 975	$ 920	$ 1,140

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Substantially all of the UTBs as of December 31, 2011, if recognized, would affect our effective tax rate.

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.

During the year ended December 31, 2009, we settled the examination of our U.S. income tax returns with the IRS for certain matters, primarily related to transfer pricing tax positions, for the years ended December 31, 2005 and 2006. Also during the year ended December 31, 2009, we settled the examination of our California state income tax returns for certain matters for the years ended December 31, 2004 and 2005. As a result of these developments, we remeasured our UTBs accordingly.

As of December 31, 2011, we believe it is reasonably possible that our gross liabilities for UTBs may decrease by approximately $270 million within the succeeding twelve months due to the resolution of federal and state audits.

Interest and penalties related to UTBs are included in our provision for income taxes. During 2011, 2010 and 2009, we accrued approximately $23 million, $41 million and $57 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. At December 31, 2011 and 2010, accrued interest and penalties associated with UTBs totaled approximately $105 million and $90 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, 2011, 2010 and 2009, is as follows:

	2011	2010	2009
Federal statutory tax rate	35.0 %	35.0 %	35.0 %
Foreign earnings, including earnings invested indefinitely	(19.4)%	(19.1)%	(19.6)%
State taxes	0.7 %	1.6 %	1.1 %
Credits, Puerto Rico Excise Tax	(6.5)%	0.0 %	0.0 %
Credits, primarily research and experimentation	(1.5)%	(0.9)%	(0.8)%
Legal settlements	2.2 %	0.0 %	0.0 %
Audit settlements	0.0 %	(3.1)%	(4.2)%
Other, net	0.8 %	(0.5)%	0.0 %
Effective tax rate	11.3 %	13.0 %	11.5 %

We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be invested indefinitely outside of 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, 2011, the

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cumulative amount of these earnings was approximately $19.5 billion. If these earnings were repatriated to the United States, we would be required to accrue and pay approximately $6.9 billion of additional income taxes based on the current tax rates in effect.

Our total foreign income before income taxes was approximately $2.6 billion, $3.1 billion and $3.1 billion for the years ended December 31, 2011, 2010 and 2009, respectively.

Commencing January 1, 2011, Puerto Rico imposes a temporary excise tax on the acquisition of goods and services from a related manufacturer in Puerto Rico. The excise tax is imposed over 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). 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.

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, 2006, or to California state income tax examinations for tax years ending on or before December 31, 2003.

Income taxes paid during the years ended December 31, 2011, 2010 and 2009, totaled $595 million, $1,344 million and $497 million, respectively.

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 principally include: shares that may be issued under our stock option, RSU 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.

Upon conversion of our convertible notes, the principal amount would be settled in cash, and the excess of the conversion value, as defined, over the principal amount may be settled in cash and/or shares of our common stock. 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 years ended December 31, 2011, 2010 and 2009, the conversion values for 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.

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The computation for basic and diluted EPS was as follows (in millions, except per share data):

	2011	2010	2009
Income (Numerator):			
Net income for basic and diluted EPS	$ 3,683	$ 4,627	$ 4,605
Shares (Denominator):			
Weighted-average shares for basic EPS	905	960	1,016
Effect of dilutive securities	7	5	5
Weighted-average shares for diluted EPS	912	965	1,021
Basic EPS	$ 4.07	$ 4.82	$ 4.53
Diluted EPS	$ 4.04	$ 4.79	$ 4.51

For the years ended December 31, 2011, 2010 and 2009, there were employee stock-based awards, calculated on a weighted-average basis, to purchase 33 million, 43 million and 42 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. These arrangements involve 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, regulatory and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration agreements are performed on a best efforts basis 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 of 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 agreement in the fourth quarter of 2013, we will be required to pay Pfizer 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.

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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, 2011, 2010 and 2009, ENBREL sales aggregated $3.7 billion, $3.5 billion and $3.5 billion, respectively.

During the years ended December 31, 2011, 2010 and 2009, the ENBREL profit share expense was $1,288 million, $1,184 million and $1,163 million, respectively, and is included in Selling, general and administrative expense in the Consolidated Statements of Income. In addition, cost recoveries from Pfizer for their share of the selling and marketing expense were $84 million, $87 million and $75 million for the years ended December 31, 2011, 2010 and 2009, respectively, and 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. In the future, 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, 2011 and 2010, product sales in the Primary Territories for osteoporosis indications were $62 million and $5 million, respectively. In the Expansion Territories, we record product sales to Glaxo. During the years ended December 31, 2011 and 2010, product sales of denosumab to Glaxo for the Expansion Territories were not material.

During the years ended December 31, 2011, 2010 and 2009, the net recoveries from Glaxo were $30 million, $46 million and $29 million, respectively, and are included in Selling, general and administrative expense in the Consolidated Statements of Income. In addition, during 2010, we received payments aggregating $75 million for the achievement of certain commercial milestones, which were recognized upon the achievement of the related milestone events as Other revenue in our Consolidated Statement of Income. Under these agreements, we also received an initial payment of $45 million during the year ended December 31, 2009, which was deferred and is being recognized as Other revenue in our Consolidated Statements of Income, over our estimated period of continuing involvement of approximately 13 years.

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Takeda Pharmaceutical Company Limited

We are in a collaboration with Takeda Pharmaceutical Company Limited (Takeda), which provides Takeda 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 for the worldwide development and commercialization of our product candidate, motesanib, in the oncology area. The Japanese market products include: (i) Vectibix®, which received regulatory approval in Japan, in 2010, for unresectable, advanced or recurrent colorectal cancer with wild-type *KRAS*, (ii) AMG 386, which is in a phase 3 trial for recurrent ovarian cancer, and (iii) ganitumab (AMG 479), which is in a phase 3 trial for first-line metastatic pancreatic cancer. Through collaboration committees, the parties jointly coordinate and oversee Takeda s development and commercialization of the Japanese market products in Japan. The parties share responsibility for the development of motesanib outside Japan and Takeda is responsible for development in Japan. Additionally, Amgen shall be responsible for commercialization of motesanib in North America and Takeda shall be responsible for commercialization outside of North America. Each party has the right to participate in the commercialization of motesanib in the other party s territory. In addition, under the collaboration Amgen will manufacture and supply Takeda motesanib and the Japanese market products for both clinical and commercial purposes. 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.

For the Japanese market products Takeda is obligated to pay Amgen up to an additional $60 million of future worldwide development costs for these products in 2012 and a reduced amount of such costs, thereafter. Takeda will be solely responsible for all development and commercialization costs of these products in Japan and will pay Amgen royalties on future sales in Japan. Amgen has the right to participate in the promotion of these products in Japan. With respect to motesanib, Takeda is obligated to pay 60% of future worldwide development costs (excluding Japan, for which Takeda shall bear all such costs), and the parties will share equally all other costs and profits resulting from the commercialization of motesanib outside Japan. If approved for sale, Amgen will receive royalties on future sales of motesanib in Japan.

The collaboration agreements will continue in effect unless terminated earlier in accordance with their terms.

In connection with the collaboration, Amgen received upfront payments of $300 million in 2008 which were deferred and are being recognized as Other revenue in our Consolidated Statements of Income, over our 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 revenue in our Consolidated Statement of Income upon the achievement of the related milestone events. We may also receive numerous individually immaterial milestones aggregating $472 million upon the achievement of various substantive success-based development and regulatory approval milestones. The receipt of these amounts, however, is contingent upon the occurrence of various future events which have a high degree of uncertainty of occurring.

During the years ended December 31, 2011, 2010 and 2009, cost recoveries from Takeda were $83 million, $91 million and $112 million, respectively, and are included in Research and development expense in the Consolidated Statements of Income. In addition, for the years December 31, 2011 and 2010, we recognized royalties on sales of Vectibix® in Japan of $20 million and $7 million, respectively.

Daiichi Sankyo Company, Limited

We are in a collaboration with Daiichi Sankyo Company, Limited (Daiichi Sankyo), which provides Daiichi Sankyo the exclusive rights to develop and commercialize denosumab in Japan for osteoporosis, oncology and

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certain other indications. As part of the agreement, Amgen received exclusive worldwide rights to certain Daiichi Sankyo intellectual property to the extent applicable to denosumab. Through collaboration committees, the parties jointly coordinate and oversee Daiichi Sankyo s development and commercialization of denosumab in Japan.

Under the terms of the agreement, Daiichi Sankyo assumed all related development and commercialization costs in Japan and agreed to reimburse Amgen for certain worldwide development costs related to denosumab. As of December 31, 2009, Daiichi Sankyo had substantially satisfied its obligations to reimburse Amgen for these costs. If approved for sale, Amgen will receive royalties on future sales of denosumab recorded by Daiichi Sankyo in Japan.

Pursuant to the terms of the agreement, we paid Daiichi Sankyo milestone payments aggregating $60 million, in 2010, as a result of various regulatory approvals of denosumab. The milestone payments were capitalized within Intangible assets, net in the Consolidated Balance Sheets and are being amortized over 11 years and the amortization expense is included in Cost of sales (excludes amortization of certain acquired intangible assets) in the Consolidated Statements of Income.

The collaboration agreement will expire in 2027 unless terminated earlier in accordance with its terms.

During the years ended December 31, 2011, 2010 and 2009, cost recoveries from Daiichi Sankyo were $4 million, $3 million and $64 million, respectively. The cost recoveries are included in Research and development expense in the Consolidated Statements of Income.

Other

We have various other collaborations, in addition to those discussed above, 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, regulatory 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. For the years ended December 31, 2011, 2010 and 2009, our share of K-A s profits was $47 million, $71 million and $72 million, respectively. During 2009, we received $110 million in dividends from K-A. At both December 31, 2011 and 2010, 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.

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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. (Roche) under separate product license contracts for certain geographic areas outside of the United States. During the years ended December 31, 2011, 2010 and 2009, K-A earned royalties from us of $298 million, $322 million and $327 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, 2011, 2010 and 2009, we earned revenues from K-A of $130 million, $96 million and $102 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 $125 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, 2011, 2010 and 2009, we recorded cost recoveries from K-A of $85 million, $88 million and $96 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, 2011 and 2010, we owed K-A $75 million and $62 million, respectively, which are included in Accrued liabilities in the Consolidated Balance Sheets.

8. Cost savings initiatives and restructuring

Manufacturing operations optimization

As part of our continuing efforts to optimize our network of manufacturing facilities and improve cost efficiencies, 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 was approved by Amgen s Board of Directors in December 2010 and closed in March 2011. In connection with the closing of this transaction, BI has assumed our obligations under certain of the facility s operating lease contracts and has 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).

We considered the transaction with BI to be a potential indicator of impairment, and accordingly, we performed an impairment analysis of the carrying values of the related fixed assets as of December 31, 2010. Based on this analysis, we determined that no future economic benefit would be received from a manufacturing line at the facility that had not yet been completed. As a result, 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. The carrying values of the remaining fixed assets, aggregating approximately $133 million at December 31, 2010, were determined to be fully recoverable.

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 continue to be carried on our Consolidated Balance Sheets.

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As a result of this transaction, we reduced the estimated useful lives of the remaining fixed assets to coincide with the supply period. During the year ended December 31, 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 presented separately) in the Consolidated Statement of Income.

Other cost savings initiatives

As part of our continuing efforts to improve cost efficiencies in our operations, we recorded certain charges, primarily severance-related, aggregating approximately $109 million during the year ended December 31, 2011, which are included in Other operating expenses in the Consolidated Statement of Income.

Restructuring

On August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure. This restructuring plan was primarily the result of regulatory and reimbursement developments that began in 2007 involving erythropoiesis-stimulating agents (ESAs), including our marketed ESAs, Aranesp® and EPOGEN®, and the resulting impact on our operations. As of December 31, 2009, we completed all of the actions included in our restructuring plan and subsequently identified initiatives. During the year ended December 31, 2009, we recorded charges associated with these actions aggregating $70 million, comprised primarily of staff separation costs of $25 million, included principally in Other operating expenses in the Consolidated Statement of Income, and integration-related costs of $32 million, which were included principally in Selling, general and administrative expenses in the Consolidated Statement of Income.

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, 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:				
Obligations of U.S. government agencies and FDIC-guaranteed bank debt	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
Mortgage- and asset-backed securities	1,789	6	(10)	1,785
Money market mutual funds	6,266			6,266
Total debt security investments	19,772	224	(35)	19,961
Equity securities	42			42

Total available-for-sale investments	$ 19,814	$ 224	$ (35)	$ 20,003

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Type of security as of December 31, 2010	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. Treasury securities	$ 5,044	$ 50	$ (14)	$ 5,080
Other government-related debt securities:				
Obligations of U.S. government agencies and FDIC-guaranteed bank debt	2,158	51	(1)	2,208
Foreign and other	837	16	(1)	852
Corporate debt securities:				
Financial	2,252	53	(9)	2,296
Industrial	2,441	71	(5)	2,507
Other	307	10	(1)	316
Mortgage- and asset-backed securities	841	5	(5)	841
Money market mutual funds	3,030			3,030
Other short-term interest-bearing securities	147			147
Total debt security investments	17,057	256	(36)	17,277
Equity securities	50		(2)	48
Total available-for-sale investments	$ 17,107	$ 256	$ (38)	$ 17,325

The fair values of available-for-sale investments by classification in the Consolidated Balance Sheets were as follows as of December 31, 2011 and 2010 (in millions):

Classification in the Consolidated Balance Sheets	2011	2010
Cash and cash equivalents	$ 6,266	$ 3,142
Marketable securities	13,695	14,135
Other assets noncurrent	42	48
Total available-for-sale investments	$ 20,003	$ 17,325

Cash and cash equivalents in the table above excludes cash of $680 million and $145 million as of December 31, 2011 and 2010, respectively.

The fair values of available-for-sale debt security investments by contractual maturity were as follows as of December 31, 2011 and 2010 (in millions):

Contractual maturity	2011	2010
Maturing in one year or less	$ 6,811	$ 4,118
Maturing after one year through three years	6,346	6,736
Maturing after three years through five years	5,710	5,812
Maturing after five years	1,094	611

Total debt securities	$ 19,961	$ 17,277

For the years ended December 31, 2011, 2010 and 2009, realized gains totaled $191 million, $115 million and $104 million, respectively, and realized losses totaled $37 million, $25 million and $62 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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, 2011 and 2010, 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, 2011 and 2010 (in millions):

	2011	2010
Raw materials	$ 158	$ 128
Work in process	1,802	1,382
Finished goods	524	512
Total inventories	$ 2,484	$ 2,022

11. Property, plant and equipment

Property, plant and equipment consisted of the following as of December 31, 2011 and 2010 (dollar amounts in millions):

	Useful life (in years)	2011	2010
Land		$ 366	$ 361
Buildings and improvements	10-40	3,463	3,392
Manufacturing equipment	8-12	1,897	1,802
Laboratory equipment	8-12	1,016	955
Other	3-15	3,745	3,547
Construction in progress		744	631
Property, plant and equipment, gross		11,231	10,688
Less accumulated depreciation and amortization		(5,811)	(5,166)
Property, plant and equipment, net		$ 5,420	$ 5,522

During the years ended December 31, 2011, 2010 and 2009, we recognized depreciation and amortization charges associated with our property, plant and equipment of $679 million, $594 million and $624 million, respectively.

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12. Intangible assets

Finite-lived and indefinite-lived identifiable intangible assets consisted of the following as of December 31, 2011 and 2010 (in millions):

	2011			2010		
	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	$ (1,811)	$ 1,061	$ 2,872	$ (1,619)	$ 1,253
Core technology	1,348	(850)	498	1,348	(760)	588
Trade name	190	(120)	70	190	(107)	83
Acquired R&D technology rights	350	(350)		350	(329)	21
Other acquired intangible assets	686	(406)	280	627	(342)	285
Total finite-lived intangible assets	5,446	(3,537)	1,909	5,387	(3,157)	2,230
Indefinite-lived intangible assets IPR&D	675		675			
Total identifiable intangible assets	$ 6,121	$ (3,537)	$ 2,584	$ 5,387	$ (3,157)	$ 2,230

Amortization of finite-lived intangible assets is provided over their estimated useful lives ranging from 5 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 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 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, 2011, 2010 and 2009, we recognized amortization charges associated with our finite-lived intangible assets of $380 million, $423 million and $425 million, respectively. The total estimated amortization for each of the next five years for our intangible assets is $354 million, $359 million, $340 million, $327 million and $317 million in 2012, 2013, 2014, 2015 and 2016, respectively.

IPR&D relates to identifiable intangible assets acquired in connection with the acquisition of BioVex. (See Note 2, Business combinations BioVex Group, Inc.)

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13. Accrued liabilities

Accrued liabilities consisted of the following as of December 31, 2011 and 2010 (in millions):

	2011	2010
Sales deductions	$ 1,326	$ 1,144
Employee compensation and benefits	916	764
Sales returns reserve	339	339
Legal reserve	780	
Other	1,667	1,119
Total accrued liabilities	$ 5,028	$ 3,366

See Note 18, Contingencies and commitments, for further discussion of the legal reserve.

14. Financing arrangements

The carrying values and the fixed contractual coupon rates of our long-term borrowings were as follows as of December 31, 2011 and 2010 (in millions):

	2011	2010
0.125% convertible notes due 2011 (0.125% 2011 Convertible Notes)	$	$ 2,488
0.375% convertible notes due 2013 (0.375% 2013 Convertible Notes)	2,346	2,213
1.875% notes due 2014 (1.875% 2014 Notes)	1,000	
4.85% notes due 2014 (4.85% 2014 Notes)	1,000	1,000
2.30% notes due 2016 (2.30% 2016 Notes)	748	
2.50% notes due 2016 (2.50% 2016 Notes)	999	
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)	714	
5.70% notes due 2019 (5.70% 2019 Notes)	998	998
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	
3.875% notes due 2021 (3.875% 2021 Notes)	1,745	
5.50% pound sterling denominated notes due 2026 (5.50% 2026 pound sterling Notes)	739	
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	696
4.95% notes due 2041 (4.95% 2041 Notes)	595	595

5.15% notes due 2041 (5.15% 2041 Notes)	2,232	
5.65% notes due 2042 (5.65% 2042 Notes)	1,244	
Other notes, including our zero-coupon convertible notes	184	183
Total debt	21,428	13,362
Less current portion	(84)	(2,488)
Total noncurrent debt	$ 21,344	$ 10,874

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Debt repayments

In February 2011, our 0.125% 2011 Convertible Notes became due, and we repaid the $2.5 billion aggregate principal amount. As 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. The total aggregate amount repaid, including the amount related to the debt discount of $643 million resulting from the bifurcation, is included in Cash flows from financing activities in the Consolidated Statement of Cash Flows. No debt was due or repaid in 2010, and we repaid $1.0 billion aggregate principal amount of notes with a fixed interest rate of 4.00% in 2009.

Debt issuances

We issued debt securities in various offerings during the three years ended December 31, 2011, including:

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.

In 2009, we issued $2.0 billion aggregate principal amount of notes, comprised of the 5.70% 2019 Notes and the 6.40% 2039 Notes. Debt issuance costs incurred in connection with these debt offerings in 2011, 2010 and 2009 totaled $55 million, $17 million and $13 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 0.375% 2013 Convertible Notes and 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 0.375% 2013 Convertible Notes, the 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. While outstanding, the notes are convertible into shares of our common stock upon the occurrence of specified events. In February 2011, $2.5 billion principal amount of the convertible notes (the 0.125% 2011 Convertible Notes) became due and were repaid in full. While outstanding, the conversion rate on the 0.125% 2011 Convertible Notes was 12.5247 shares per $1,000 principal amount of notes, which represented a conversion price of approximately $79.84 per share. The conversion rate on the $2.5 billion principal amount of convertible notes, which mature in February 2013 (the 0.375% 2013 Convertible Notes), was 12.7473 shares per $1,000 principal amount of notes at December 31, 2011, which represents a conversion price of approximately $78.45 per share. This conversion rate is adjusted as we make specified types of distributions, including paying cash dividends on our common stock, or enter into

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certain other transactions with respect to our common stock. The 0.375% 2013 Convertible Notes may only be converted: (i) during any calendar quarter if the closing price of our common stock exceeds 130% of the then conversion price per share during a defined period at the end of the previous quarter, (ii) if we make specified distributions to holders of our common stock or specified corporate transactions occur 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 period following the conversion date. The conversion value will be paid 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 exceeds the principal amount of the note (the excess conversion value). In addition, upon a change in control, as defined, the holders may require us to purchase for cash all or a portion of their notes for the principal amount of the notes plus accrued interest. As of December 31, 2011, the 0.375% 2013 Convertible Notes were not convertible. While outstanding, the 0.125% 2011 Convertible Notes had terms similar to the 0.375% 2013 Convertible Notes.

Concurrent with the issuance of the 0.375% 2013 Convertible Notes, we purchased a convertible note hedge. The convertible note hedge allows 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. This convertible note hedge will terminate at the earlier of the maturity of the 0.375% 2013 Convertible Notes or the first day none of these notes remain outstanding due to conversion or otherwise. 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) at an exercise price of $107.90 per share. 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 can be settled at our option in cash or shares of our common stock, and these contracts meet 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.

As required for cash settleable convertible notes, the debt and equity components of the 0.375% 2013 Convertible Notes were bifurcated and accounted for separately. The resulting discounted carrying value of the debt is being accreted back to the principal amount through the scheduled maturity date, resulting in the recognition of non-cash interest expense. After giving effect to this bifurcation, the effective interest rate on this borrowing is 6.35%. For the years ended December 31, 2011, 2010 and 2009, total interest expense for the 0.375% 2013 Convertibles Notes was $143 million, $134 million, and $127 million, respectively, including non-cash interest expense of $133 million, $125 million, and $118 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, 2010 and 2009, total interest expense for the 0.125% 2011 Convertible Notes was $13 million, $149 million, and $140 million, respectively, including non-cash interest expense of $12 million, $146 million, and $136 million, respectively.

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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, 2011 and 2010 (in millions):

	Liability component			Equity component
0.375% 2013 Convertible Notes	**Principal balance**	**Unamortized discount**	**Net carrying amount**	**Net carrying amount**
December 31, 2011	$ 2,500	$ 154	$ 2,346	$ 829
December 31, 2010	$ 2,500	$ 287	$ 2,213	$ 829

Other

Other notes include zero-coupon convertible notes due in 2032 with a carrying value of $84 million and $83 million at December 31, 2011 and 2010, respectively, and notes due in 2097 with a carrying value of $100 million.

Interest rate swaps

To achieve a desired mix of fixed and floating interest rate debt, we enter into interest rate swap contracts that effectively convert 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 qualify and are designated as fair value hedges. The effective interest rates on these notes after giving effect to the related interest rate swap contracts and the notional amounts of these interest rate swap contracts were as follows as of December 31, 2011 and 2010 (dollar amounts in millions):

		Notional amount	
	Effective interest rate	**2011**	**2010**
4.85% 2014 Notes	LIBOR + 0.3%	$ 1,000	$ 1,000
5.85% 2017 Notes	LIBOR + 2.5%	1,100	1,100
6.15% 2018 Notes	LIBOR + 1.8%	500	500
5.70% 2019 Notes	LIBOR + 2.6%	1,000	1,000
		$ 3,600	$ 3,600

Cross currency swaps

In order to hedge our exposure to foreign currency exchange rate risk associated with our pound sterling denominated long-term notes issued in 2011, we entered into cross currency swap contracts. These cross currency swap contracts qualify and are designated as cash flow hedges. Under the terms of these contracts, we receive interest payments in pounds sterling at a fixed rate of 5.5% on £475 million and pay interest in U.S. dollars at a fixed rate of 5.8% on $748 million, the aggregate notional amounts paid to/received from the counterparties upon exchange of currencies at the inception of these contracts. We will pay U.S. dollars to and receive pounds sterling from the counterparties at the maturity of the contracts for the 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 pounds sterling to U.S. dollars.

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Shelf registration statements and other facilities

As of December 31, 2011, 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, 2011 and 2010, 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. We would be charged interest at LIBOR plus 0.9% for any amounts borrowed under this facility. As of December 31, 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, 2011 and 2010, 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, 2011.

Contractual maturities of long-term debt obligations

The aggregate contractual maturities of all long-term debt obligations due subsequent to December 31, 2011, are as follows (in millions):

Maturity date	Amount
2012[1]	$ 84
2013[2]	2,500
2014	2,000
2015	
2016	1,750
Thereafter	15,312
Total	$ 21,646

(1) This amount represents the accreted value of our zero-coupon convertible notes due in 2032 which will be redeemed on March 1, 2012.

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(2) This amount represents the 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 expense, net, for the years ended December 31, 2011, 2010 and 2009, was $610 million, $604 million and $578 million, respectively. Interest costs capitalized for the years ended December 31, 2011, 2010 and 2009, were $22 million, $33 million and $32 million, respectively. Interest paid, net of interest rate swaps, during the years ended December 31, 2011, 2010 and 2009, totaled $446 million, $323 million and $293 million, respectively.

15. Stockholders equity

Stock repurchase program

Activity under our stock repurchase program was as follows for the years ended December 31, 2011, 2010 and 2009 (in millions):

	2011		2010		2009	
	Shares	Dollars	Shares	Dollars	Shares	Dollars
First quarter		$	29.1	$ 1,684	37.5	$ 1,997
Second quarter	12.9	732	10.3	616		
Third quarter	45.4	2,421	6.6	364		
Fourth quarter	86.0	5,154[1]	20.5	1,136	21.7	1,211
Total stock repurchases	144.3	$ 8,307	66.5	$ 3,800	59.2	$ 3,208

(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 April 2011, the Board of Directors authorized us to repurchase up to an additional $5.0 billion of our common stock under our stock repurchase program, and in October 2011, the Board of Directors further increased the total authorization for stock repurchases by $6.1 billion to $10.0 billion. As of December 31, 2011, $5.0 billion remained available under the program.

In July and October 2011, the Board of Directors declared quarterly cash dividends of $0.28 per share of common stock, which were paid in September and December 2011, respectively. Additionally, on December 15, 2011, the Board of Directors declared a quarterly cash dividend of $0.36 per share of common stock, which will be paid on March 7, 2012, to all stockholders of record as of the close of business on February 15, 2012.

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Accumulated other comprehensive income

The components of Accumulated Other Comprehensive Income (AOCI) are as follows for the years ended December 31, 2011, 2010 and 2009 (in millions):

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2008	$ 25	$ 50	$ 49	$ (7)	$ 117
Foreign currency translation adjustments	25				25
Unrealized (losses) gains		(213)	116	(12)	(109)
Reclassification adjustments to income		8	(42)		(34)
Other				5	5
Income taxes	(10)	73	(28)	6	41
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

Income tax expense or benefit for unrealized gains and losses and the related reclassification adjustments to income for cash flow hedges was a $20 million benefit and $41 million expense in 2011, a $71 million expense and $16 million benefit in 2010 and a $76 million benefit and $3 million expense in 2009, respectively. Income tax expense/benefit for unrealized gains and losses and the related reclassification adjustments to income for available-for-sale securities was a $45 million expense and $59 million benefit for 2011, a $60 million expense and $35 million benefit in 2010 and a $44 million expense and $16 million benefit in 2009, 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, 2011 and 2010, no shares of preferred stock were issued or outstanding.

16. Fair value measurement

To determine 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

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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, 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:				
Obligations of U.S. government agencies and FDIC-guaranteed bank debt		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
Mortgage- and asset-backed securities		1,785		1,785
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

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Fair value measurement as of December 31, 2010, 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	$ 5,080	$	$	$ 5,080
Other government-related debt securities:				
Obligations of U.S. government agencies and FDIC-guaranteed bank debt		2,208		2,208
Foreign and other		852		852
Corporate debt securities:				
Financial		2,296		2,296
Industrial		2,507		2,507
Other		316		316
Mortgage- and asset-backed securities		841		841
Money market mutual funds	3,030			3,030
Other short-term interest-bearing securities		147		147
Equity securities	48			48
Derivatives:				
Foreign currency contracts		154		154
Interest rate swap contracts		195		195
Total assets	$ 8,158	$ 9,516	$	$ 17,674
Liabilities:				
Derivatives:				
Foreign currency contracts	$	$ 103	$	$ 103
Total liabilities	$	$ 103	$	$ 103

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.

Substantially all 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 AA+ by Standard & Poor s (S&P) and AAA or equivalent by Moody s Investors Service, Inc. (Moody s) or Fitch, Inc. (Fitch); and our corporate debt securities portfolio has a weighted-average credit rating of A- by S&P and A 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; and other observable inputs.

Our mortgage and asset backed securities portfolio is composed entirely of senior tranches, with credit ratings of AAA 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

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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 a minimum credit rating 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, 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. As of December 31, 2011 and 2010, we had open foreign currency forward contracts with notional amounts of $3.5 billion and $3.2 billion, respectively, and open foreign currency option contracts with notional amounts of $292 million and $398 million, respectively, that were primarily euro-based and were designated as cash flow hedges. In addition, as of December 31, 2011 and 2010, we had $389 million and $670 million, respectively, of open foreign currency forward contracts to reduce exposure to fluctuations in value of certain assets and liabilities denominated in foreign currencies that were primarily euro-based and that were not designated as hedges. (See Note 17, Derivative instruments.)

Our interest rate and cross currency swap contracts are with counterparties that have a minimum credit rating 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, swap rates, obligor credit default swap rates and cross currency basis swap spreads. We had interest rate swap contracts with an aggregate notional amount of $3.6 billion as of December 31, 2011 and 2010, that were designated as fair value hedges. We had cross currency swap contracts on all of our 5.50% 2026 pound sterling Notes as of December 31, 2011, that were designated as cash flow hedges. (See Note 17, Derivative instruments.)

Contingent consideration obligations in connection with a business combination result from our acquisition of BioVex in March 2011. The fair value measurements of these obligations are based on significant unobservable inputs, and accordingly, such amounts are considered Level 3 measurements. There were no changes in assumptions that had a material impact on the estimated fair values of these obligations during the period from the acquisition date to December 31, 2011, and accordingly, there was no significant impact on net income for this period. For a description of the valuation methodology and related assumptions used for estimating the fair values of these obligations, see Note 2, Business combinations.

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, 2011 and 2010, of assets and liabilities that are not measured at fair value on a recurring basis, except as discussed in Note 8, Cost savings initiatives and restructuring, regarding an impairment of fixed assets that we recognized in 2010.

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.

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Borrowings

We estimate the fair values of our convertible notes 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 (Level 2). The fair value of our convertible notes represent only the liability components of these instruments, as 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 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; and other observable inputs (Level 2). As of December 31, 2011 and 2010, the aggregate fair values of our long-term debt were $23.0 billion and $14.5 billion, respectively, and the carrying values were $21.4 billion and $13.4 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 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 or 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 primarily 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, 2011, 2010 and 2009, we had open foreign currency forward contracts with notional amounts of $3.5 billion, $3.2 billion and $3.4 billion and open foreign currency option contracts with notional amounts of $292 million, $398 million and $376 million, respectively. These foreign currency forward and option contracts, primarily euro-based, have been designated as cash flow hedges, and accordingly, the effective portion 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.

In order to hedge our exposure to foreign currency exchange rate risk associated with our pound sterling denominated long-term notes issued in 2011, we entered into cross currency swap contracts. Under the terms of these contracts, we receive interest payments in pounds sterling at a fixed rate of 5.5% on £475 million and pay interest in U.S. dollars at a fixed rate of 5.8% on $748 million, the aggregate notional amounts paid to/received from the counterparties upon exchange of currencies at the inception of these contracts. We will pay U.S. dollars to and receive pounds sterling from the counterparties at the maturity of the contracts for the 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 pounds sterling to U.S. dollars. These cross currency

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swap contracts have been designated as cash flow hedges, and accordingly, the effective portion 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.

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 OCI for our derivative instruments designated as cash flow hedges was as follows (in millions):

	Years ended December 31,		
Derivatives in cash flow hedging relationships	**2011**	**2010**	**2009**
Foreign currency contracts	$ (25)	$ 191	$ (202)
Cross currency swap contracts	(26)		
Forward interest rate contracts		(5)	(11)
Total	$ (51)	$ 186	$ (213)

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 was as follows (in millions):

		Years ended December 31,		
Derivatives in cash flow hedging relationships	**Statements of Income location**	**2011**	**2010**	**2009**
Foreign currency contracts	Product sales	$ (108)	$ 47	$ (7)
Cross currency swap contracts	Interest and other income, net	(3)		
Forward interest rate contracts	Interest expense, net	(1)	(1)	(1)
Total		$ (112)	$ 46	$ (8)

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 gain for the year ended December 31, 2011, and approximately $1 million of loss for both the years ended December 31, 2010 and 2009. As of December 31, 2011, the amounts expected to be reclassified from AOCI into earnings over the next 12 months are approximately $75 million of net gains on 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 have entered into interest rate swap contracts, which qualify and have been designated as fair value hedges. The terms of these interest rate swap contracts correspond to the related hedged debt

instruments and effectively convert a fixed interest rate coupon to a floating LIBOR-based coupon over the lives of the respective notes. The rates on these swaps range from LIBOR plus 0.3% to LIBOR plus 2.6%. As of December 31, 2011, 2010 and 2009, we had interest rate swap contracts with aggregate notional amounts of $3.6 billion, $3.6 billion and $1.5 billion,

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respectively. The interest rate swap contracts as of December 31, 2011 and 2010, were for our 4.85% 2014 Notes, 5.85% 2017 Notes, 6.15% 2018 Notes and 5.70% 2019 Notes, and, as of December 31, 2009, for our 4.85% 2014 Notes and 6.15% 2018 Notes. 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. For the years ended December 31, 2011 and 2010, we included unrealized losses on the hedged debt of $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 $182 million and $105 million, respectively, on the related interest rate swap contracts. For the year ended December 31, 2009, we included the unrealized gain on the hedged debt of $116 million in the same line item, Interest expense, net, in the Consolidated Statement of Income, as the offsetting unrealized loss of $116 million on the related interest rate swap contracts.

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, 2011, 2010 and 2009, the total notional amounts of these foreign currency forward contracts, primarily euro-based, were $389 million, $670 million and $414 million, respectively.

The location in the Consolidated Statements of Income and the amount of gain/(loss) recognized in earnings for the derivative instruments not designated as hedging instruments was as follows (in millions):

		Years ended December 31,		
Derivatives not designated as hedging instruments	**Statements of Income location**	**2011**	**2010**	**2009**
Foreign currency contracts	Interest and other income, net	$ (1)	$ 32	$ (24)

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The fair values of both derivatives designated as hedging instruments and derivatives not designated as hedging instruments included in the Consolidated Balance Sheets were as follows (in millions):

	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

	Derivative assets		Derivative liabilities	
December 31, 2010	**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	$ 195	Accrued liabilities/ Other noncurrent liabilities	$
Foreign currency contracts	Other current assets/ Other noncurrent assets	154	Accrued liabilities/ Other noncurrent liabilities	103
Total derivatives designated as hedging instruments		349		103
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets		Accrued liabilities	
Total derivatives not designated as hedging instruments				
Total derivatives		$ 349		$ 103

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Our derivative contracts that were in liability positions as of December 31, 2011, 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, 2011, 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. As more fully described below, in the three months ended September 30, 2011, excluding fees paid to our external counsel, the Company recorded a $780 million legal settlement charge associated with the proposed settlement of the allegations arising out of the previously disclosed federal civil and criminal investigations pending in the U.S. Attorney s Offices for the Eastern District of New York and the Western District of Washington. The charge is included in Other operating expenses in the Consolidated Statements of Income.

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. Except for the proposed settlement of the litigation referenced above, 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, some pending matters have not yet 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. 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, including further adverse determinations associated with the pending investigations described above, 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:

Roche U.S. International Trade Commission Complaint

On April 11, 2006, Amgen filed a complaint with the U.S. International Trade Commission (ITC) in Washington D.C. requesting that the ITC institute an investigation of the importation of pegylated erythropoietin

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(alternatively referred to as peg-EPO or MIRCERA®) into the United States as Amgen believes that importation of peg-EPO is unlawful because peg-EPO, and the method of its manufacture, are covered by Amgen s EPO patents. Amgen asked the ITC to issue a permanent exclusion order that would prohibit importation of peg-EPO into the United States. The ITC instituted an investigation naming Roche Holding Ltd., F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively, Roche) as respondents in the investigation. On July 7, 2006, the Administrative Law Judge (ALJ) at the ITC issued a summary determination that Roche s importation and use of peg-EPO in the United States had been subject to a clinical trial exemption to patent infringement under 35 U.S.C. 271(e)(1). On August 31, 2006, the ITC adopted the ALJ s summary determination terminating the investigation.

On October 11, 2006, Amgen filed a petition for review of the ITC s decision with the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court). On March 19, 2008, the Federal Circuit Court reversed the ITC s dismissal of the investigation on jurisdictional grounds. In response to Roche s request for rehearing, on April 30, 2009, the Federal Circuit Court vacated the ITC s dismissal of the ITC investigation for non-infringement. The Federal Circuit Court remanded the case back to the ITC for further proceedings to determine if patent infringement had occurred and to provide a remedy, if appropriate.

Amgen had previously filed a separate lawsuit in November 2006 in the U.S. District Court for the District of Massachusetts (the Massachusetts District Court) against F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively, Roche Defendants) seeking a declaration by the Massachusetts District Court that the importation, use, sale or offer to sell peg-EPO infringes Amgen s EPO patents, specifically U.S. Patent Nos. 5,547,933; 5,621,080; 5,955,422; 5,756,349; 5,618,698 and 5,441,868. After a jury trial and an appeal, on December 22, 2009, the Massachusetts District Court entered final judgment and a permanent injunction against the Roche Defendants prohibiting the Roche Defendants from infringing the five Amgen patents-in-suit. The judgment was accompanied by the Roche Defendants admission that the patents involved in the lawsuit are valid, enforceable and infringed by the Roche Defendant s peg-EPO product, and by Amgen allowing Roche to begin selling peg-EPO in the United States in mid-2014 under terms of a limited license agreement. The settlement terms did not include any financial payments between the parties. Thereafter, in the ITC matter Amgen filed a motion for summary determination of violation with a request for entry of a limited exclusion order. The Roche respondents notified the ITC that they were not opposing Amgen s motion. On March 11, 2011, the ITC issued an order to show cause why the investigation should not be terminated without a determination of violation or by way of consent order in view of the resolution of the Massachusetts District Court proceedings. In response, on April 21, 2011, the parties filed a joint response requesting termination of the investigation on the basis of a proposed Consent Order and Stipulation. On October 17, 2011, the ITC terminated the investigation without entry of a consent order on the basis of the December 2009 settlement between the parties and resolution of the parallel litigation in the Massachusetts District Court.

Average Wholesale Price (AWP) Litigation

Amgen and its wholly owned subsidiary Immunex Inc. are named as defendants, either separately or together, in numerous civil actions broadly alleging that they, together with many other pharmaceutical manufacturers, reported prices for certain products in a manner that allegedly inflated reimbursement under Medicare and/or Medicaid programs and commercial insurance plans, including co-payments paid to providers who prescribe and administer the products. The complaints generally assert varying claims under the Medicare and Medicaid statutes, as well as state law claims for deceptive trade practices, common law fraud and various related state law claims. The complaints seek an undetermined amount of damages, as well as other relief, including declaratory and injunctive relief.

The AWP litigation was commenced against Amgen and Immunex on December 19, 2001 with the filing of Citizens for Consumer Justice, et al. v. Abbott Laboratories, Inc., et al. Additional cases have been filed since

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that time. Most of these actions, as discussed below, have been consolidated, or are in the process of being consolidated, in a federal Multi-District Litigation proceeding (the MDL Proceeding), captioned In Re: Pharmaceutical Industry Average Wholesale Price Litigation MDL No. 1456 and pending in the Massachusetts District Court.

The following cases have been consolidated into the MDL Proceeding, and include cases brought by consumer classes and certain state and local governmental entities:

Citizens for Consumer Justice, et al., v. Abbott Laboratories, Inc., et al.; Teamsters Health & Welfare Fund of Philadelphia, et al., v. Abbott Laboratories, Inc., et al.; Action Alliance of Senior Citizens of Greater Philadelphia v. Immunex Corporation; Constance Thompson, et al., v. Abbott Laboratories, Inc., et al.; Ronald Turner, et al., v. Abbott Laboratories, Inc., et al.; Congress of California Seniors v. Abbott Laboratories, Inc., et al.

In the MDL Proceeding, the Massachusetts District Court has set various deadlines relating to motions to dismiss the complaints, discovery, class certification, summary judgment and other pre-trial issues. For the private class action cases, the Massachusetts District Court has divided the defendant companies into a Track I group and a Track II group. Both Amgen and Immunex are in the Track II group. On March 2, 2006, plaintiffs filed a fourth amended master consolidated complaint, which did not include their motion for class certification as to the Track II group. On September 12, 2006, a hearing before the Massachusetts District Court was held on plaintiffs motion for class certification as to the Track II group defendants, which include Amgen and Immunex. On March 7, 2008, the Track II defendants reached a tentative class settlement of the MDL Proceeding, which was subsequently amended on April 3, 2008. The tentative Track II settlement relates to claims against numerous defendants, including Abbott Laboratories, Inc., Amgen Inc., Aventis Pharmaceuticals Inc., Hoechst Marion Roussel, Inc., Baxter Healthcare Corporation, Baxter International Inc., Bayer Corporation, Dey, Inc., Fujisawa Healthcare, Inc., Fujisawa USA, Inc., Immunex Corporation, Pharmacia Corporation, Pharmacia & Upjohn LLC (f/k/a Pharmacia & Upjohn, Inc.), Sicor, Inc., Gensia, Inc., Gensia Sicor Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc. and ZLB Behring, L.L.C. Following repeated hearings on the sufficiency of the notice given by the plaintiffs, the Massachusetts District Court approved the Track II settlement on December 8, 2011, and dismissed with prejudice the fourth amended master consolidated complaint effective January 31, 2012.

The following AWP litigation case is not part of the MDL Proceeding:

State of Louisiana v. Abbott Laboratories, Inc., et al. The State of Louisiana filed a complaint against Amgen and several other pharmaceutical manufacturers, on November 3, 2010, in the Parish of East Baton Rouge, 19th Judicial District (the Louisiana Court). Amgen was served the complaint on November 9, 2010. The complaint alleges that the manufacturers misrepresented product pricing information reported to the state by falsely inflating those prices. On May 12, 2011, Amgen and the other defendants filed joint exceptions seeking to dismiss the complaint. On October 27, 2011 the Louisiana Court denied the defendants joint exceptions.

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.,

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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. On January 3, 2012, Amgen filed a motion to stay the mandate and the Ninth Circuit Court granted the motion and stayed the mandate on January 12, 2012. The staying of the mandate effectively stays the underlying action in the California Central District Court for ninety days pending the filing of a writ of certiorari with the U.S. Supreme Court. Amgen has until March 27, 2012 to file a petition for certiorari with the U.S. Supreme Court.

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.

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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 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. On February 24, 2011, plaintiff filed a notice of appeal with the California State Appellate Court. The briefing schedule for the appeal was issued by the California State Appellate Court and plaintiff s opening brief was filed September 7, 2011. The opposition brief from Amgen and the individual defendants was filed on November 21, 2011. No date has been set for oral argument.

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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 the 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, which remains pending before 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.

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Pursuant to the parties stipulation, the Ramos matter has been stayed pending the outcome of the Harris matter appeal. Oral argument before the Ninth Circuit Court on the plaintiffs appeal of the California Central District Court s dismissal of the plaintiffs claims occurred on May 8, 2009. On July 14, 2009, the Ninth Circuit Court reversed the California Central District Court s decision and remanded the case back to the 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 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 being 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 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 stated that the relator in the Massachusetts Qui Tam Action is a former Amgen employee. Further, 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 and one pending in the U.S. District Court for the Western District of Washington (together, the Qui Tam Actions). In the filing made public on May 7, 2009, the U.S. government represented that these ten 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 (the States) 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.

On October 24, 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. In connection with the agreement in principle, Amgen recorded a $780 million charge in the three months ended September 30, 2011. This amount represents Amgen s currently estimable loss with respect to these matters. If the ongoing discussions are successfully concluded, Amgen expects that the proposed settlement will resolve the Federal Investigations, the related state Medicaid claims and the claims in *U.S. ex rel. Westmoreland v. Amgen, et al.* and the other nine Qui Tam Actions in a manner that will not result in exclusion from U.S. federally-funded health care programs. In connection with the settlement discussions, the Massachusetts District Court vacated the previously scheduled trial date and administratively closed that case. The relators in the Qui Tam Actions have

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the opportunity to join in the proposed settlement or, if they object, to have the settlement evaluated in a federal court fairness hearing to determine whether it is fair, adequate and reasonable under all the circumstances. The proposed settlement remains subject to continuing discussions regarding the components of the agreement and the completion and execution of all required documentation, and until the proposed settlement becomes final, there can be no guarantee that these matters will be resolved by the agreement in principle.

In addition, on September 19, 2011, Amgen filed a petition for certiorari with the U.S. Supreme Court in the *U.S. ex rel. Westmoreland v. Amgen, et al.* matter. The petition sought leave to appeal the First Circuit Court s reinstatement of the claims of the states of California, Illinois, Indiana, Massachusetts, New Mexico and New York, which had been dismissed by the Massachusetts District Court. However, as described above, Amgen expects that these state claims will be resolved if the ongoing settlement discussions are successfully concluded. Accordingly, on December 12, 2011, Amgen withdrew its petition for certiorari and the U.S. Supreme Court subsequently dismissed the petition on December 29, 2011.

As part of the settlement discussions described above, Amgen was made aware that it is a defendant in several other civil qui tam actions. These other qui tam actions are in addition to the Qui Tam Actions described above. One of these other qui tam actions, *U.S. ex rel. May v. Amgen, et al.* was filed by Samuel May on June 6, 2010, in the U.S. District Court for the Northern District of California, and was unsealed in connection with it being dismissed by the Court on January 5, 2012 for failure to prosecute the matter. The remaining other qui tam actions remain under seal in the U.S. federal courts in which they were filed. Included with these other actions (including the *May* action) are allegations that Amgen s promotional, contracting, sales and marketing activities relating to Enbrel® and Aranesp® caused the submission of various false claims under the Federal Civil False Claims Act and various State False Claims Acts. Certain of the allegations in these remaining other actions are not encompassed in the proposed settlement described above, and Amgen intends to cooperate fully with the government in its investigation of these new allegations. Amgen continues to explore with the government whether these remaining matters will be resolved in connection with the proposed settlement discussed above.

U.S. ex rel. Streck v. Allergan, et al.

A complaint filed in the U.S. District Court for the Eastern District of Pennsylvania against Amgen and numerous other pharmaceutical manufacturers, pursuant to the Qui Tam provisions of the Federal Civil False Claims Act and on behalf of 24 named states and the District of Columbia under their respective State False Claims Acts, was unsealed and became public on or about June 6, 2011. The plaintiff, Ronald Streck, alleges that from 2004 to the present, defendants failed to report accurate pricing data to Medicare and Medicaid, including data used to calculate average sales price and average manufacturer s price, thereby causing the federal and state governments to reimburse defendants at inflated rates and causing the manufacturers to underpay Medicaid rebates. This matter, in which the federal government has declined to intervene, is not affected by the proposed settlement described above. On September 7, 2011, plaintiff filed a fourth amended complaint and on December 9, 2011, defendants filed a joint motion to dismiss the plaintiff s complaint.

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2011 (in millions):

2012	$ 116
2013	104
2014	85
2015	76
2016	65
Thereafter	328
Total minimum operating lease commitments	$ 774

Included in the table above are future rental commitments for abandoned leases in the amount of $254 million. Rental expense on operating leases for the years ended December 31, 2011, 2010 and 2009, was $131 million, $115 million and $114 million, respectively.

In addition, we have minimum contractual purchase commitments with third-party manufacturers through 2014 that total $157 million as of December 31, 2011. Amounts purchased under these contractual purchase commitments for the years ended December 31, 2011, 2010 and 2009, were $87 million, $68 million and $207 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.

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenues

Revenues were as follows for the years ended December 31, 2011, 2010 and 2009 (in millions):

	2011	2010	2009
Product sales:			
Neulasta® U.S.	$ 3,006	$ 2,654	$ 2,527
NEUPOGEN® U.S.	959	932	901
Neulasta® International	946	904	828
NEUPOGEN® International	301	354	387
ENBREL U.S.	3,458	3,304	3,283
ENBREL Canada	243	230	210
Aranesp® U.S.	986	1,103	1,251
Aranesp® International	1,317	1,383	1,401
EPOGEN® U.S.	2,040	2,524	2,569
Sensipar® U.S.	518	459	429
Sensipar® (Mimpara®) International	290	255	222
Vectibix® U.S.	122	115	97
Vectibix® International	200	173	136
Nplate® U.S.	163	129	78
Nplate® International	134	100	32
Prolia® U.S.	130	26	
Prolia® International	73	7	
XGEVA® U.S.	343	8	
XGEVA® International	8		
Other International	58		
Total product sales	15,295	14,660	14,351
Other revenues	287	393	291
Total revenues	$ 15,582	$ 15,053	$ 14,642

Geographic information

Outside the United States, we sell products principally in Europe and Canada. The geographic classification of product sales was based upon the location of the customer. The geographic classification of all other revenues was based upon the domicile of the entity from which the revenues were earned.

Certain geographical information with respect to revenues and long-lived assets (consisting of property, plant and equipment) was as follows (in millions):

	Years ended December 31,		
	2011	2010	2009

Revenues:			
United States	$ 11,985	$ 11,636	$ 11,421
International countries	3,597	3,417	3,221
Total revenues	$ 15,582	$ 15,053	$ 14,642

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AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	December 31, 2011	2010
Long-lived assets:		
United States	$ 3,144	$ 3,248
Puerto Rico	1,993	2,079
International countries	283	195
Total long-lived assets	$ 5,420	$ 5,522

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, 2011, 2010 and 2009. For 2011, on a combined basis, these customers accounted for 72% and 90% 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, 2011, 2010 and 2009, was as follows (dollar amounts in millions):

	2011	2010	2009
AmerisourceBergen Corporation:			
Gross product sales	$ 7,574	$ 7,678	$ 7,179
% of total gross revenues	36%	38%	37%
% of U.S. gross product sales	45%	47%	46%
McKesson Corporation:			
Gross product sales	$ 4,591	$ 3,913	$ 3,694
% of total gross revenues	22%	19%	19%
% of U.S. gross product sales	27%	24%	24%
Cardinal Health, Inc:			
Gross product sales	$ 3,021	$ 2,813	$ 2,841
% of total gross revenues	14%	14%	15%
% of U.S. gross product sales	18%	17%	18%

At December 31, 2011 and 2010, amounts due from these three customers each exceeded 10% of gross trade receivables, and accounted for 60% and 54%, respectively, of net trade receivables on a combined basis. At December 31, 2011 and 2010, 39% and 44%, 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, 2011 and 2010, was not material.

20. Subsequent event

On January 26, 2012, we announced that we had entered into an agreement to acquire 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. The

acquisition includes blinatumomab, a Bispecific T cell Engager (BiTE) antibody in phase 2 clinical development for acute lymphoblastic leukemia and BiTE antibody technology, which is proprietary to Micromet, which provides an

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innovative platform for future clinical research. Blinatumomab is also in clinical development for the treatment of non-Hodgkin s lymphoma and could have applications in other hematologic malignancies. In connection with this acquisition, which will be accounted for as a business combination, we have commenced a tender offer to acquire all of the outstanding shares of Micromet s common stock at a price of $11 per share in cash, which values Micromet at approximately $1.16 billion. Upon its acquisition, Micromet will become a wholly owned subsidiary of Amgen. This acquisition will provide us with an opportunity to further expand our oncology pipeline. Micromet will be included in our consolidated financial statements commencing on the acquisition date. The acquisition, which is subject to customary closing conditions, is expected to close during the three months ended March 31, 2012.

21. Quarterly financial data (unaudited)

	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

	2010 Quarters ended			
(In millions, except per share data)	**December 31[2]**	**September 30[3]**	**June 30**	**March 31**
Product sales	$ 3,760	$ 3,759	$ 3,613	$ 3,528
Gross profit from product sales	3,188	3,172	3,060	3,020
Net income	1,022	1,236	1,202	1,167
Earnings per share:				
Basic	$ 1.09	$ 1.29	$ 1.25	$ 1.19
Diluted	$ 1.08	$ 1.28	$ 1.25	$ 1.18

(1) We recorded a $780 million legal settlement charge ($705 million, net of tax) in connection with an agreement in principle to settle allegations relating to our sales and marketing practices.

(2) We recorded $113 million of income tax benefit as the result of resolving certain transfer pricing issues with tax authorities for prior periods and a $118 million ($74 million, net of tax) asset impairment charge associated with a strategic decision to optimize our network of manufacturing facilities and improve cost efficiencies.

(3) We recorded $38 million of income tax benefit as the result of resolving certain transfer pricing issues with tax authorities for prior periods.

See Note 4, Income taxes, and Note 18, Contingencies and commitments, for further discussion of the items described above.

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SCHEDULE VALUATION ACCOUNTS

SCHEDULE II

AMGEN INC.

VALUATION ACCOUNTS

Years ended December 31, 2011, 2010 and 2009

(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, 2011	$ 42	$ 17	$	$ 5	$ 54
Year ended December 31, 2010	$ 32	$ 10	$	$	$ 42
Year ended December 31, 2009	$ 38	$ (6)	$	$	$ 32