AMGEN INC
Form 10-K
February 29, 2012
Table of Contents

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.

Table of Contents

INDEX

Table of Contents

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.)

Table of Contents

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.

Table of Contents

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

Table of Contents

(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.

Table of Contents

(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

5

Table of Contents

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

Table of Contents

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

Table of Contents

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,