AMGEN INC
Form 10-K
February 25, 2011

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, 2010

OR

o **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 o

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 o 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 o

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 o

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. o

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 o Non-accelerated filer o Smaller reporting company o
(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 o No x

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $50,355,022,164 as of June 30, 2010(A)

(A) Excludes 1,085,011 shares of common stock held by directors and officers, and any stockholders whose ownership exceeds five percent of the shares outstanding, at June 30, 2010. 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.

932,452,902

(Number of shares of common stock outstanding as of February 11, 2011)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant s Proxy Statement with respect to the 2011 Annual Meeting of stockholders to be held May 20, 2011 are incorporated by reference into Part III of this annual report.

INDEX

		Page No.
PART I		**1**
Item 1.	BUSINESS	1
	Overview	1
	Significant Developments	2
	Marketed Products	3
	Marketing and Distribution	17
	Reimbursement	18
	Manufacturing, Distribution and Raw Materials	24
	Business Relationships	27
	Government Regulation	29
	Research and Development and Selected Product Candidates	33
	Human Resources	39
	Executive Officers of the Registrant	39
	Geographic Area Financial Information	40
	Investor Information	40
Item 1A.	RISK FACTORS	41
Item 1B.	UNRESOLVED STAFF COMMENTS	59
Item 2.	PROPERTIES	60
Item 3.	LEGAL PROCEEDINGS	61
Item 4.	RESERVED	61
PART II		**62**
Item 5.	MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	62
Item 6.	SELECTED FINANCIAL DATA	65
Item 7.	MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	68
Item 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	85
Item 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	87
Item 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES	87
Item 9A.	CONTROLS AND PROCEDURES	87
Item 9B.	OTHER INFORMATION	90
PART III		**90**
Item 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE OF THE REGISTRANT	90
Item 11.	EXECUTIVE COMPENSATION	90
Item 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	91
Item 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE	93
Item 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	93
PART IV		**94**

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES 94
SIGNATURES 102
EX-21
EX-31
EX-32
EX-101 INSTANCE DOCUMENT
EX-101 SCHEMA DOCUMENT
EX-101 CALCULATION LINKBASE DOCUMENT
EX-101 LABELS LINKBASE DOCUMENT
EX-101 PRESENTATION LINKBASE DOCUMENT
EX-101 DEFINITION LINKBASE DOCUMENT

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 biotechnology 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, 2010, we had 17,400 staff members worldwide. Approximately 6,700 of our staff members work in our research and development (R&D) function, approximately 4,600 work in manufacturing, approximately 4,200 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, nephrology and inflammation. Our principal products are: Aranesp® (darbepoetin alfa) and EPOGEN® (Epoetin alfa), erythropoiesis-stimulating agents (ESAs) that stimulate the production of red blood cells; 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); and Enbrel® (etanercept), an inhibitor of tumor necrosis factor (TNF), a substance that plays a role in the body s response to inflammatory diseases. Our principal products represented 91%, 93% and 94% of our sales in 2010, 2009 and 2008, 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); and Nplate® (romiplostim), a thrombopoietin (TPO) receptor agonist that mimics endogenous TPO, the primary driver of platelet production. In addition, in 2010 we launched Prolia® (denosumab) and XGEVA™ (denosumab) both of which contain the same active ingredient but which 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, nephrology, cardiovascular and general medicine, which includes neurology. 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 commercial and/or clinical manufacturing facilities 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 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 also 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 2010 and early 2011 affecting our business. A more detailed discussion of each development follows in the appropriate section.

Denosumab

The FDA approved Prolia® for the treatment of postmenopausal women with osteoporosis at a high risk of fracture.

The European Commission (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.

The FDA approved XGEVA™ for the prevention of skeletal related events (SREs) in patients with bone metastases from solid tumors. XGEVA™ is not indicated for the prevention of SREs in patients with multiple myeloma.

We submitted a marketing authorization application to the European Medicines Agency (EMA) for denosumab for the reduction of SREs in cancer patients.

We announced that a phase 3 trial evaluating XGEVA™ versus placebo in men with castrate-resistant prostate cancer met its primary endpoint by significantly improving bone metastasis-free survival. This study will form the basis of planned marketing applications, which we expect to submit to regulatory authorities beginning in the first half of 2011, for the prevention of bone metastases in prostate cancer.

Healthcare Reform

A new healthcare reform law was enacted in the United States that, among other provisions, imposes additional costs on the biotechnology and pharmaceutical industries and authorizes the FDA to approve biosimilars.

ESAs

The Centers for Medicare & Medicaid Services (CMS) released its Final Rule on Bundling in Dialysis, effective January 1, 2011, which provides a single payment for all dialysis services, including drugs that were previously reimbursed separately (except for oral drugs without intravenous equivalents for which the bundling rules have been postponed).

Table of Contents

CMS engaged in a number of activities to examine the use of ESAs in certain patients with kidney disease, including holding a March 2010 meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), opening a National Coverage Analysis (NCA) in June 2010 to examine the use of ESAs to manage anemia in patients with chronic kidney disease (CKD) and dialysis-related anemia as well as holding another MEDCAC meeting in January 2011 to review the impact of ESA use on renal transplant graft survival.

We announced that the FDA approved a risk evaluation and mitigation strategy (REMS) for ESAs that requires, among other elements, that healthcare providers and institutions who prescribe ESAs to patients with cancer receive additional training and document their risk discussions with their cancer patients prior to initiating a new course of ESA therapy. Healthcare providers and institutions who fail to comply with the REMS program requirements, including enrolling in the ESA REMS program and meeting ongoing compliance obligations, will have their access to ESAs suspended. Beginning February 16, 2011, we must ensure that our distributors do not ship ESAs to any healthcare provider or institution until such provider or institution has enrolled in the ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs) Oncology Program.

We are working with the FDA to determine the appropriate use of ESAs in CKD patients and to determine any future ESA labeling changes required in connection with our Trial to Reduce Cardiovascular Events with Aranesp® Therapy (TREAT) study or the October 2010 Cardiovascular and Renal Drug Advisory Committee (CRDAC) meeting.

Vectibix®

We submitted our application to the EMA for 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 filed supplemental Biologics License Application (BLA) submissions with the FDA for first- and second-line mCRC.

We announced that a phase 3 trial evaluating Vectibix® as a first-line treatment in patients with recurrent and/or metastatic squamous cell head and neck cancer failed to meet its primary endpoint.

Other Developments

We initiated a phase 3 study in recurrent ovarian cancer for AMG 386.

We announced plans to begin a phase 3 study in first-line metastatic pancreatic cancer for ganitumab (AMG 479).

We announced that we anticipate data for a phase 3 motesanib study for advanced non small cell lung cancer (NSCLC) in the first half of 2011.

We recently announced an agreement to acquire BioVex Group, Inc. (BioVex). BioVex is a privately held biotechnology company developing treatments for cancer and the prevention of infectious disease, including OncoVEX$^{GM\text{-}CSF}$, a novel oncology vaccine in phase 3 trials for the treatment of melanoma and head and neck cancer. The acquisition, which is subject to customary closing conditions, is expected to close during the three months ended March 31, 2011.

Marketed Products

We market our principal products, Aranesp®, EPOGEN®, Neulasta®, NEUPOGEN® and ENBREL in supportive cancer care, nephrology and inflammation. 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

Table of Contents

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, the existing patents on our principal products will begin to 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 highly similar 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. Consequently, we expect to face greater competition, including from manufacturers with biosimilar products approved in Europe that may seek to quickly obtain U.S. approval, subject to our ability to enforce our patents. In the European Union (EU), we are already facing increasing competition from biosimilars given an established regulatory pathway for biosimilars in the EU.

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, particularly in supportive cancer care, 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. 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. A postmarketing requirement (PMR) is a trial or study that a sponsor company is required by statute or regulation to conduct. A postmarketing commitment (PMC) is a trial or study that a sponsor company agrees to in writing, but is not required by law, to conduct. We currently have PMRs or PMCs for a number of our marketed products. 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 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.)

ESAs

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

malignancies.

ESA products, including ours, have faced and continue to face challenges. For example, based on adverse safety results observed beginning in late 2006 in various ESA studies, performed by us and by others, that explored

Table of Contents

the use of ESAs in settings different from those outlined in the FDA approved label, the product labeling of our ESA products 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 ESA products 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. Certain of these developments have had a material adverse impact on sales of our ESA products, in particular Aranesp® sales in the U.S. supportive cancer care setting, reflecting an overall decline in the segment.

Further, we believe that the following recent and pending developments could also have a material adverse impact on future sales of Aranesp® and/or EPOGEN®:

On January 1, 2011, the Final Rule on Bundling in Dialysis became effective which provides a single payment for all dialysis services, including drugs, supplies, and non-routine laboratory tests that were previously reimbursed separately. Under the Final Rule, dialysis providers were given the choice of opting into the new bundled payment system in its entirety on January 1, 2011, or phasing in over time. Substantially all dialysis providers in the United States have opted into the bundled payment system in its entirety. We expect the bundled payment system to decrease dose utilization of EPOGEN® and that this decrease will have a material adverse impact on our EPOGEN® sales.

On March 24, 2010, CMS held a MEDCAC meeting to examine the currently available evidence on the use of ESAs to manage anemia in patients who have CKD. Although there was no clear outcome from the MEDCAC meeting, 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, which is generally CMS s first step toward developing a National Coverage Determination (NCD). Generally, an NCD is a national policy statement granting, limiting or excluding Medicare coverage or reimbursement for a specific medical item or service. Medicare currently does not have an NCD for the use of ESAs for anemia in patients who have CKD but has historically reimbursed for the use of ESAs in this setting. CMS has stated that the NCA process for ESAs will conclude on or before June 16, 2011, but CMS could propose an NCD at any time prior to that deadline. In addition, on January 19, 2011, CMS held another MEDCAC meeting, this time to review the available evidence on the impact of ESA use on renal transplant graft survival.

On February 16, 2010, Amgen and Centocor Ortho Biotech Products, L.P. (Centocor), a subsidiary of Johnson & Johnson (J&J), announced that the FDA had approved a REMS for ESAs which includes Aranesp®, EPOGEN® and PROCRIT® (Epoetin alfa), a product marketed by J&J. In order to ensure continued access to ESAs for healthcare providers and institutions who prescribe ESAs to patients with cancer, healthcare providers and institutions are required to train and enroll in the ESA APPRISE Oncology Program. Enrolled healthcare providers and institutions are required to document that a discussion about the risks of ESAs took place with each patient prior to the initiation of each new course of ESA therapy. Beginning February 16, 2011, we must ensure that our distributors do not ship ESAs to any healthcare provider or institution until such provider or institution is enrolled in the APPRISE program. We are responsible for tracking and documenting certain elements of healthcare provider and institution compliance with the REMS and for providing the FDA with periodic assessment reports to demonstrate that the goals of the REMS are being met. Healthcare providers and institutions that fail to comply with the APPRISE program requirements will have their access to ESAs suspended. Direct patient registration or approval prior to ESA administration is not required through the ESA APPRISE Oncology Program. As required, we will work with the FDA if it is determined any modifications to the REMS are needed based on the REMS assessments we submit.

On October 18, 2010, the FDA held a CRDAC meeting to review results from the TREAT study conducted in CRF patients not on dialysis with type-2 diabetes and moderate anemia, and how those results inform the appropriate use of ESAs in patients with CKD. Prior to the CRDAC meeting, we submitted for the FDA s review 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 (hemoglobin (Hb) levels <10 grams per deciliter (g/dL)), and who are at high risk for transfusion and for whom

Table of Contents

transfusion avoidance is considered clinically important, including those in whom it is important to preserve kidney transplant eligibility. In addition to narrowing the patient population, we are proposing a more conservative dosing algorithm in those patients. We are working with the FDA to determine the appropriate use of ESAs in CKD patients and to determine any future ESA labeling changes required in connection with TREAT or the CRDAC meeting.

We are working with the FDA to make ESA product package insert changes associated with the Physician s Labeling Rule (PLR) conversion process. During the process of converting from the existing format to the new PLR format, the FDA and Amgen are evaluating the package insert information to ensure that it accurately reflects current knowledge and may revise, add to or remove information appearing in the old format that could substantively impact the content of the product package insert.

In addition to the above, following the FDA s Oncologic Drugs Advisory Committee (ODAC) meeting in May 2004, we proposed a pharmacovigilance program for Aranesp® comprised of five studies to explore the use of ESAs in settings different from those outlined in the FDA approved label. The studies were subsequently 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 ESA products and changes in reimbursement, as noted above. Of the five studies, three are complete with final results of the remaining studies expected in 2011. In addition, Johnson and Johnson Pharmaceutical Research & Development (J&JPRD), a subsidiary of J&J, and/or its investigators have conducted numerous studies proposed at the 2004 ODAC meeting. All of these studies are closed to enrollment and summary results were submitted to the FDA.

Based on our discussions with the FDA in response to the May 2007 ODAC meeting, we and J&JPRD 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 have initiated 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, J&JPRD s EPO-ANE-3010 study in breast cancer is also ongoing. Both studies are designated by the FDA as PMR clinical trials.

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

Aranesp® (darbepoetin alfa)

We were granted an exclusive license by Kirin-Amgen, Inc. (KA), a joint venture between Kirin Holdings Company, Limited (Kirin) and Amgen (see Business Relationships Kirin Holdings Company, Limited), 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, 2010, 2009 and 2008 were $2.5 billion, $2.7 billion and $3.14 billion, respectively. For the years ended December 31, 2010, 2009 and 2008, U.S. Aranesp® sales were $1.1 billion, $1.3 billion and $1.65 billion, respectively, and international Aranesp® sales were $1.4 billion,

$1.4 billion and $1.49 billion, respectively.

Table of Contents

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 negatively impact Aranesp® sales. In the United States, Aranesp® competes with EPOGEN®, primarily in the U.S. hospital dialysis clinic setting. The following table reflects companies and their currently marketed products that compete with Aranesp® in the United States and Europe in the supportive cancer care and nephrology segments, unless otherwise indicated. The table 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]	Centocor[2]
Europe	EPREX®/ERYPO®	Janssen-Cilag[2]
Europe	NeoRecormon®	F. Hoffmann-La Roche Ltd. (Roche)
Europe	Retacrit™[3]/Silapo®[3]	Hospira Inc.. (Hospira)/Stada Arzneimittel AG
Europe	Binocrit®[3]/Epoetin alfa Hexal®[3]/ Abseamed®[3]	Sandoz GmbH (Sandoz)/Hexal Biotech Forschungs GmbH (Hexal)/Medice Arzneimittel Pütter GmbH & Company KG
Europe	MIRCERA®[4]	Roche
Europe	Eporatio®/Biopoin®	ratiopharm GmbH (ratiopharm[5])/CT Arztneimittel GmbH (CT Arztneimittel)

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

(2) A subsidiary of J&J.

(3) Biosimilar product.

(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 Industries Ltd. (Teva Pharmaceutical).

In addition to competition from these marketed products, the following products in development could compete with Aranesp® in the future:

Affymax Inc. and Takeda Pharmaceutical Company Limited (Takeda) are co-developing peginesatide, an ESA for the treatment of anemia in CRF patients on dialysis and they have announced plans to file for regulatory approval in the United States in the second quarter of 2011.

Reliance Life Sciences Pvt. Ltd. (Reliance Life Sciences) has an epoetin biosimiliar (Epostim) that they filed for regulatory approval for in Europe.

Table of Contents

EPOGEN® (Epoetin alfa)

We were granted an exclusive license to manufacture and market EPOGEN® in the United States under a licensing agreement with KA. 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 Centocor), a license to commercialize recombinant human erythropoietin as a human therapeutic in the United States in all indications other than dialysis. (See Business Relationships Johnson & Johnson.)

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, 2010, 2009 and 2008 were $2.5 billion, $2.6 billion and $2.5 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

Any products or technologies that are directly or indirectly successful in addressing anemia associated with renal failure 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 in development noted in the Aranesp® section above that may be used in dialysis in the United States.

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 KA. (See Business Relationships Kirin Holdings Company, Limited.)

Neulasta® and NEUPOGEN® stimulate production of certain white blood cells known as neutrophils. Neutrophils defend 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 (PEG) is added to enlarge the Filgrastim molecule, thereby extending its half-life and causing it to be removed more slowly from the body. Because pegfilgrastim is eliminated through binding to its receptor on neutrophils and their

precursors, 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. Neulasta® and NEUPOGEN® are prescribed more frequently in the curative setting, in which myelosuppressive chemotherapy is administered with the intent to cure cancer, rather than in the palliative setting, in which myelosuppressive chemotherapy is administered to treat other complications of cancer by managing tumor growth.

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

Table of Contents

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, 2010, 2009 and 2008 were $4.8 billion, $4.6 billion and $4.7 billion, respectively. U.S. Neulasta®/NEUPOGEN® sales for the years ended December 31, 2010, 2009 and 2008 were $3.6 billion, $3.4 billion and $3.4 billion, respectively. International Neulasta®/NEUPOGEN® sales for the years ended December 31, 2010, 2009 and 2008 were $1.2 billion, $1.2 billion and $1.3 billion, respectively.

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

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.

Neulasta® and/or NEUPOGEN® also face competition in some circumstances from companies marketing or developing treatments for neutropenia associated with chemotherapy, for bone marrow and PBPC transplant patients, severe chronic neutropenia and AML. 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.

Table of Contents

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 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
Europe	Granocyte®	Chugai Pharmaceuticals Co., Ltd./Sanofi-Aventis
Europe	Ratiograstim®(1)/Filgrastim Ratiopharm®(1)/Biograstim®(1)	ratiopharm(2)/CT Arztneimittel
Europe	Tevagrastim®(1)	Teva Pharmaceutical
Europe	Zarzio®(1)/Filgrastim Hexal®(1)	Sandoz/Hexal
Europe	Nivestim®(1)	Hospira

(1) Biosimilar product.

(2) A subsidiary of Teva Pharmaceutical.

In February 2010, Teva Pharmaceutical announced that the FDA had accepted for review its BLA seeking U.S. approval to market XM02 to boost white blood cells 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 Neutroval™. Neutroval™ is currently sold under the brand name Tevagrastim® in several European countries. If approved in the United States, this drug would compete with NEUPOGEN® and Neulasta®. 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. Pretrial proceedings are ongoing and no trial date has yet been set. (See Note 19, Contingencies and commitments to the Consolidated Financial Statements.)

Other companies with short-acting filgrastims in phase 3 clinical development for Europe are:

Merck & Company, Inc. (Merck) (MK-4214).

Intas/Apotex Inc. (Neukine).

Reliance Life Sciences (Religrast).

Biocon Ltd./Celgene Corporation (Celgene) (Nufil).

In addition, Teva Pharmaceutical has two long-acting filgrastims in phase 3 clinical development for Europe (XM-22 and Neugranin).

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 is similar to a protein that the body produces naturally, and like this protein, it 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 November 1998 for the treatment of rheumatoid arthritis (RA). In addition, ENBREL is now indicated for the treatment of adult patients with the following conditions: moderately to severely active RA; chronic moderate to severe plaque psoriasis patients who are candidates for systemic therapy or phototherapy; active psoriatic arthritis; and active ankylosing spondylitis. ENBREL is also approved for the treatment of moderately to severely active polyarticular juvenile idopathic arthritis in patients ages 2 and older.

Table of Contents

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, 2010, 2009 and 2008 were $3.5 billion, $3.5 billion and $3.6 billion, respectively.

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

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

(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. ENBREL is also sold as a lyophilized formulation that requires reconstituting before it can be administered to the patient. Accordingly, a potential competitor may be able to develop an alternative formulation of etanercept, including the lyophilized formulation, and compete in the marketplace prior to the expiration of the liquid formulation patent.

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

The following table reflects companies and their currently marketed products that primarily compete with ENBREL in the United States and Canada in the inflammatory disease setting. The table 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®	Centocor[1]/Merck
U.S. & Canada	Rheumatology & Dermatology	HUMIRA®	Abbott Laboratories (Abbott)
U.S. & Canada	Rheumatology & Dermatology	Simponi®	Centocor[1]
U.S. & Canada	Rheumatology	Cimzia®	UCB/ Nektar Therapeutics
U.S. & Canada	Rheumatology	Orencia®	Bristol-Myers Squibb Corporation (BMS)
U.S. & Canada	Rheumatology	Rituxan®	Roche
U.S.	Rheumatology	Actemra®	Roche
U.S. & Canada	Dermatology	Stelara®	Centocor[1]
U.S. & Canada	Dermatology	Amevive®	Biogen IDEC Inc.

(1) A subsidiary of J&J.

In addition to competition from the above-noted marketed products, various competitors are developing products that may compete with ENBREL in the future, as discussed below:

BMS submitted a supplemental BLA in the United States in October 2010 for subcutaneous Orencia®.

Pfizer released phase 3 data for its small molecule oral JAK program (tofacitinib) in RA and has initiated phase 3 trials in psoriasis.

AstraZeneca PLC and Rigel Pharmaceuticals Inc. initiated phase 3 trials in RA for their small molecule (fostamatinib).

Celgene initiated phase 3 clinical trials in both psoriasis and psoriatic arthritis for its small molecule (apremilast).

Table of Contents

In addition, several pharmaceutical companies announced their intent to produce biosimilars that may compete with ENBREL.

Other

Our other marketed products are 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 where a parathyroidectomy is not clinically appropriate or is contraindicated. We market Sensipar® primarily in the United States and Mimpara® primarily in Europe.

In addition, as previously discussed, CMS released the Final Rule on Bundling in Dialysis, effective January 1, 2011, resulting in a bundled payment system for dialysis facilities. 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.)

Worldwide Sensipar®/Mimpara® sales for the years ended December 31, 2010, 2009 and 2008 were $714 million, $651 million and $597 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.[(1)]	Calcium receptor-active molecules	12/14/2016
U.S.	Methods of treatment	12/14/2016
Europe[(2)]	Calcium receptor-active molecules	10/23/2015

(1) An election of U.S. Patent No. 6,011,068 for patent term extension has been submitted to the U.S. Patent and Trademark Office which will extend this patent until March 8, 2018.

(2) 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 negatively impact Sensipar®/Mimpara® sales.

Table of Contents

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 and discussion below 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 Pharmaceuticals USA, Inc. and Teva Pharmaceutical (together defined as 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. (See Note 19, Contingencies and commitments to the Consolidated Financial Statements.) 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. 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). In December 2008, 2009 and 2010, the EU conditional marketing authorization was renewed with an additional specific obligation to conduct a clinical trial in the existing approved 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.

Table of Contents

On April 16, 2010, our application for marketing authorization for the use of Vectibix® in first- and second-line treatment of mCRC in patients whose tumors contain wild-type *KRAS* genes was submitted to the EMA. In the United States, we filed supplemental BLA submissions for first- and second-line mCRC with the FDA on October 29, 2010 and November 4, 2010. Both the EMA and FDA filings included the data from the 203 and 181 clinical trials. In addition, the FDA has indicated that in order for Vectibix® to be approved for these indications, there must be a commercially available, FDA-approved *KRAS* test kit. We continue to work with our partner QIAGEN N.V. to support their submission of a Premarket Application for approval of this test kit.

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®, the confirmatory 181 study, and participated in an open discussion with the ODAC on the accelerated approval process.

Worldwide Vectibix® sales for the years ended December 31, 2010, 2009 and 2008 were $288 million, $233 million and $153 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 negatively impact Vectibix® sales. The following table reflects companies and their currently marketed products that compete with Vectibix® in the United States and Europe. The table may not be exhaustive.

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

Nplate® (romiplostim)

In August 2008, the FDA approved Nplate®, our platelet producer 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 KA to manufacture and market Nplate® in the United States, all European countries, Canada, Australia, New Zealand, Mexico, all Central and South American countries and certain countries in Central Asia, Africa and the Middle East.

In February 2009, we announced that the EC had granted marketing authorization for Nplate® for the treatment of splenectomized adult chronic ITP patients who are refractory to other treatments (eg, corticosteroids, immunoglobulins). In the EU, Nplate® may also be considered as second-line treatment for adult non-splenectomized ITP patients where surgery is contraindicated.

We currently have an approved REMS for Nplate®, which includes a medication guide, a healthcare provider communication plan and certain elements to assure safe use (including restricted distribution, registry, healthcare provider, institution and patient enrollment). As required, we have submitted REMS assessment reports to the FDA and are working with the FDA to determine any additional modifications to the REMS that will be needed.

Table of Contents

Worldwide Nplate® sales for the years ended December 31, 2010, 2009 and 2008 were $229 million, $110 million and $17 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
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 negatively impact Nplate® sales. The following table reflects currently marketed products that compete with Nplate® in the United States and Europe. The table 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. We estimate that the majority of potential U.S. Prolia® patients are covered under Medicare and the remaining patients under commercial plans. (See Reimbursement.) Future U.S. product sales for Prolia® will depend on the willingness of primary care physicians to prescribe, 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. 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, on July 1, 2010, Prolia® received reimbursement authority in Germany. On October 27, 2010, the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom (UK) recommended Prolia® for National Health Service (NHS) reimbursement as a treatment option for certain postmenopausal women who are at increased

risk of primary and secondary osteoporotic fractures if other treatments available on the publicly-funded NHS are unsuitable.

Worldwide Prolia® sales for the year ended December 31, 2010 were $33 million.

Table of Contents

The following table and discussion reflect other companies and their currently marketed products that compete with Prolia®. The table and the discussion of competitor marketed products and product 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.

Over the next several years, we expect certain additional marketed products noted above to lose patent protection, at which time we expect that generic versions of these products would become commercially available and compete with Prolia®.

In addition to competition from the above-noted marketed products, Merck has a new cathepsin-K inhibitor, odanacatib, in phase 3 clinical trials that could compete with Prolia® in the future.

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.

We also submitted a marketing authorization application to the EMA on June 4, 2010 for denosumab for the reduction of SREs in cancer patients.

On December 12, 2010, we announced top-line results from a phase 3 trial evaluating XGEVA™ versus placebo in men with castrate-resistant prostate cancer. The trial, known as the 147 study, 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 groups (secondary endpoint). This study will form the basis of planned marketing applications, which we expect to submit to regulatory authorities beginning in the first half of 2011, for the prevention of bone metastasis in prostate cancer. (See Research and Development and Selected Product Candidates.)

U.S. XGEVA™ sales for the year ended December 31, 2010 were $8 million.

Table of Contents

The following table reflects currently marketed products that compete with XGEVA™. The table 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.

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	11/28/2023
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) The expiration dates may be subject to change if delays in regulatory approval lead to extensions of patent terms in the United States and/or supplemental protection in Europe.

Marketing and Distribution

We maintain sales and marketing forces primarily in the United States, Europe and Canada to support our currently marketed products. We have also entered into agreements with third parties to assist in the commercialization and marketing of certain of our products in specified geographic areas. (See Business Relationships.) Together with our partners, we market our products to healthcare providers, including physicians or their clinics, dialysis centers, hospitals and pharmacies. We also market certain products directly to consumers through direct-to-consumer print and television advertising, 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 providing 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 wholesale distributors of pharmaceutical products. 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 wholesalers depending on the distribution practice in each country. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits, requiring letters of credit and obtaining credit insurance, as we deem appropriate.

We had product sales to three large wholesaler customers each accounting for more than 10% of total revenues for the years ended December 31, 2010, 2009 and 2008. On a combined basis, these distributors accounted for 71% and 88% for 2010 of worldwide gross revenues and U.S. gross product sales, respectively, as noted in the table

Table of Contents

below. Certain information with respect to these distributors for the years ended December 31, 2010, 2009 and 2008 is as follows (dollar amounts in millions):

	2010	2009	2008
AmerisourceBergen Corporation:			
Gross product sales	$ 7,678	$ 7,179	$ 7,099
% of total gross revenues	38%	37%	37%
% of U.S. gross product sales	47%	46%	46%
McKesson Corporation:			
Gross product sales	$ 3,913	$ 3,694	$ 3,594
% of total gross revenues	19%	19%	19%
% of U.S. gross product sales	24%	24%	23%
Cardinal Health, Inc.:			
Gross product sales	$ 2,813	$ 2,841	$ 2,823
% of total gross revenues	14%	15%	15%
% of U.S. gross product sales	17%	18%	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 their services 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.

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 and end stage renal disease (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 issue Medicare NCDs which are national policy statements granting, limiting or

excluding Medicare coverage for specific medical items or services. In addition, CMS has authority to issue manual policy issuances and updates as well as reimbursement codes for drugs and other items, which determine how products and services are reimbursed. Medicare Administrative Contractors have authority to issue local coverage determinations. CMS sometimes uses advisory committees of external experts in order to obtain

Table of Contents

independent expert advice on scientific, technical and policy matters. For example, the 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 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 and are reasonable and necessary for a medically accepted diagnosis or treatment. Medicare Part B also covers certain drugs pursuant to a specific statutory directive, such as blood-clotting factors and certain immunosuppressive drugs, erythropoietin and certain oral cancer drugs, if they fall under a specific statutory benefit category and they are safe and effective as established by FDA approval. 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, the primary payer for dialysis treatment. 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. Beginning January 1, 2011, dialysis treatment is 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. The list of prescription drugs covered by Medicare Part D plans varies by plan, but drug lists maintained by individual plans must cover certain classes of drugs and biologicals; specifically the statute stipulates that Medicare Part D plans have at least two drugs in each unique therapeutic category or class, subject to certain exceptions. Medicare patients who obtain ENBREL and Sensipar® under retail coverage, where they are primarily provided, are typically covered by Medicare Part D.

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 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.

Table of Contents

Reimbursement of Our Principal Products

Aranesp®, Neulasta® and NEUPOGEN®. Medicare and Medicaid payment policies for drugs and biologicals are subject to various laws and regulations. The Medicare program covers our principal products Aranesp®, Neulasta® and NEUPOGEN® (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 and dialysis 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 statutorily 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, in the physician office setting under Medicare Part B, Aranesp®, Neulasta® and NEUPOGEN® have been reimbursed at 106% of their ASP (sometimes referred to as ASP+6%), and in 2011 will continue to be reimbursed at this rate pursuant to the 2011 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%, but rose in 2011 to ASP+5% pursuant to the 2011 Hospital Outpatient Prospective Payment Final Rule. 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. The ESRD Program reimburses Medicare providers for 80% of allowed dialysis costs; the remainder is 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 EPOGEN® and Aranesp®) 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 facilities which provides a single payment for all dialysis services including drugs, supplies and non-routine laboratory tests that were previously reimbursed separately. Key provisions under the new system include:

Unit of payment CMS will provide a per treatment unit of payment. Consistent with past policy, ESRD facilities can be paid for up to three treatments per week, unless medical necessity justifies more frequent treatments.

Payment rate for 2011, the base rate is $229.63 per treatment.

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

Table of Contents

Dialysis providers were given the choice of opting into the new bundled payment system 100% on January 1, 2011, or phasing in over a four-year period. Substantially, all dialysis providers in the United States have opted into the bundled payment system in its entirety.

To encourage dialysis facilities to continue to provide quality dialysis treatment under the new bundled payment system, on December 29, 2010, CMS issued the Final Rule to implement the ESRD Quality Improvement Program (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, the penalty will be based on a composite score of measures as follows:

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.

The percent of Medicare patients with an average Urea Reduction Ratio of greater than or equal to 65% constitutes 25% of the weighting.

Notwithstanding the implementation of the QIP in 2012, we expect the bundled payment system to decrease dose utilization of EPOGEN® and that this decrease will have a material adverse impact on EPOGEN® sales. Further, if CMS issues an NCD for the use of ESAs in patients who have kidney disease (see Other ESA Reimbursement Developments below), CMS could further adjust the bundled payment system and/or the QIP.

Other ESA Reimbursement Developments. Since April 1, 2006, Medicare reimbursement for ESAs administered to dialysis patients has been subject to a Erythropoietin Monitoring Policy (EMP), the Medicare payment review mechanism used by CMS to monitor EPOGEN® and Aranesp® utilization and appropriate hematocrit outcomes of dialysis patients. The EMP was revised, effective January 1, 2008, requiring a 50% reduction in Medicare reimbursement if a patient s Hb is above 13 g/dL for three or more consecutive months. In addition, the revised EMP reduces the monthly dosing limits to 400,000 international units (IUs) of EPOGEN®, from 500,000 IUs, and to 1,200 micrograms (mcgs) of Aranesp®, from 1,500 mcgs.

On March 14, 2007, CMS announced a review of all Medicare policies related to the administration of ESAs in non-renal disease applications as part of an NCA, which is generally CMS first step toward developing an NCD. As a result of that review, CMS initiated an NCD for non-renal ESAs. After various CMS proposals and a public comment period, CMS issued a final NCD on July 30, 2007. The 2007 NCD 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. 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. We believe this restriction on coverage of ESAs in the 2007 NCD has had a material adverse effect on the coverage, reimbursement and sales of Aranesp®, and our business and results of operations. In addition, many private payers have implemented portions of the 2007 NCD and we believe many healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage.

On March 24, 2010, CMS held a MEDCAC meeting to examine the currently available evidence on the use of ESAs to manage anemia in patients who have CKD. Although there was no clear outcome from the MEDCAC meeting, on June 16, 2010, CMS opened a new NCA to examine the use of ESAs to manage anemia in patients with CKD and dialysis-related anemia, which is generally CMS first step toward developing an NCD. CMS has stated that the NCA process for ESAs will conclude on or before June 16, 2011, but CMS could propose a new NCD at any time prior to that deadline. Additionally, on January 19, 2011, CMS held another MEDCAC meeting, this time to review the

available evidence on the impact of ESA use on renal transplant graft survival.

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.

Table of Contents

Prolia® Reimbursement

We estimate that the majority of potential U.S. Prolia® patients are covered under Medicare and the remaining under commercial plans. Beginning in 2010, Prolia® has been reimbursed under Medicare Part B through the buy and bill process. (See Reimbursement of Our Principal Products Aranesp®, Neulasta® and NEUPOGEN®.) The buy and bill reimbursement process for Prolia® has required, and is expected to continue to require, time to become established, particularly among primary care physicians who may have limited experience using this reimbursement process. We expect that U.S. Medicare Part D plans will begin to cover Prolia® in 2011 and that commercial coverage will continue to expand as more commercial plans make their decisions about Prolia® coverage and reimbursement.

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 new 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 new U.S. healthcare reform law, and we expect CMS to shortly issue a proposed rule further defining the new AMP definition. Until that rule is issued, we will be required to make reasonable assumptions when calculating AMP. Once CMS proposed rule is issued, and clarification is provided on the calculation of AMP, we will have to determine whether our reasonable assumptions need to be amended to comply with the regulation s definition of AMP, and whether we 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 new healthcare reform law.

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

Table of Contents

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 Healthcare 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 new healthcare reform law. The new 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 will affect the reimbursement of our products.

The new 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 new healthcare reform law also expanded the list of provider institutions to which we must extend discounts under the PHS 340B drug pricing program. The new 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 healthcare reform law also imposed a new 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 new 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 is payable in 2011. This annual fee will be 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. We estimate that we will be required to pay $150 million to $200 million as our portion of the 2011 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 doughnut hole. The new 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 new 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.

We estimate that the total impact of U.S. healthcare reform in 2011 to us, including the industry fee described above, will be in the range of $400 million to $500 million.

Table of Contents

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, with the advent of Health Technology Assessment (HTA) organizations (eg, 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 prices become more transparent and payers seek lower-price benchmarks against which to compare themselves. Additional cost-containment measures can include therapeutic reference pricing (eg, setting the reimbursement rate for a given class of agents at the lowest price within the class), generic substitution and government-mandated price cuts.

While mandatory price reductions have been a recurring aspect of business for the pharmaceutical and biotechnology industries in the EU, given the current worldwide economic conditions, some EU governmental agencies have increased the frequency and/or size of such mandatory price reductions to extract further cost savings. For example, in 2010, countries such as Greece announced price reductions and/or mandated rebates for certain pharmaceutical and biological products that substantially exceeded prior levels. Other countries may follow and/or take similar or more extensive actions to reduce expenditures on drugs and biologics, including implementing mandatory price reductions, establishing preferences for biosimilar products, or reducing the amount of reimbursement.

In many countries, the influence of regional and hospital payers also contributes to whether patients have access to certain products. For example, a product may be 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. Finally, payers in some countries are beginning to experiment with alternative payment mechanisms (eg, payment caps) as a means to maintain access to innovative therapies.

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 cell culture, which are the processes by which our proteins are produced. The proteins are purified to a high quality and then formulated into a stable form. The fill process

Table of Contents

dispenses the formulated bulk protein into vials or syringes. Finally, in the finish process, our products are packaged for distribution.

We operate commercial and/or clinical manufacturing facilities in the United States, Puerto Rico and the Netherlands. (See Item 2. Properties.) Manufacturing of Sensipar®/Mimpara®, our small molecule product, is currently performed by third-party contract manufacturers, although we are in the process of transferring certain finishing aspects to our facility in Puerto Rico. 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, including ENBREL, Nplate®, Prolia® and XGEVA™ as well as a number of our clinical product candidates. In addition to producing our own commercial quantities of Epoetin alfa, we also supply Epoetin alfa in the United States to J&J under a supply agreement. (See Business Relationships Johnson & Johnson.)

The global supply of our principal products depends on actively managing the inventory produced at our facilities and by third-party contract manufacturers and the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers. 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.)

We have obtained from various parties certain licenses we deem necessary or desirable for the manufacture of our products. The licenses generally require us to pay royalties to the licensors based on product sales.

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 all of the commercial bulk manufacturing of all of our proteins except ENBREL, Prolia® and XGEVA™, which we supplement with a third-party contract manufacturer.

Commercial Formulation, Fill and Finish Manufacturing

Our primary commercial formulation, fill and finish manufacturing facility is located in Puerto Rico. We perform the commercial formulation, fill and finish manufacturing for our proteins at that facility, except for Vectibix® and Nplate®. We operate a commercial formulation, fill and finish manufacturing facility in the United States for Vectibix® and the formulation, fill and finish for Nplate® is performed by a third-party contract manufacturer. 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.) Certain finishing activities for our clinical products are 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

Table of Contents

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 mitigate risks while continuing to ensure adequate supply of our commercial products. For example, we are completing the construction and qualification of a new formulation and filling facility at our Puerto Rico site in order to mitigate the risk associated with the majority of our formulation and fill operations being performed in a single facility and we are qualifying the expansion of our existing bulk protein facilities at our Puerto Rico site in order to maintain supply and to satisfy anticipated future demand for denosumab. Upon completion, the facilities will require licensure by the various regulatory authorities.

We have also entered into an agreement with Boehringer Ingelheim (BI) for the divestiture of our manufacturing facility in Fremont, California to further optimize our manufacturing network.

In addition to these projects, we have initiatives 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, 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, their ability to supply our needs and the market conditions for these items.

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 (HSA). 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.)

Table of Contents

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.

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 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, R&D 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.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require parties to business relationships 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 Holdings Company, Limited

We formed KA, a 50-50 joint venture with Kirin in 1984. KA develops and commercializes certain of our and Kirin s product rights, which have been transferred to this joint venture. KA has given exclusive licenses to us to manufacture and market: (i) darbepoetin alfa 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, (ii) pegfilgrastim and G-CSF in the United States, Europe, Canada, Australia and New Zealand, (iii) recombinant human erythropoietin in the United States and (iv) romiplostim 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. We currently market darbepoetin alfa, pegfilgrastim, G-CSF, recombinant human erythropoietin and romiplostim under the brand names Aranesp®, Neulasta®, NEUPOGEN®/GRANULOKINE®, EPOGEN® and Nplate®, respectively.

KA has also given exclusive licenses to Kirin to manufacture and market: (i) darbepoetin alfa, pegfilgrastim, G-CSF and romiplostim in Japan, the People s Republic of China (China), Taiwan, Korea and certain other countries in Asia, and (ii) recombinant human erythropoietin in Japan and China. Kirin markets darbepoetin alfa in Japan under the brand name NESP®. Kirin markets G-CSF and recombinant human erythropoietin in China under separate agreements with KA. Kirin markets its G-CSF product in its respective territories under the trademark GRAN®/Grasin®/Filgrastim®. Kirin markets its recombinant human erythropoietin product in Japan under the trademark ESPO®. Kirin also markets G-CSF and recombinant human erythropoietin in China under a separate agreement with Amgen Greater China Ltd., a subsidiary of Amgen Inc.

KA has licensed to J&J rights to recombinant human erythropoietin in all geographic areas of the world outside the United States, China and Japan. (See Johnson & Johnson.) Under its agreement with KA, J&J pays a royalty to KA based on sales. KA has also licensed to Roche rights to pegfilgrastim and G-CSF in certain geographic areas of the world.

In connection with our various license agreements with KA, we pay KA royalties based on product sales. In addition, we also receive payment from KA for conducting certain R&D activities on its behalf. (See Note 7, Related party transactions to the Consolidated Financial Statements.)

27

Table of Contents

Johnson & Johnson

We granted J&J a license to commercialize recombinant human erythropoietin as a human therapeutic in the United States in all indications other than dialysis and diagnostics. All recombinant human erythropoietin sold by J&J in the United States is manufactured by us and sold by J&J under the trademark PROCRIT® (Epoetin alfa). PROCRIT® brand Epoetin alfa is identical to EPOGEN® brand Epoetin alfa, which is manufactured and sold by us in the U.S. market for the dialysis indication. Pursuant to the license agreement with J&J, we earn a 10% royalty on net sales of PROCRIT® by J&J in the United States.

Outside the United States, with the exception of China and Japan, J&J was granted rights to manufacture and commercialize recombinant human erythropoietin as a human therapeutic for all uses under a licensing agreement with KA. With respect to its sales outside of the United States, J&J manufactures and commercializes its own brand of Epoetin alfa which is then sold by a subsidiary of J&J under various trademarks such as EPREX® and ERYPO®. We are not involved in the manufacture of Epoetin alfa sold by J&J outside of the United States.

Pfizer Inc.

Amgen and Pfizer are in a collaboration agreement 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. The brand team, with equal representation from each party, prepares and implements the annual marketing plan, which requires a minimum level of financial and sales personnel commitment from each party, and is responsible for all sales activities. Further, pursuant to the collaboration agreement, 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 the annual gross profits on our ENBREL sales in the United States and Canada attributable to all approved indications for ENBREL on a scale that increases as gross profits increase; however, we maintain a majority share of ENBREL profits. After expiration of the collaboration agreement in the fourth quarter of 2013, we are required to pay Pfizer a percentage of net ENBREL sales in the United States and Canada for three years. The annual amount of such payments is anticipated to be significantly less than the current ENBREL profit share.

Glaxo Group Limited

In July 2009, we entered into a collaboration agreement with Glaxo for the commercialization of denosumab for osteoporosis indications in Europe, Australia, New Zealand and Mexico (the Primary Territories). We 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 do not currently have a commercial presence, including China, Brazil, India, Taiwan and South Korea (the Expansion Territories). In the Expansion Territories, Glaxo will be responsible for all development and commercialization costs and will purchase denosumab from us to meet demand. We have the option of expanding our role in the future 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 will also be responsible for bearing a portion of the cost of certain specified development activities in the Primary Territories.

Takeda Pharmaceutical Company Limited

In February 2008, we entered into a collaboration agreement with Takeda, which provides Takeda the exclusive rights to develop and commercialize for the Japanese market up to 12 clinical stage molecules from our pipeline across a range of therapeutic areas, including oncology and inflammation. The products include Vectibix® which received regulatory approval in Japan in 2010 for unresectable, advanced or recurrent colorectal cancer with wild-type *KRAS*, AMG 386, which is in a phase 3 trial in the United States for recurrent ovarian cancer, and

Table of Contents

ganitumab (AMG 479) which is expected to enter into a phase 3 trial in the United States for first-line metastatic pancreatic cancer in 2011. We have the right to participate in the promotion of the products in Japan. In addition, we entered into a collaboration agreement with Takeda for the worldwide development and commercialization of our product candidate motesanib in the oncology area. Each party has the right to participate in the commercialization of motesanib in the other party s territory.

Daiichi Sankyo Company, Limited

In July 2007, we entered into a collaboration and license agreement with Daiichi Sankyo, which provides Daiichi Sankyo the exclusive rights to develop and commercialize denosumab in Japan in postmenopausal osteoporosis (PMO), 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.

Fresenius Medical Care North America

In October 2006, we entered into a five-year sole sourcing and supply agreement with an affiliate of Fresenius Medical Care North America (Fresenius North America) (a wholly owned subsidiary of Fresenius Medical Care), on its behalf and on behalf of certain of its affiliates, whereby Fresenius North America agreed to purchase, and we have agreed to supply, all of Fresenius North America s commercial requirements for ESAs for use in managing the anemia of its hemodialysis patients in the United States and Puerto Rico, based on forecasts provided by Fresenius and subject to the terms and conditions of the agreement.

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 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

Table of Contents

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 a new drug application (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;

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.

Table of Contents

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, ENBREL, Prolia® and Nplate®. Because 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. Also under the FDA s PLR implemented in 2006, we are required to make changes to the existing format of U.S. product package inserts for human prescription drug and biological products with the intent of making product information more easily accessible. The PLR requires revised standards of content and format of labeling and provides timelines for when new and previously approved products must comply with the new regulations. During the PLR conversion process from an old format to the new PLR format, the FDA has the authority to evaluate the package insert information to ensure that it accurately reflects current knowledge and the FDA may revise, add or remove information in the old format that could substantively impact the content of the product package insert for the new format. Failure to implement FDA-mandated changes may result in civil or criminal penalties. (See Item 1A. Risk Factors Our ESA products continue to be under review and receive scrutiny by regulatory authorities and Our current products and products in development cannot be sold if we do not maintain or gain regulatory approval.) The package inserts for our ENBREL and Neulasta® products have already been converted to the new PLR format and we are currently working with the FDA on converting the package inserts for Aranesp®, EPOGEN® and Sensipar®. Our Vectibix®, Nplate®, Prolia® and XGEVA™ products were approved in the PLR format.

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 CRDAC and the Advisory Committee for Reproductive Health Drugs, among others, to address certain issues related to our products, including Aranesp®, EPOGEN® and Prolia®.

FDA Approval of Biosimilar Products. The new 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. While the FDA now has the authority to approve biosimilar products, the FDA has not announced whether it will first

Table of Contents

publish guidance or rules for biosimilar applicants before approving biosimilar products. The FDA held a public meeting in November 2010 to seek stakeholder input on the subject and accepted written comments through 2010.

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 (off-label promotion) 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 (GMP) 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 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 innovators. 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 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

Table of Contents

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.

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, nephrology, cardiovascular and general medicine, which includes neurology. 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.

We have major R&D centers in several locations throughout the United States and in the United Kingdom, as well as smaller research centers in Canada and Germany, and smaller development facilities throughout Europe and in Canada, Australia, Mexico, Hong Kong and India. (See Item 2. Properties.)

To execute our clinical trial programs, we need to maintain an effective development organization and associated R&D support organizations. We conduct clinical trial activities with 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

Table of Contents

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 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 licenses and collaboration agreements 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 collaborative 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 collaborative 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.

Table of Contents

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 9, 2011, 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
Ganitumab (AMG 479)	Pancreatic cancer	Hematology/Oncology
Aranesp® (darbepoetin alfa)	Anemia in heart failure	Nephrology
Motesanib	First-line non-small cell lung cancer	Hematology/Oncology
Prolia® (denosumab)	Male osteoporosis	Bone
Sensipar®/Mimpara® (cinacalcet)	Cardiovascular disease in patients with secondary hyperparathyroidism and chronic kidney disease undergoing maintenance dialysis	Nephrology
Vectibix® (panitumumab)	First- and second-line colorectal cancer	Hematology/Oncology
XGEVA™ (denosumab)	Prevention of bone metastases in prostate cancer	Hematology/Oncology
XGEVA™ (denosumab)	Prevention of bone metastases in breast cancer	Hematology/Oncology
Phase 2 Programs		
AMG 386	Various cancer types	Hematology/Oncology
Ganitumab (AMG 479)	Various cancer types	Hematology/Oncology
AMG 785	Bone-related conditions, including postmenopausal osteoporosis and fracture healing	Bone
AMG 827	Inflammatory diseases	Inflammation
AMG 853	Asthma	Inflammation
Conatumumab	Various cancer types	Hematology/Oncology
Denosumab	Rheumatoid arthritis	Inflammation
Motesanib	First-line breast cancer	Hematology/Oncology
Nplate® (romiplostim)	Chemotherapy-induced thrombocytopenia	Hematology/Oncology
Nplate® (romiplostim)	Myelodysplastic syndromes	Hematology/Oncology
Omecamtiv mecarbil (AMG 423)	Heart failure	Cardiovascular
Rilotumumab (AMG 102)	Various cancer types	Hematology/Oncology
Sensipar®/Mimpara® (cinacalcet)	Post Renal Transplant	Nephrology
Vectibix® (panitumumab)	Locally advanced head and neck cancer	Hematology/Oncology
Phase 1 Programs		
AMG 139	Inflammatory diseases	Inflammation
AMG 145	Hypercholesterolemia	Cardiovascular
AMG 151	Type 2 diabetes	General Medicine
AMG 157	Asthma	Inflammation
AMG 167	Bone-related conditions	Bone
AMG 181	Ulcerative colitis	Inflammation
AMG 191	Inflammatory diseases	Inflammation
AMG 208	Various cancer types	Hematology/Oncology
AMG 221	Type 2 diabetes	General Medicine

AMG 319	Hematologic malignancies	Hematology/Oncology
AMG 337	Various cancer types	Hematology/Oncology
AMG 557	Systemic lupus erythematosus	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 888	Various cancer types	Hematology/Oncology
AMG 900	Various cancer types	Hematology/Oncology
Dulanermin (rhApo2L/TRAIL)	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.

Table of Contents

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 Ang1 and Ang2. It is being investigated as a cancer treatment.

In 2007 and 2008, we initiated five randomized phase 2 studies of AMG 386 for the treatment of renal cell carcinoma (RCC), metastatic breast cancer, ovarian cancer, gastric cancer and colorectal cancer, and numerous other supportive studies. In June 2010 at a medical meeting, we presented the results from the phase 2 recurrent ovarian cancer trial. Based on study results, we initiated a phase 3 study in recurrent ovarian cancer in 2010. We also initiated a phase 1b study in first-line ovarian cancer in 2010. We are initiating other phase 2 studies in 2011.

Ganitumab (AMG 479)

Ganitumab (AMG 479) is a fully human monoclonal antibody antagonist of IGF-1 receptor. It is being investigated as a cancer treatment.

In 2007, we initiated a phase 2 study of ganitumab (AMG 479) as a potential cancer therapeutic in Ewing s sarcoma. We also initiated, in 2008, phase 2 studies for the treatment of advanced breast, pancreatic, colorectal and small cell lung cancers. We reported the results from the phase 2 Ewing s sarcoma and pancreatic cancer studies at a medical meeting in June 2010 and results from the breast cancer study at a meeting in December 2010. Results from a study in mCRC in combination with Vectibix® were reported at a meeting in January 2011. We are initiating a phase 3 study in first-line metastatic pancreatic cancer in 2011.

Aranesp® (darbepoetin alfa)

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

The Reduction of Events with Darbepoetin alfa in Heart Failure (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 completion of the study in 2012.

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/Millennium Pharmaceuticals.

Enrollment in the phase 3 first-line NSCLC study (MONET1) evaluating motesanib in combination with paclitaxel and carboplatin for the first-line treatment of advanced NSCLC is complete. Based on current event rates, we anticipate completion of the study in the first half of 2011.

At a medical meeting in June 2010, we shared the results of biomarkers as predictors of response to treatment with motesanib or bevacizumab in combination with carboplatin/paclitaxel in patients with NSCLC or in combination with paclitaxel in patients with locally recurrent or metastatic breast cancer.

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, RA and numerous tumor types across the spectrum of cancer-related bone diseases.

Prolia® (denosumab)

The phase 3 study evaluating Prolia® patients with male osteoporosis is ongoing.

Table of Contents

XGEVA™ (denosumab)

In February 2010, we announced that a pivotal, phase 3, head-to-head study evaluating XGEVA™ versus Zometa® (zoledronic acid) in the treatment of bone metastases in 1,901 men with advanced prostate cancer met its primary and secondary endpoints. XGEVA™ demonstrated superiority over Zometa® for both delaying the time to the first on-study SRE (fracture, radiation to bone, surgery to bone or spinal cord compression) (hazard ratio (HR) 0.82, 95% confidence interval (CI): 0.71, 0.95), and reducing the rate of multiple SREs (HR 0.82, 95% CI: 0.71, 0.94). Both results were statistically significant.

In December 2010, we announced top-line results from a phase 3 trial evaluating XGEVA™ versus placebo in 1,432 men with non-metastatic castrate-resistant prostate cancer. The trial, known as the 147 study, demonstrated that XGEVA™ significantly improved median bone metastasis-free survival by 4.2 months (HR=0.85, 95% CI 0.73-0.98, p=0.03) 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 groups (secondary endpoint). Overall rates of adverse events and serious adverse events were generally similar between XGEVA™ and placebo, with hypocalcemia and osteonecrosis of the jaw (ONJ) observed at increased frequencies in the XGEVA™ arm. The yearly rate of ONJ in the XGEVA™-treated group was similar to what has been observed in prior XGEVA™ trials. This study will form the basis of planned marketing applications, which we expect to submit to regulatory authorities beginning in the first half of 2011, for a new indication for the prevention of bone metastases in prostate cancer.

Also, we are currently conducting a study for the prevention of bone metastases in patients with breast cancer and are planning an additional 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 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® in mortality and cardiovascular morbidity in patients with CKD undergoing maintenance dialysis. The E.V.O.L.V.E™ study completed enrollment in January 2008. Based on current event rates, we anticipate completion of the study in dialysis patients in 2012.

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

Vectibix® (panitumumab)

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

On April 16, 2010, our application for marketing authorization for the use of Vectibix® in first- and second-line treatment of mCRC in patients whose tumors contain wild-type *KRAS* genes was submitted to the EMA. In the United States, we filed supplemental BLA submissions for first- and second-line mCRC with the FDA on October 29, and November 4, 2010.

In August 2010, we announced top-line results from a randomized phase 3 trial evaluating Vectibix® as a first-line treatment in patients with recurrent and/or metastatic squamous cell head and neck cancer. The data showed the

addition of Vectibix® to platinum-based chemotherapy did not result in a statistically significant improvement in overall survival, the primary endpoint, compared to chemotherapy alone [median 11.1 months versus 9.0 months, HR 0.87 (95% CI: 0.73, 1.05)]. Secondary endpoints of progression-free survival [median 5.8 months versus 4.6 months, HR 0.78 (95% CI: 0.66, 0.92)] and objective response rate (36% versus 25%) were numerically improved but were not tested for statistical significance.

Additionally, we have two ongoing phase 2 trials in locally advanced head and neck cancer.

Table of Contents

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 PMO and fracture healing.

In 2009, we initiated phase 2 studies of AMG 785 for the treatment of PMO and fracture healing (tibial diaphyseal).

In 2010, we initiated a phase 2 study of AMG 785 for the treatment of fracture healing (hip).

AMG 827

AMG 827 is a fully 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 disorders.

In 2009, we initiated phase 2 studies of AMG 827 as a potential treatment for psoriasis and RA. In 2010, we initiated phase 2 studies of AMG 827 as a potential treatment for Crohn s disease and asthma. We received the results from the phase 2 study in psoriasis in 2010 and plan to share these data at an upcoming medical meeting.

AMG 853

AMG 853 is an orally-administered small molecule antagonist of the CRTH2 and D-prostanoid receptors of prostaglandin D2. It is being investigated as a treatment for asthma.

Phase 1 single- and multiple-ascending dose studies have been completed. A global, randomized, double-blind, placebo controlled, multiple dose phase 2 study in subjects with inadequately controlled asthma was initiated in December 2009 and is ongoing.

Conatumumab

Conatumumab is a fully human monoclonal antibody agonist that targets death receptor 5 and induces apoptosis in sensitive tumor cells. It is being investigated as a cancer treatment.

We have an ongoing phase 2 study in mCRC.

Nplate® (romiplostim)

Nplate® is a peptibody agonist of the TPO receptor.

In December 2010, we announced results at a medical meeting from studies evaluating Nplate® in adult and pediatric patients with chronic immune (idiopathic) thrombocytopenic purpura.

Results from completed phase 2 studies in myelodysplastic syndromes (MDS) were presented in 2010. In late February 2011, an independent Data Monitoring Committee (DMC) recommended that we modify the study conduct in another ongoing phase 2 study exploring the use of Nplate® in MDS, expressing concern that the demonstrated benefits seen in treated patients might not outweigh the potential risks of accelerated disease progression to AML. The DMC was also concerned that transient blast cell increases in the Nplate® arm put patients at risk for diagnosis of, and treatment for, AML, irrespective of whether or not the disease had actually developed. We accepted the recommendation of the DMC and notified investigators that subjects in this study should discontinue Nplate®

treatment and enter into the observational long-term follow-up phase of the study.

Nplate® is also being evaluated in chemotherapy-induced thrombocytopenia.

Omecamtiv mecarbil (AMG 423)

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. (Cytokinetics).

Table of Contents

Rilotumumab (AMG 102)

Rilotumumab (AMG 102) is a fully human monoclonal antibody that blocks the action of hepatocyte growth factor/scatter factor. It is being investigated as a cancer treatment.

Results from a study in mCRC in combination with Vectibix® were reported at a meeting in January 2011. Phase 2 combination studies with rilotumumab (AMG 102) in the gastric, prostate, mCRC and small cell lung cancer settings continue.

Human Resources

As of December 31, 2010, Amgen had approximately 17,400 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 11, 2011 are as follows:

Mr. Kevin W. Sharer, age 62, 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. From May 2000 to May 2010, Mr. Sharer also served as the Company s President. 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 62, 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. Mr. Beier is a director of ARYx Therapeutics, Inc.

Dr. Fabrizio Bonanni, age 64, became Executive Vice President, Operations in August 2007. He has served as Senior Vice President, Manufacturing of the Company since 2004. 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 48, became President and Chief Operating Officer of Amgen in May 2010. 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. Mr. Bradway joined Morgan Stanley in New York as a health care industry investment banker in 1985 and moved to London in 1990 where he served as head of the firm s international health care investment banking activities until assuming broader corporate finance management responsibilities.

Table of Contents

Mr. Brian McNamee, age 54, 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 resource positions at GE.

Mr. Jonathan M. Peacock, age 52, 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 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.

Dr. Roger M. Perlmutter, age 58, became Executive Vice President, Research and Development in January 2001. From July 1999 to December 2000, Dr. Perlmutter was Executive Vice President, Worldwide Basic Research and Preclinical Development of Merck Research Laboratories. From February 1999 to July 1999, Dr. Perlmutter served as Executive Vice President of Merck Research Laboratories, and from February 1997 to January 1999, as Senior Vice President of Merck Research Laboratories. From May 1989 to January 1997, Dr. Perlmutter was also Chairman of the Department of Immunology, University of Washington, and from January 1991 to January 1997, Professor in the Departments of Immunology, Biochemistry and Medicine, University of Washington. From July 1984 to January 1997, Dr. Perlmutter served as Investigator at the Howard Hughes Medical Institute at the University of Washington. Dr. Perlmutter currently serves on the Board of Directors of StemCells, Inc.

Ms. Anna S. Richo, age 50, 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 58, 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 20, 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.

Table of Contents

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 also may impair our business, operations, liquidity and stock price materially and adversely.

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 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. While mandatory price reductions have been a recurring aspect of business for the pharmaceutical and biotechnology industries in Europe, given the current worldwide economic conditions, certain European country governments have increased the frequency and size of such mandatory price reductions to extract further cost savings. For example, in 2010 countries such as Greece announced price reductions and/or mandated rebates for certain pharmaceutical and biological products that substantially exceeded prior levels. We expect that other countries may follow and/or take similar or more extensive actions to reduce expenditure on drugs and biologics, including mandatory price reductions, preference for biosimilar products or reduction in the amount of reimbursement. While we cannot fully predict the extent of further price reductions by countries in Europe or the impact such price reductions will have on our business, such reductions in price and/or the coverage and reimbursement for our products in European countries could have a material adverse effect on our product sales and results of operations.

In March 2010 the United States adopted significant healthcare reform through the enactment of the PPACA and the Heathcare and Education Reconciliation Act. (See Reimbursement U.S. Healthcare Reform.) A major goal of the new healthcare reform law is to provide greater access to healthcare coverage for more Americans. Accordingly, the new 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 in January 2014. We do not expect a significant increase in sales of our products as a result of the 2014 expansions in healthcare coverage. The new healthcare reform law does have several components, with varied implementation dates that began in 2010, that have and are expected to continue to adversely impact our business. While we cannot fully predict the ultimate impact the new healthcare reform law will have on us, we expect that the new law will continue to have a material adverse effect on our business and results of operations.

Public and private insurers have pursued, and continue to pursue, aggressive cost containment initiatives, including increased focus on comparing the effectiveness, benefits and costs of similar treatments, which could result in lower reimbursement rates for our products. A substantial portion of our U.S. business relies on reimbursement under Medicare Part B coverage. Any deterioration in the timeliness or certainty of payment from CMS 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

Table of Contents

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 ASP payment methodology. 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 would 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 2011, 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 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 average manufacturers price (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 definition of AMP recently changed and we expect CMS to shortly issue a proposed rule further defining the new AMP definition. Until that rule is issued, we will be required to apply our judgment in certain aspects of the AMP calculation. Once the CMS rule is issued, we will have to determine whether our interpretation of AMP follows the rule or would need to be restated 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 has had a significant impact to our business.

The reimbursement of ESAs in the nephrology setting is also receiving attention. On March 24, 2010, CMS held a MEDCAC meeting to examine the currently available evidence on the use of ESAs to manage anemia in patients who have CKD and 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. This NCA initiates the process of reviewing and evaluating potential changes in Medicare coverage policies for the use of ESAs in those patients and may result in the issuance of a new NCD by CMS. The 30-day public comment period on the NCA ended on July 17, 2010 and CMS has stated that the NCA process for ESAs will conclude on or before June 16, 2011, but CMS could propose a new NCD at any time prior to that deadline. Additionally, on January 19, 2011, CMS held another MEDCAC meeting, this time to review the available evidence on the impact of ESA use on renal transplant graft survival. This development continues CMS s process of reviewing and evaluating potential changes in Medicare coverage policies for the use of ESAs in patients with CKD. We cannot predict if and when a new NCD will be issued or the details of any potentially changed coverage decisions for the use of ESAs in patients with CKD, including whether or how a new NCD could change CMS s bundled payment system and/or the ESRD QIP. However, similar to the impact of the 2007 NCD on the use of ESAs in oncology, a new NCD around the use of ESAs to manage anemia in patients with CKD and dialysis-related anemia may negatively affect use, coverage and reimbursement, and/or product sales of our ESA products in the nephrology setting, which could have a material adverse effect on our business and results of operations.

Further, the list of potential future NCDs issued by CMS in late 2008 included 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

Table of Contents

thrombopoiesis stimulating agents and, while Prolia® is not a bisphosphonate, 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 the ESRD Program of Medicare. The ESRD Program reimburses approved dialysis providers for 80% of allowed dialysis costs while the remainder is paid by other sources, including patients, state Medicaid programs, private insurance and, to a lesser extent, state kidney patient programs. The ESRD Program reimbursement methodology is established by federal law and is implemented by CMS. Until January 1, 2011, Medicare reimbursed for separately billable dialysis drugs (including EPOGEN® and Aranesp®) 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 facilities which provides a single payment for all dialysis services including drugs, supplies, and non-routine laboratory tests that were previously reimbursed separately. (See Reimbursement Reimbursement of Our Principal Products Dialysis Reimbursement.) Dialysis providers were given the choice of opting into the new bundled payment system in its entirety on January 1, 2011, or phasing in ratably over a four-year period beginning in 2011. Substantially all dialysis providers in the United States have opted into the bundled payment system in its entirety beginning in 2011. We expect that the implementation of the bundled payment system by ESRD facilities will have a material adverse impact on the reimbursement, use and sales of EPOGEN® beginning in 2011, and Sensipar® beginning in 2014.

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. For example, since April 2006, the Medicare reimbursement for ESAs administered to dialysis patients has also been subject to an EMP, the Medicare payment review mechanism used by CMS to monitor EPOGEN® and Aranesp® utilization and hematocrit outcomes of dialysis patients. CMS revised the EMP, effective January 2008, further limiting reimbursement for EPOGEN® and Aranesp® in certain cases. Further reduction in reimbursement in the dialysis setting could have a material adverse effect on sales of EPOGEN® and Aranesp®, and our business.

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 our results of operations.

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

Our business is subject to extensive regulation by numerous state and federal governmental authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in foreign countries to obtain approval from regulatory authorities before we can manufacture, market and sell our products. Once approved, the FDA and other U.S. and foreign regulatory agencies have substantial authority to require additional testing, 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 new healthcare reform law; renegotiation of the Prescription Drug User Fee Act, 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 impact on our business.

Table of Contents

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.

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. Further some of our products are approved by U.S. and foreign regulatory authorities on a conditional basis with full approval conditioned upon fulfilling requirements of regulators. Vectibix®, for example, received conditional approval in the United States and EU, with full approval conditioned on conducting additional clinical trials of the use of Vectibix® as a therapy in treating mCRC. (See Marketed Products and Selected Product Candidates 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 and may be required to change the products labeled indications or even withdraw the products from the market. 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.

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 ESA products 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 clinical trials (including sub-analyses and meta-analyses), market use or other sources are receiving greater scrutiny. Actual or perceived safety problems 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

44

Table of Contents

- 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

- new legislation or rules by regulatory agencies

For example, in December 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. 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. We are working with the FDA to determine the appropriate use of ESAs in CKD patients and to determine any future ESA labeling changes required in connection with TREAT or the CRDAC meeting. (See Our ESA products 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 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

- 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

- 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, ENBREL, 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 Nplate® and ESA REMS each require 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 Nplate® and 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.

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

Table of Contents

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 formulation with glass vials during the shelf life of the product. The recalls were executed in close collaboration 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 adversely affect the sales of our products. 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 adversely affect the sales of our products and our business and results of operations.

If regulatory authorities determine that we have not complied with regulations in the R&D of a product candidate, a new indication for an existing product or information to support a current indication, they may 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 would be materially and adversely affected. Further, safety signals, trends, adverse events or results from clinical trials or studies performed by us or by others (including our licensees or independent investigators) 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.

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

Beginning in 2006, adverse safety results involving ESA products were observed and since that time our ESAs have been the subject of ongoing review and scrutiny by regulatory authorities and reimbursement agencies. In the United States, the FDA continues to review the benefit-risk profile of ESAs, which have resulted and could result in future changes to ESA labeling and usage. For example, we revised the labeling for our ESAs in August 2008, 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. 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. CMS held a MEDCAC meeting on March 24, 2010 to examine the currently available evidence on the use of ESAs to manage anemia in patients who have CKD, which considered the results from the TREAT study, and on June 16, 2010, CMS opened a new NCA to examine the use of ESAs to manage anemia in patients with CKD and dialysis-related anemia. On October 18, 2010 the FDA s CRDAC discussed the results from the TREAT study conducted in patients not on dialysis, and how those results informed the appropriate use of ESAs in patients with CKD. Prior to the CRDAC meeting, we submitted 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

Table of Contents

considered clinically important, including those in whom it is important to preserve kidney transplant eligibility. A variety of opinions regarding the appropriate use of ESAs in patients with CKD were offered at the CRDAC meeting by the various meeting participants. On January 19, 2011, CMS held another MEDCAC meeting, this time to review the available evidence on the impact of ESA use on renal transplant graft survival. (See Our sales depend on coverage and reimbursement from third-party payers.) We are working with the FDA to determine the appropriate use of ESAs in CKD patients and we continue to cooperate with CMS in determining appropriate reimbursement for our ESAs. Although we cannot predict what impact all of these activities (including the revised ESA labeling; any future ESA labeling changes required in connection with TREAT or the CRDAC meeting or from our ongoing discussions with the FDA regarding the conversion of the format of our ESA U.S. labels in accordance with the Physician s Labeling Rule; the outcome from the NCA or MEDCAC meetings, including an NCD; and the impact of the approved REMS for ESAs) could have on our business, these activities could, individually or together, have a material adverse impact on the coverage, reimbursement, use and/or sales of our ESAs, which would have a material adverse effect on our business and results of operations. (See Our current products and products in development cannot be sold if we do not maintain or gain regulatory approval.)

We also have ongoing PMCs for our ESAs that must be conducted to maintain regulatory approval and marketing authorization. We have agreed with the FDA to a robust pharmacovigilance program to continue to study the safety surrounding the use of ESAs in the oncology setting and we initiated Study 782 as part of our Aranesp® pharmacovigilance program, a phase 3 non-inferiority study evaluating overall survival when comparing NSCLC patients on Aranesp® to patients receiving placebo. We continue to identify clinical sites for Study 782 and to enroll patients in the study. In addition, J&JPRD s EPO-ANE-3010 study, which evaluates the use of Epoetin alfa in patients with breast cancer, is ongoing and is designated as an FDA PMC. Further, in 2008 the FDA and the EMA reviewed interim results from the Preoperative Epirubicin Paclitaxel Aranesp® (PREPARE) study in neo-adjuvant breast cancer, a PMC study, which were ultimately incorporated into the ESA labeling in both the United States and the EU. We received the final results from the PREPARE study in 2009, which were substantially consistent with the interim results, and provided that data to the FDA and EMA. 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 adverse results from clinical trials, including PMCs, could have a material adverse impact on the reimbursement, use and sales of our ESAs, which would have a material adverse effect on our business and results of operations.

Regulatory authorities outside the United States have also reviewed and scrutinized the use of our ESA products. 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. Since the October 2008 revision, we have experienced a reduction of Aranesp® sales in the supportive cancer care setting in the EU and, although we cannot predict what further impact the revised EU ESA product information could have on our business, the coverage, reimbursement, use and sales of Aranesp® in Europe could further be materially adversely affected, which would have a material adverse effect on our business and results of operations.

Moreover, we continue to receive results from meta-analyses or previously initiated clinical trials using ESAs, including PMCs, and adverse results could negatively impact the use and sales of our ESAs. For example, in September 2008, we announced that we had received a summary of preliminary results from the Cochrane Collaboration s 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.

Table of Contents

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. For example, in 2006 we delayed the start of our phase 3 trial in first-line NSCLC due to an increased frequency of cholecystitis (inflammation of the gall bladder) in patients treated with our late-stage product candidate motesanib. Following initiation of the trial in November 2008, enrollment in this phase 3 trial was temporarily suspended following a planned safety data review of 600 patients by the study s independent DMC. In February 2009, the DMC recommended the trial resume enrollment of patients with non-squamous NSCLC only, and in June 2009, we reinitiated enrollment in this patient population following an FDA-approved revision to the study protocol.

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, East Asia 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 would be materially 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.)

Further, we rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations. In the event that any of these vendors has unforeseen issues that negatively impact the quality of its work, our ability to 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.

Patients may also suffer adverse medical events or side effects in the course of our, our licensees, partners or independent investigator s 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

render the product candidate commercially unfeasible or limit our ability to market existing products completely or in certain therapeutic areas.

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

Table of Contents

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® pharmacovigilance program. (See Our ESA products continue to be under review and receive scrutiny by regulatory authorities.) 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 may have a material adverse effect on 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 which could impact our profitability.

We currently face competition in Europe from biosimilar products, and we expect to face increasing competition from biosimilars in the future. Lawmakers in the United States have recently 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. 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. 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 results of operations.

On March 23, 2010, President Obama signed into law the PPACA which authorized the FDA to approve biosimilar products under a new abbreviated pathway. The new 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 new law does not change the duration of patents granted on biologic products. As part of

the implementation process, the FDA published several questions in the Federal Register for public comment. The FDA held a public meeting in November 2010 to seek stakeholder input on the subject and accepted written comments through 2010. The agency has the authority to approve biosimilar products but has not announced whether it will first publish guidance or rules for biosimilar applicants before approving biosimilar products. With the likely introduction of biosimilars in the United States, we expect in the future to face greater competition from

Table of Contents

biosimilar products and downward pressure on our product prices, sales and revenues, subject to our ability to enforce our patents. 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 2012 budget includes a proposal to lower the data exclusivity period to seven years, but this would require new legislation be passed by the Congress. Critics may also encourage the FDA to interpret narrowly the law s provisions regarding which new products receive data exclusivity.

We may not be able to develop commercial products.

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

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results, for reasons that could include changes in the standard of care of medicine
- the product candidate was not effective or more effective than currently available therapies in treating a specified condition or illness
- the product candidate is not cost effective in light of existing therapeutics
- the product candidate had harmful side effects in humans or animals
- the necessary regulatory bodies, such as the FDA or EMA, did not approve our product candidate for an intended use
- the product candidate was not economical for us to manufacture and commercialize
- 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
- the regulatory pathway to approval for product candidates is uncertain or not well-defined

For example, after discussions with the FDA we have decided not to file for approval of motesanib in refractory thyroid cancer until there is more clarity on what would constitute an appropriate regulatory filing package for that indication. Further, 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 generic manufacturers of pharmaceutical products are expanding into the biotechnology field with increasing frequency. These companies may have greater resources than we do. In addition, some of our competitors may have technical

Table of Contents

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 Inc. and Fresenius North America own or manage a large number of the outpatient dialysis facilities located in the United States and account for a substantial majority of all EPOGEN® sales in the free-standing dialysis clinic setting. Due to this concentration, these entities have substantial purchasing leverage, which may put pressure on our pricing by their potential ability to extract price discounts on our products or fees for other services, correspondingly negatively impacting our bargaining position and profit margins. In October 2006, we entered into a five-year sole sourcing and supply agreement with an affiliate of Fresenius North America, on its behalf and on behalf of certain of its affiliates, whereby they have agreed to purchase, and we have agreed to supply, all of Fresenius North America s commercial requirements for ESAs for use in managing the anemia of its hemodialysis patients in the United States and Puerto Rico, based on forecasts provided by Fresenius North America and subject to the terms and conditions of the agreement.

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
- discovery of previously unknown or undetected imperfections in raw materials, medical devices or components

These events could adversely affect our ability to satisfy demand for our products, which could adversely affect our product use, sales and operating results materially. For example, we have experienced shortages in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility without impact on our ability to supply these products. 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.

Table of Contents

Also, certain of the raw materials required in the commercial and clinical manufacturing of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues. In addition, one of our marketed products also uses bovine serum and human serum albumin. Some countries in which we market our products may restrict the use of certain biologically derived substances in the manufacture of drugs. We continue to investigate alternatives to certain biological sources and alternative manufacturing processes that do not require the use of certain biologically derived substances because such raw materials may be subject to contamination and/or recall.

A material shortage, contamination, recall and/or restriction of the use of certain biologically derived substances or other raw materials, which may be sourced from other countries and that are used in the manufacture of our products could adversely impact or disrupt the commercial manufacturing of our products or could result in a mandated withdrawal of our products from the market. This could adversely affect our ability to satisfy demand for our products, which could adversely affect our product sales and operating results materially. 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 affect on our 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® and XGEVA™ 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 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

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 and results of operations.

Table of Contents

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, we are completing the construction and qualification of a new formulation and filling facility at our Puerto Rico site in order mitigate the risk associated with the majority of our formulation and fill operations being performed in a single facility. 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 a single distribution center in Louisville, Kentucky for the United States and another 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, such as earthquakes or volcanic eruptions, 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 EPOGEN®, Aranesp®, Neulasta®, NEUPOGEN®, Prolia® and XGEVA™ and substantially all of the formulation, fill and finish operations for ENBREL, and all of the bulk manufacturing for Aranesp®, Neulasta®, and NEUPOGEN® at our manufacturing facility in Juncos, Puerto Rico. In addition, we expect/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 also 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 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

Table of Contents

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 adversely affect our product sales and operating results materially. Although we have obtained limited insurance to protect against certain business interruption losses, there can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all. The extent of the coverage of our insurance could limit our ability to mitigate for lost sales and such losses could materially adversely affect our product sales 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.)

If our intellectual property positions are challenged, invalidated, circumvented or expire, or if we fail to prevail in present and future intellectual property litigation, our business could be adversely affected.

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 are currently, and in the future may be, involved in patent litigation. (See Note 19, Contingencies and commitments in the notes to our consolidated financial statements in our annual report.) 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, despite the ongoing litigation, Teva has stated that it intends 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, products approved by the FDA under a NDA may be the subject of patent litigation with generic competitors before the five year period of data exclusivity provided for under the Hatch-Waxman Act has expired and prior to the expiration of the patents listed for the product.

Over the next several years, the existing patents on our principal products will begin to 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 result in a reduction in the use and sales of our products. While we

have, and we continue to seek, additional patent protection on certain of our products, including for specific processes for making our products, formulations and particular uses of our products, competitors may be able to design around or otherwise circumvent any such additional patents and sell competing products. Although we continue to develop and obtain patent protection for new product candidates, we may not be able to replace the revenue lost upon the expiration of the patents on our current products.

Table of Contents

In recent years, policymakers have proposed reforming U.S. patent laws and regulations. For example, patent reform legislation was introduced in both the House and the Senate during the 111th Congress in 2009 but was not adopted into law. Legislation was again introduced in the Senate and passed the Senate Judiciary Committee on February 3, 2011. In general, the proposed legislation attempts to address issues surrounding the increase in patent litigation by, among other things, establishing new procedures for challenging patents. While we cannot predict what form any new patent reform laws or regulations may ultimately take, final legislation could introduce new substantive rules and procedures for challenging patents, and certain reforms that make it easier for competitors to challenge our patents could have a material adverse effect on our business.

Our business may be affected by litigation and government investigations.

We and certain of our subsidiaries are involved in legal proceedings. (See Note 19, 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 results of operations, financial position or cash flows. 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. We have received subpoenas from a number of 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 have been 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 have been issued pursuant to state specific statutes relating to consumer fraud laws and state false claims acts. The government is allowed to use materials produced in response to a section 3486 administrative subpoena in both criminal and civil investigations. In general, the subpoenas request 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, we now believe the subpoenas we received from the U.S. Attorney s Offices for the Eastern District of New York and the Western District of Washington also relate to nine additional Qui Tam Actions which are purportedly pending 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. The U.S. government filing further alleges that a large number of states are involved in the Qui Tam investigations, led by the State of New York. These investigations are represented to be joint criminal and civil investigations.

Throughout these investigations, and in litigation, 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 results of operations, financial position or cash flows in the period in which such liabilities are incurred.

Table of Contents

Our stock price is volatile.

Our stock price, like that of our peers in the biotechnology industry, 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.

The capital and credit markets may experience extreme volatility and disruption which may lead to uncertainty and liquidity issues for both borrowers and investors. Historically, we have occasionally and opportunistically accessed the capital markets to support certain business activities including acquisitions, in-licensing activities, share repurchases and to refinance existing debt. 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.

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

Our operations and performance have been, and may continue to be, affected by economic conditions. 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.) In the United States, there is an increased focus from 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. 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 biosimilar or generic 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 affect on the sales of our products, our business and results of operations.

We are exposed to sovereign risk in some European countries where we sell directly to public healthcare systems. Economic and fiscal conditions in these countries could affect the amount and timing of the collection of our receivables. For example, the government of Greece has issued one-, two- and three-year zero-coupon bonds to various pharmaceutical vendors in lieu of payment of past due receivables dating from 2007 to 2009.

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 continue to adversely affect our business and results of operations. Any resulting decrease in demand

Table of Contents

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.

Additionally, we 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 affect on 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 has and may continue to contribute to lower sales of our products. For example, in the first quarter of 2009, certain of our wholesale distributors lowered their levels of inventory on hand, which we believe was done to reduce their carrying costs and improve their results of operations. 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 negatively impact our business and results of operations.

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.

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

In August 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 Kidney Disease: Improving Global Outcomes group (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. KDIGO has stated that its new guidelines are expected to be released for public review and comment in early to mid-2011 and 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.

Table of Contents

In addition, Health Technology Assessment organizations, such as NICE in the United Kingdom 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 adversely affect our product sales and operating results materially. 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 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 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 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 materially adversely affected, which could have a material adverse effect on our product sales and results of operations.

Continual process improvement efforts 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 continuous process improvement activities 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 process improvement 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 affect on our results of operations.

Table of Contents

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 statutory tax rates, changes in the valuation of deferred tax assets and liabilities, and changes in applicable tax laws. In addition, President Obama s administration has announced proposals for U.S. tax legislation that, if adopted, could adversely affect our provision for income taxes. There are also other tax proposals that have been introduced, that are being considered, or that have been enacted by the U.S. Congress or the legislative bodies in foreign jurisdictions that could materially adversely affect our provision for income taxes, tax liabilities or our results of operations. For example, the Commonwealth of Puerto Rico recently enacted tax legislation effective on January 1, 2011 that, in certain circumstances, imposes a temporary excise tax for companies that purchase products from related Puerto Rico manufacturers.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Table of Contents

Item 2. PROPERTIES

The following table summarizes our significant properties and their primary functions as of December 31, 2010. For additional information regarding manufacturing initiatives, see Item 1. Business Manufacturing, Distribution and Raw Materials.

Table of Contents

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 19, Contingencies and commitments to our Consolidated Financial Statements in our 2010 Form 10-K and are hereby incorporated by reference.

Item 4. RESERVED

Table of Contents

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 11, 2011, there were approximately 10,156 holders of record of our common stock. No cash dividends have been paid on the common stock to date.

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, 2010	**High**	**Low**
Fourth quarter	$ 57.96	$ 52.69
Third quarter	56.32	50.93
Second quarter	61.14	50.36
First quarter	60.09	55.71
Year ended December 31, 2009		
Fourth quarter	$ 61.83	$ 52.12
Third quarter	64.41	51.47
Second quarter	53.11	45.11
First quarter	59.65	46.27

Table of Contents

Performance graph

The following graph shows the value of an investment of $100 on December 31, 2005 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, 2005

	12/31/2005	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010
Amgen (AMGN)	$ 100.00	$ 86.62	$ 58.89	$ 73.23	$ 71.73	$ 69.62
Amex Biotech (BTK)	100.00	110.77	115.51	95.05	138.36	190.57
Amex Pharmaceutical (DRG)	100.00	110.59	111.71	93.74	109.66	112.41
S&P 500 (SPX)	100.00	115.61	121.95	77.38	97.44	111.88

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.

Table of Contents

Stock repurchase program

Repurchases under our stock repurchase program reflect, in part, our confidence in the long-term value of our common stock. Additionally, we believe it is an effective way of returning cash to our stockholders. The manner of purchases, the amount we spend and the number of shares repurchased will vary based on a number of factors including stock price, blackout periods in which we are restricted from repurchasing shares, and the impact of repurchases on our credit rating and may include private block purchases as well as market transactions.

During the three months ended December 31, 2010, we had one outstanding stock repurchase program. A summary of our repurchase activity for the three months ended December 31, 2010 is as follows:

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced program	Maximum $ value that may yet be purchased under the program[(1)]
October	7,822,000	$ 56.42	7,822,000	$ 2,858,007,633
November	8,900,000	55.34	8,900,000	2,365,472,020
December	3,725,580	54.23	3,725,580	2,163,426,209
	20,447,580	55.55	20,447,580	

(1) In December 2009, the Board of Directors authorized us to repurchase up to an additional $5.0 billion of common stock.

Table of Contents

Item 6. SELECTED FINANCIAL DATA

Consolidated Statement of Income Data:	Years ended December 31, 2010	2009	2008	2007	2006
	(In millions, except per share data)				
Revenues:					
Product sales	$ 14,660	$ 14,351	$ 14,687	$ 14,311	$ 13,858
Other revenues	393	291	316	460	410
Total revenues	15,053	14,642	15,003	14,771	14,268
Operating expenses[1][2]:					
Cost of sales (excludes amortization of certain acquired intangible assets presented below)[3]	2,220	2,091	2,296	2,548	2,095
Research and development[4]	2,894	2,864	3,030	3,266	3,366
Selling, general and administrative	3,983	3,820	3,789	3,361	3,366
Amortization of certain acquired intangible assets[5]	294	294	294	298	370
Write-off of acquired in-process research and development[6]				590	1,231
Other charges[7]	117	67	380	728	
Net income[11]	4,627	4,605	4,052	3,078	2,809
Diluted earnings per share[11]	4.79	4.51	3.77	2.74	2.36
Cash dividends declared per share					

Consolidated Balance Sheet Data:	As of December 31, 2010	2009	2008	2007	2006
	(In millions)				
Total assets[2]	$ 43,486	$ 39,629	$ 36,427	$ 34,618	$ 33,711
Total debt[8][9][11]	13,362	10,601	9,352	10,114	7,725
Stockholders equity[9][10][11]	23,944	22,667	20,885	18,512	19,841

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 Form 10-K s 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.

(1) 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 for certain facilities that will not be used in our business.

(2) In 2008, we completed the acquisition of Dompé Biotec, S.p.A (Dompé). The purchase price paid was approximately $168 million, which included the carrying value of our existing 49% ownership in Dompé. In July 2007, we acquired all of the outstanding shares of Ilypsa, Inc. (Ilypsa) for a net purchase price of approximately $400 million. Also in July 2007, we acquired all of the outstanding shares of Alantos Pharmaceuticals Holding, Inc. (Alantos) for a net purchase price of approximately $300 million. In October

2006, we acquired all of the outstanding stock of Avidia, Inc. (Avidia) for a net purchase price of approximately $275 million. In April 2006, we acquired all of the outstanding common stock of Abgenix for a purchase price of approximately $2.2 billion.

(3) Included in cost of sales (excludes amortization of certain acquired intangible assets) for 2007 is a charge of $30 million related to the write-off of the cost of a semi-completed manufacturing asset that will not be used due to a change in manufacturing strategy.

Table of Contents

(4) Included in R&D expenses for 2010, 2009, 2008, 2007 and 2006 is the ongoing, non-cash amortization of the R&D technology intangible assets acquired with alternative future uses of $70 million ($44 million, net of tax), $70 million ($44 million, net of tax), $70 million ($44 million, net of tax), $71 million ($44 million, net of tax) and $48 million ($30 million, net of tax), respectively, acquired with the acquisitions of Avidia and Abgenix in 2006.

(5) Primarily represents the non-cash amortization of acquired product technology rights, related primarily to ENBREL, acquired in the Immunex acquisition. Amortization charges, net of tax, for the five years ended December 31, 2010 were $186 million, $186 million, $183 million, $185 million and $200 million, respectively.

(6) As part of the accounting for the business combinations of Alantos and Ilypsa in 2007 and Avidia and Abgenix in 2006, 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 in 2007, respectively, and $130 million and $1.1 billion in 2006, 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.

(7) In 2010 we incurred an asset impairment charge of $118 million ($74 million, net of tax) associated with a strategic decision to optimize our network of manufacturing facilities. In 2009, we recorded loss accruals for settlements of certain legal proceedings aggregating $33 million. 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. In 2007, we recorded a loss accrual for an ongoing commercial legal proceeding and recorded an expense of $34 million. The remaining amounts included in Other charges in 2009, 2008 and 2007, related primarily to charges for cost saving initiatives and restructuring. (See Note 8, Cost savings initiatives and restructuring to the Consolidated Financial Statements.)

(8) In 2010, we issued $900 million aggregate principal amount of notes due in October 2020 (the October 2020 Notes), $700 million aggregate principal amount of notes due in 2040 (the 2040 Notes), $600 million aggregate principal amount of notes due in 2041 (the 2041 Notes) and $300 million aggregate principal amount of notes due in March 2020 (the March 2020 Notes). In 2009, we issued $1.0 billion aggregate principal amount of notes due in 2019 (the 2019 Notes) and $1.0 billion aggregate principal amount of notes due in 2039 (the 2039 Notes). In 2009, we repaid our $1.0 billion 4.00% notes. In 2008, we issued $500 million aggregate principal amount of notes due in 2018 (the 2018 Notes) and $500 million aggregate principal amount of notes due in 2038 (the 2038 Notes). In 2008, we repaid our $2.0 billion of floating rate notes.

(9) In 2007, as a result of holders of substantially all of our outstanding 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. In 2007, we issued $2.0 billion aggregate principal amount of floating rate notes due in 2008, $1.1 billion aggregate principal amount of notes due in 2017 and $900 million aggregate principal amount of notes due in 2037. A total of $3.2 billion of the net proceeds raised from the issuance of those notes was used to repurchase shares of our common stock under an accelerated share repurchase program entered into in May 2007. In 2006, we issued $2.5 billion aggregate principal amount of convertible notes due in 2011 (the 2011 Notes) and $2.5 billion aggregate principal amount of convertible notes due in 2013 (the 2013 Notes). In connection with the issuance of those notes, a total of $3.0 billion of our common stock was repurchased under our stock repurchase program. Also, concurrent with the issuance of those notes, we purchased convertible note hedges in private transactions. The cost of the convertible note hedges, which aggregated approximately $1.5 billion, was recorded as a reduction of equity. Also, concurrent with the issuance of those notes, we sold warrants to acquire shares of our common stock. Proceeds received from the issuance of the warrants totaled approximately $774 million.

(10) Throughout the five years ended December 31, 2010, we had share repurchase programs authorized by the Board of Directors through which we repurchased $3.8 billion, $3.2 billion, $2.3 billion, $5.1 billion and $5.0 billion, respectively, of Amgen common stock.

Table of Contents

(11) 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, including our 2011 Convertible Notes, 2013 Convertible Notes and zero coupon 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 2010, 2009, 2008, 2007 and 2006 is the incremental non-cash interest expense of $266 million ($168 million, net of tax), $250 million ($155 million, net of tax), $235 million ($144 million, net of tax), $168 million ($88 million, net of tax) and $197 million ($141 million, net of tax), respectively, related to the adoption of the new accounting standard.

Table of Contents

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, and continue, as well as variations of such words and similar expressions are intended to identify such forward looking statements. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in Item 1A. Risk Factors. We have based our forward looking statements on our management s beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecast by our forward looking statements. Reference is made in particular to forward looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, earnings per share (EPS), liquidity and capital resources and trends. 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 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, nephrology and inflammation. Our principal products include Aranesp®, EPOGEN®, Neulasta®, NEUPOGEN® and ENBREL, all of which are sold in the United States. ENBREL is marketed under a collaboration agreement with Pfizer in the United States and Canada. Our international product sales consist principally of European sales of Aranesp®, Neulasta® and NEUPOGEN®. For additional information about our products, their approved indications and where they are marketed, see Item 1. Business Marketed Products.

Throughout 2010 and early 2011, various developments occurred regarding our business, including regulatory and reimbursement developments associated with certain of our marketed products and product candidates. Most notably, the FDA approved Prolia® and XGEVA™, and the EC granted marketing authorization for Prolia® for certain indications. In addition, healthcare reform legislation was enacted in the United States. As a result of these and other developments, we have various opportunities to grow our business but will also continue to face various challenges. The following summarizes certain key opportunities and challenges.

We have various opportunities to grow our business. In the near term, we believe the currently approved indications for Prolia® and XGEVA™ represent significant commercial opportunities. In addition, receipt of regulatory approvals in new geographic territories or for additional indications for these products may also provide further significant opportunities. For example, the results of our recently announced phase 3 trial evaluating

Table of Contents

XGEVA™ versus placebo in men with castrate-resistant prostate cancer met its primary endpoint. This study will form the basis of planned marketing applications, which we expect to submit to regulatory authorities beginning in the first half of 2011, for the prevention of bone metastases in prostate cancer. Longer-term growth may also be achieved by the successful development of our late-stage pipeline and strategic business development opportunities, such as our recently announced agreement to acquire BioVex. In addition, longer-term growth may also be achieved by expansion into emerging markets and Japan.

Looking forward, we believe our products will continue to face various regulatory, reimbursement and competitive challenges. Our ESA products, in particular, have several near-term challenges that could result in further reductions in sales. For example, EPOGEN® sales will be impacted by the Final Rule on Bundling in Dialysis that became effective in 2011. Further, the NCA opened by CMS in June 2010 and the results of the MEDCAC meetings held in March 2010 and January 2011 could lead to an NCD for the use of ESAs in patients with kidney disease, which could impact the use of or reimbursement for ESAs to manage anemia in patients with CKD and/or dialysis-related anemia. In addition, the FDA-approved REMS for ESAs may continue to impact Aranesp® sales in the supportive cancer care setting. Future product label changes (including those we proposed prior to the 2010 CRDAC meeting, any others required in connection with TREAT or the CRDAC meeting and any from the PLR conversion process), may also impact the use of ESAs in CKD. Since we rely in large part on the reimbursement of our products through government programs such as Medicare and Medicaid, the recently enacted healthcare reform law has had and will continue to have a material adverse impact on sales of our products in the United States and on our results of operations. The provisions of the new legislation impacted our U.S. product sales by approximately $200 million in 2010, and we anticipate that our U.S. product sales in 2011 will be impacted by $250 million to $300 million. Furthermore, we estimate that our results of operations for 2011 will be impacted by an additional $150 million to $200 million related to a new fee on manufacturers and importers of branded prescription drugs established by that legislation, which is not deductible for U.S. federal income tax purposes. Certain of our products will also continue to face increasing competitive pressure, in particular ENBREL in the United States, as well as Aranesp®, Neulasta® and NEUPOGEN® in Europe as a result of biosimilars. In addition, over the next several years, the existing patents on our principal products will begin to expire, and we expect to face increasing competition thereafter. (See Item 1. Business Marketed Products.)

Certain of these developments are expected to have a material adverse impact on our sales and results of operations. However, these effects may be mitigated by certain of the opportunities we have to grow our business, discussed above, by other strategic initiatives or by increased efforts to manage our expenses.

Selected Financial Data

The following table presents selected financial data for the years ended December 31, 2010 and 2009 (amounts in millions, except percentages and per share data):

	2010	Change	2009
Product sales:			
U.S.	$ 11,254	1%	$ 11,135
International	3,406	6%	3,216
Total product sales	14,660	2%	14,351
Other revenues	393	35%	291
Total revenues	$ 15,053	3%	$ 14,642

Operating expenses	$ 9,508	4%	$ 9,136
Operating income	$ 5,545	1%	$ 5,506
Net income	$ 4,627		$ 4,605
Diluted EPS	$ 4.79	6%	$ 4.51
Diluted shares	965	(5)%	1,021

The following discusses certain key changes in our results of operations for the year ended December 31, 2010 as well as our financial condition as of December 31, 2010.

Table of Contents

The increase in our U.S. product sales for 2010 reflects overall growth for all of our marketed products, except for our ESA products, which declined 5%. The growth in sales of our non-ESA products reflects increases primarily in average net sales prices and, to a lesser extent, favorable changes in wholesaler inventories. U.S. product sales in 2010 were unfavorably impacted by $198 million as a result of the recently enacted U.S. healthcare reform law.

The increase in our international product sales for 2010 reflects overall growth for all of our marketed products, except for Aranesp®, which declined 1%.

The increase in other revenues for 2010 was due primarily to milestone payments earned from Glaxo in connection with certain commercial milestones for Prolia® in the EU and from Takeda in connection with certain regulatory milestones for Vectibix® in Japan.

The increase in operating expenses for 2010 was due principally to higher cost of sales, due primarily to higher bulk manufacturing costs, as well as higher selling, general and administrative (SG&A) expenses, due primarily to increased promotional costs for Prolia® and our other marketed products.

Net income was relatively unchanged in 2010 as the increases in operating income, discussed above, and interest and other income were offset substantially by an increase in our provision for income taxes. The increase in interest and other income was due primarily to higher net realized gains on sales of investments and higher interest income. The increase in our provision for income taxes was due principally to reduced benefits resulting from settlements with tax authorities in 2010.

The increase in diluted EPS for 2010 principally reflects a reduction in our weighted-average shares used to compute diluted EPS resulting from our stock repurchase program, including approximately 67 million shares repurchased in 2010 at a total cost of $3.8 billion.

Although changes in foreign currency 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 impact, 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.

As of December 31, 2010, our cash, cash equivalents and marketable securities totaled $17.4 billion, and total debt outstanding was $13.4 billion, including $2.5 billion which was repaid in February 2011. Of our total cash, cash equivalents and marketable securities balance as of December 31, 2010, approximately $15.1 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 those funds were repatriated for use in our U.S. operations, we would be required to pay additional U.S. federal and state income taxes at the applicable marginal tax rates.

Table of Contents

Results of Operations

Product sales

For the years ended December 31, 2010, 2009 and 2008, worldwide product sales and total product sales by geographic region were as follows (dollar amounts in millions):

	2010	Change	2009	Change	2008
Aranesp®	$ 2,486	(6)%	$ 2,652	(15)%	$ 3,137
EPOGEN®	2,524	(2)%	2,569	5%	2,456
Neulasta®/NEUPOGEN®	4,844	4%	4,643		4,659
ENBREL	3,534	1%	3,493	(3)%	3,598
Sensipar®/Mimpara®	714	10%	651	9%	597
Vectibix®	288	24%	233	52%	153
Nplate®	229		110		17
Prolia®	33				
XGEVA™	8				
Other					70
Total product sales	$ 14,660	2%	$ 14,351	(2)%	$ 14,687
Total U.S.	$ 11,254	1%	$ 11,135	(3)%	$ 11,460
Total International	3,406	6%	3,216		3,227
Total product sales	$ 14,660	2%	$ 14,351	(2)%	$ 14,687

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;
- 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;

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;

Table of Contents

competitive products, including biosimilars;

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.

Our U.S. product sales are also subject to certain other influences throughout the year, including wholesaler and end-user buying patterns (eg, 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 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.)

Aranesp®

For the years ended December 31, 2010, 2009 and 2008, total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	2010	Change	2009	Change	2008
Aranesp® U.S.	$ 1,103	(12) %	$ 1,251	(24) %	$ 1,651
Aranesp® International	1,383	(1) %	1,401	(6) %	1,486
Total Aranesp®	$ 2,486	(6) %	$ 2,652	(15) %	$ 3,137

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

U.S. sales of Aranesp® for 2008 benefited from certain changes in accounting estimates related to product sales return reserves. Excluding the positive impact of these changes in accounting estimates, the decrease in U.S. Aranesp® sales of approximately 21% for 2009 was due primarily to a decline in unit demand and a low single-digit percentage point decrease in the average net sales price. The decline in unit demand reflects the negative impact, primarily in the supportive cancer care setting, of a product safety-related label change in August 2008 as well as an overall decline in the segment and a slight loss of segment share. Excluding an $85 million unfavorable foreign exchange impact, international Aranesp® sales for 2009 remained unchanged.

Table of Contents

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 REMS for our ESAs approved by the FDA in February 2010;
- product label changes, including those proposed prior to the October 2010 CRDAC meeting and any others required in connection with TREAT or the CRDAC meeting, as well as any from the PLR conversion process;

reimbursement developments, including the potential imposition of an NCD or other developments resulting from the NCA opened by CMS in June 2010 and the associated MEDCAC meetings; 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 could 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 herein for further discussion of certain of the above factors that could impact our future product sales.

EPOGEN®

For the years ended December 31, 2010, 2009 and 2008, total EPOGEN® sales were as follows (dollar amounts in millions):

		2010	Change	2009	Change	2008
EPOGEN®	U.S.	$ 2,524	(2)%	$ 2,569	5%	$ 2,456

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

The increase in EPOGEN® sales for 2009 was due primarily to an increase in unit demand and, to a lesser extent, an increase in the average net sales price. The increase in unit demand was due principally to patient population growth and increased dose utilization.

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

reimbursement developments, including those resulting from:

- CMS s Final Rule on Bundling in Dialysis;

- Other CMS activities, including the potential imposition of an NCD or other developments resulting from the NCA opened by CMS in June 2010 and the associated MEDCAC meetings;

regulatory developments, such as those resulting from product label changes, including those proposed prior to the October 2010 CRDAC meeting and any others required in connection with TREAT or the CRDAC meeting, as well as any from the PLR conversion process;

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

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

Certain of the above factors are expected to 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.

Table of Contents

Neulasta®/NEUPOGEN®

For the years ended December 31, 2010, 2009 and 2008, total Neulasta®/NEUPOGEN® sales by geographic region were as follows (dollar amounts in millions):

	2010	Change	2009	Change	2008
Neulasta® U.S.	$ 2,654	5%	$ 2,527	1%	$ 2,505
NEUPOGEN® U.S.	932	3%	901	1%	896
U.S. Neulasta®/NEUPOGEN® Total	3,586	5%	3,428	1%	3,401
Neulasta® International	904	9%	828	2%	813
NEUPOGEN® International	354	(9)%	387	(13)%	445
International Neulasta®/NEUPOGEN® Total	1,258	4%	1,215	(3)%	1,258
Total Neulasta®/NEUPOGEN®	$ 4,844	4%	$ 4,643		$ 4,659

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® to Neulasta®, offset partially by a decline in NEUPOGEN® as a result of biosimilar competition.

The increase in U.S. sales of Neulasta®/NEUPOGEN® for 2009 was due primarily to a low single-digit percentage point increase in the average net sales price, offset partially by unfavorable changes in wholesaler inventories. Excluding a $94 million unfavorable foreign exchange impact, international Neulasta®/NEUPOGEN® sales increased 4% for 2009, due primarily to an increase in demand, reflecting the continued conversion from NEUPOGEN® to Neulasta®.

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

For the years ended December 31, 2010, 2009 and 2008, total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	2010	Change	2009	Change	2008

ENBREL	U.S.	$ 3,304	1%	$ 3,283	(3)%	$ 3,389
ENBREL	Canada	230	10%	210		209
Total ENBREL		$ 3,534	1%	$ 3,493	(3)%	$ 3,598

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 decline in unit demand, resulting primarily from share declines in dermatology. ENBREL continues to maintain a leading position in both the rheumatology and dermatology segments.

The decrease in ENBREL sales for 2009 was due primarily to an unfavorable change in wholesaler inventories resulting from an approximate $100 million wholesaler inventory build in 2008 related to a shift of ENBREL to a wholesaler distribution model and a decline in unit demand as a result of competitive activity, offset partially by a mid single-digit percentage point increase in the average net sales price.

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.

Table of Contents

Selected operating expenses

The following table summarizes our operating expenses for the years ended December 31, 2010, 2009 and 2008 (dollar amounts in millions):

	2010	Change	2009	Change	2008
Operating expenses:					
Cost of sales (excludes amortization of certain acquired intangible assets presented below)	$ 2,220	6%	$ 2,091	(9)%	$ 2,296
% of product sales	15.1%		14.6%		15.6%
Research and development	$ 2,894	1%	$ 2,864	(5)%	$ 3,030
% of product sales	19.7%		20.0%		20.6%
Selling, general and administrative	$ 3,983	4%	$ 3,820	1%	$ 3,789
% of product sales	27.2%		26.6%		25.8%
Amortization of certain acquired intangible assets	$ 294		$ 294		$ 294
Other charges	$ 117	75%	$ 67	(82)%	$ 380

Cost of sales

Cost of sales, which excludes the amortization of certain acquired intangible assets, 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.

Cost of sales decreased to 14.6% of product sales for 2009, driven primarily by lower excess capacity charges, lower excess inventory write-offs, due primarily to the $84 million write-off of inventory in 2008 resulting from a strategic decision to change manufacturing processes, and lower royalty expenses. These decreases were offset partially by less favorable product mix and higher fill and finish costs resulting from lower utilization at our manufacturing facility in Puerto Rico.

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 include costs incurred under R&D arrangements with our corporate partners, such as activities performed on behalf of KA, and costs and cost recoveries associated with collaborative R&D and in-licensing arrangements, including upfront fees and milestones paid to collaboration partners in connection with technologies which have not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs for arrangements with our corporate partners is recognized when the obligations are incurred or as we become entitled to the cost recovery.

The increase in R&D expenses for 2010 was driven primarily by $110 million of lower expense recoveries associated with ongoing collaborations and higher staff-related costs of $84 million. These increases were offset largely by lower licensing fees of $115 million, associated principally with payments made in 2009 under the Cytokinetics and Array BioPharma Inc. (Array) agreements, and reduced denosumab clinical trial costs of $73 million in 2010.

The decrease in R&D expenses for 2009 was driven primarily by lower clinical trial costs of $128 million, including those associated with our denosumab and Vectibix® registrational studies, our marketed products and the delay of the phase 3 motesanib NSCLC trial, and $14 million lower staff-related costs. The higher licensing fees incurred in 2009, which were related to the $60 million expense associated with the Array agreement and the $50 million expense resulting from the payment to Cytokinetics, were offset substantially by the $100 million expense in 2008 resulting from the upfront payment associated with the Kyowa Hakko Kirin Co. Ltd. collaboration.

Table of Contents

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. 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 for collaborations is recognized when the obligations are incurred or as we become entitled to the cost recovery. In connection with a collaboration agreement, we and Pfizer market and sell ENBREL in the United States and Canada, and Pfizer is paid a share of the related profits, as defined. The share of ENBREL s profits owed to Pfizer is included in SG&A expenses.

The increase in SG&A expenses 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.

The increase in SG&A expenses for 2009 was due primarily to higher product promotional expenses of $207 million, including increased spending for activities in anticipation of the launch of Prolia®. This increase was offset substantially by lower litigation expenses of $38 million, lower expenses associated with the ENBREL profit share of $32 million, expense recoveries associated with our Glaxo collaboration agreement for Prolia® in PMO in Europe, Australia, New Zealand and Mexico of $29 million, lower staff-related costs of $28 million, lower global enterprise resource planning (ERP) system related expenses of $28 million and lower restructuring and related costs of $8 million.

For the years ended December 31, 2010, 2009 and 2008, the expense associated with the ENBREL profit share was $1,184 million, $1,163 million and $1,195 million, respectively.

Amortization of certain acquired intangible assets

Amortization of certain acquired intangible assets relates to products technology rights acquired in connection with the Immunex acquisition.

Other charges

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, the Company recorded loss accruals for settlements of certain legal proceedings aggregating $33 million. In 2008, the Company recorded loss accruals for settlements of certain commercial legal proceedings aggregating $288 million, related principally to the settlement of the Ortho Biotech antitrust suit.

Non-operating expenses/income and provision for income taxes

The following table presents non-operating expenses/income and the provisions for income taxes for the years ended December 31, 2010, 2009 and 2008 (dollar amounts in millions):

	2010	2009	2008
Interest expense, net	$ 604	$ 578	$ 551

Interest and other income, net	$ 376	$ 276	$ 352
Provisions for income taxes	$ 690	$ 599	$ 963
Effective tax rate	13.0%	11.5%	19.2%

Table of Contents

Interest expense, net

Included in interest expense, net for the years ended December 31, 2010, 2009 and 2008 is the impact of non-cash interest expense of $266 million, $250 million and $235 million, respectively, resulting from the change in the accounting for our convertible debt effective January 1, 2009.

Interest and other income, net

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. The decrease in interest and other income, net for 2009 was due primarily to: lower interest income of $45 million, due principally to lower portfolio investment returns; lower net gains on sales of investments of $28 million; and higher losses on certain leased facilities that will no longer be used in our operations of $31 million; offset partially by higher foreign currency exchange net gains of $27 million.

Income taxes

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.

The decrease in our effective tax rate for 2009 was due principally to: the favorable resolution of certain income tax examinations; higher profits and manufacturing in Puerto Rico, which are taxed under an incentive grant; and a tax benefit from adjustments to previously established deferred taxes arising from changes in California tax law enacted in 2009.

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 January 2010, we adopted a newly issued accounting standard which requires additional disclosure about the amounts of and reasons for significant transfers between levels of the fair value hierarchy discussed in Note 17, Fair value measurement. This standard also clarifies existing disclosure requirements related to the level of disaggregation of fair value measurements for each class of assets and liabilities and disclosures about inputs and valuation techniques used to measure fair value for both recurring and nonrecurring Level 2 and Level 3 measurements. In addition, effective for interim and annual periods beginning after December 15, 2010, this standard requires additional disclosure and requires an entity to present disaggregated information about activity for Level 3 fair value measurements on a gross as opposed to a net basis. As this accounting standard only requires enhanced disclosure, its adoption did not impact our consolidated financial position, results of operations or cash flows.

In January 2011, we adopted a newly issued accounting standard which addresses the accounting for the annual fee due from the pharmaceutical manufacturing industry beginning January 1, 2011, mandated by the PPACA and the companion Health Care and Education Reconciliation Act, which made certain changes and adjustments to PPACA.

We refer to these two laws collectively as the new healthcare reform law. The new healthcare reform law obligates a pharmaceutical manufacturer, upon the first gross receipt during a calendar year from prescription drug sales under any specified government program, to pay an annual fee to the U.S. government. The new accounting standard requires the liability for the annual fee to be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost established that is to be amortized and recognized as an operating expense over

Table of Contents

the calendar year that it is payable using a straight-line method of allocation unless another method better allocates the fee. We have elected to amortize this fee on a straight-line basis and it will be recorded in SG&A expense.

Financial Condition, Liquidity and Capital Resources

The following table summarizes selected financial data for the years ended December 31, 2010 and 2009 (in millions):

	2010	2009
Cash, cash equivalents and marketable securities	$ 17,422	$ 13,442
Total assets	43,486	39,629
Current debt	2,488	
Non-current debt	10,874	10,601
Stockholders equity	23,944	22,667

We believe existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our working capital, capital expenditure and debt service requirements for the foreseeable future. In addition, we plan to opportunistically pursue our stock repurchase program and other business initiatives, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sale of marketable securities, borrowings through commercial paper and/or our syndicated credit facility and access to other debt markets and equity markets. In February 2011, our 2011 Convertible Notes with an aggregate principal balance of $2.5 billion were repaid in full. (See Item 1A. Risk Factors Current economic conditions may magnify certain risks that affect our business.)

Cash, cash equivalents and marketable securities

Of our total cash, cash equivalents and marketable securities balances as of December 31, 2010, approximately $15.1 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 U.S. federal and state income taxes at the applicable marginal tax rates.

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 type and issuer.

Table of Contents

Financing arrangements

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements as of December 31, 2010 and 2009 (dollar amounts in millions):

	2010	2009
0.125% convertible notes due 2011 (2011 Convertible Notes)	$ 2,488	$ 2,342
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,213	2,088
5.85% notes due 2017 (2017 Notes)	1,099	1,099
4.85% notes due 2014 (2014 Notes)	1,000	1,000
5.70% notes due 2019 (2019 Notes)	998	998
6.40% notes due 2039 (2039 Notes)	996	995
6.375% notes due 2037 (2037 Notes)	899	899
3.45% notes due October 2020 (October 2020 Notes)	897	
5.75% notes due 2040 (2040 Notes)	696	
4.95% notes due 2041 (2041 Notes)	595	
6.15% notes due 2018 (2018 Notes)	499	499
6.90% notes due 2038 (2038 Notes)	499	499
4.50% notes due March 2020 (March 2020 Notes)	300	
Other notes	183	182
Total borrowings	13,362	10,601
Less current portion	(2,488)	
Total non-current debt	$ 10,874	$ 10,601

We issued debt securities in various offerings during the three years ended December 31, 2010, including: in 2010, $300 million principal amount of March 2020 Notes, $700 million principal amount of 2040 Notes, $900 million principal amount of October 2020 Notes and $600 million principal amount of 2041 Notes; in 2009, $1.0 billion principal amount of 2019 Notes and $1.0 billion principal amount of 2039 Notes; and in 2008, $500 million principal amount of 2018 Notes and $500 million principal amount of 2038 Notes. Debt issuance costs incurred in connection with these debt offerings totaled $17 million, $13 million and $6 million for debt issued in 2010, 2009 and 2008, respectively, and are being amortized over the respective lives of the notes.

All of these debt issuances as well as the 2017 Notes and the 2037 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 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.

In 2009, we repaid $1.0 billion aggregate principal amount of notes with a fixed interest rate of 4.00% and in 2008, we repaid $2.0 billion aggregate principal amount of floating London Interbank Offered Rate (LIBOR) based notes.

See Note 15, Financing arrangements to the Consolidated Financial Statements for further discussion of our Convertible Notes.

To achieve a desired mix of fixed and floating interest rate debt, we enter into interest rate swap agreements that effectively convert a fixed rate interest coupon to a floating LIBOR-based coupon over the life of the respective note. These interest rate swap agreements qualify and are designated as fair value hedges. As of December 31, 2010 and 2009, we had interest rate swap agreements with an aggregate face value of $3.6 billion and $1.5 billion, respectively. The effective rates on these swaps range from LIBOR plus 0.3% to LIBOR plus 2.6%. See Note 15, Financing arrangements and Note 18, Derivative instruments to the Consolidated Financial Statements for further discussion of our interest rate swap agreements.

Table of Contents

As of December 31, 2010, we have a commercial paper program that allows us to issue up to $2.3 billion of unsecured commercial paper to fund our working capital needs. At December 31, 2010, no amounts were outstanding under our commercial paper program.

As of December 31, 2010, we have a $2.3 billion syndicated, unsecured, revolving credit facility that matures in November 2012 and is available for general corporate purposes or as a liquidity backstop to our commercial paper program. Annual commitment fees for this facility are 0.05% based on our current credit rating. As of December 31, 2010, no amounts were outstanding under this facility.

We have filed a shelf registration statement with the SEC, which allows us to issue an unspecified amount 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 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 expires in April 2011.

As of December 31, 2010, we have $400 million remaining under a shelf registration statement that was established in 1997. In connection with this shelf registration, 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, 2010, no securities were outstanding under this medium-term note program.

Certain of our financing arrangements contain non-financial covenants and we were in compliance with all applicable covenants as of December 31, 2010. None of our financing arrangements contain any financial covenants.

Cash flows

The following table summarizes our cash flow activity for the years ended December 31, 2010, 2009 and 2008 (in millions):

	2010	2009	2008
Net cash provided by operating activities	$ 5,787	$ 6,336	$ 5,988
Net cash used in investing activities	(4,152)	(3,202)	(3,165)
Net cash used in financing activities	(1,232)	(2,024)	(3,073)

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 during 2010 decreased due primarily to the timing and amount of payments to taxing authorities. Cash provided by operating activities during 2009 increased due primarily to higher net income of $553 million and a higher dividend payment from KA of $102 million, offset partially by the prior-year receipt of $300 million for an upfront milestone payment related to our licensing agreement with Takeda, and the negative impact of the timing and amounts of receipts from customers and payments to vendors and others.

Investing

Net purchases of marketable securities were $3.5 billion for 2010 compared to net purchases of $2.7 billion and $2.6 billion for 2009 and 2008, respectively.

Capital expenditures totaled $580 million, $530 million and $672 million in 2010, 2009 and 2008, respectively. Capital expenditures in 2010 and 2009 were associated primarily with manufacturing capacity expansions in Puerto Rico and other site developments. Capital expenditures in 2008 were associated primarily with manufacturing capacity expansions in Puerto Rico, Fremont and other site developments and with investment in our global ERP system and other information systems projects. We currently estimate 2011 spending on capital projects and equipment to be approximately $600 million.

Table of Contents

Financing

In December 2009, the Board of Directors authorized us to repurchase up to an additional $5.0 billion of common stock of which a total of $2.2 billion remains available as of December 31, 2010. The manner of purchases, the amount we spend and the number of shares repurchased will vary based on a variety of factors, including stock price, blackout periods in which we are restricted from repurchasing shares and the impact of repurchases on our credit rating, and may include private block purchases as well as market transactions. A summary of our repurchase activity under our stock repurchase program for the years ended December 31, 2010, 2009 and 2008 is as follows (in millions):

	2010		2009		2008	
	Shares	Dollars	Shares	Dollars	Shares	Dollars
First quarter	29.1	$ 1,684	37.5	$ 1,997		$
Second quarter	10.3	616			32.7	1,549(1)
Third quarter	6.6	364				19(1)
Fourth quarter	20.5	1,136	21.7	1,211	12.6	700
Total	66.5	$ 3,800	59.2	$ 3,208	45.3	$ 2,268

(1) The total cost of shares repurchased during the three months ended June 30, 2008 excludes approximately $19 million paid in July 2008 in connection with the final settlement of an accelerated share repurchase program entered into in May 2008.

As discussed above, we issued debt securities in various offerings that resulted in net proceeds of $2.5 billion, $2.0 billion and $1.0 billion in 2010, 2009 and 2008, respectively. In addition, we repaid $1.0 billion and $2.0 billion of notes in 2009 and 2008, respectively.

We receive cash from the exercise of employee stock options. Employee stock option exercises provided $80 million, $171 million and $155 million of cash in 2010, 2009 and 2008, respectively. Proceeds from the exercise of employee stock options will vary from period to period based upon, among other factors, fluctuations in the market value of our stock relative to the exercise price of such options.

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.

Table of Contents

The following table represents our contractual obligations as of December 31, 2010, 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]	$ 22,259	$ 2,900	$ 3,389	$ 1,892	$ 14,078
Operating lease obligations	1,009	140	246	189	434
Purchase obligations[2]	3,263	1,020	560	131	1,552
Unrecognized tax benefits[3]	200	200			
Total contractual obligations	$ 26,731	$ 4,260	$ 4,195	$ 2,212	$ 16,064

(1) The long-term debt obligation amounts 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 agreements, which effectively convert a fixed rate interest coupon to a floating LIBOR-based coupon over the life of the respective note. We used an interest rate forward curve at December 31, 2010 to compute the net amounts to be included in the table above for future interest payments on our variable rate interest rate swaps. See Note 15, Financing arrangements to the Consolidated Financial Statements for further discussion of our long-term debt obligations and our interest swap agreements.

(2) 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.

(3) Long-term 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 $625 million at December 31, 2010 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 the above table, we are contractually obligated to pay additional amounts, which in the aggregate are significant, upon the achievement of various development, regulatory and commercial milestones in conjunction with collaborative agreements we have entered into with third parties. These payments are contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring. These contingent payments have not been included in the table above or recorded on our Consolidated Balance Sheets. As of December 31, 2010, the maximum amount that may be payable in the future under all such arrangements is approximately $2.1 billion.

Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with US 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

Table of Contents

reflect actual results. The following table summarizes amounts recorded in Accrued liabilities in the Consolidated Balance Sheets for sales deductions (in millions):

	Rebates	Chargebacks	Cash discounts	Other deductions	Total
Balance as of January 1, 2008	$ 755	$ 70	$ 42	$ 197	$ 1,064
Amounts charged against product sales	1,813	1,635	324	466	4,238
Payments	(2,064)	(1,621)	(323)	(418)	(4,426)
Balance as of December 31, 2008	504	84	43	245	876
Amounts charged against product sales	1,497	2,424	312	406	4,639
Payments	(1,482)	(2,380)	(328)	(355)	(4,545)
Balance as of December 31, 2009	519	128	27	296	970
Amounts charged against product sales	1,522	2,593	347	572	5,034
Payments	(1,525)	(2,548)	(345)	(442)	(4,860)
Balance as of December 31, 2010	$ 516	$ 173	$ 29	$ 426	$ 1,144

For the years ended December 31, 2010, 2009 and 2008, total sales deductions were 25%, 24% and 22% 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 less than 1% of the aggregate sales deductions charged against product sales for 2010 and 2009 and less than 2% for 2008. In late 2008, we began shifting our discount structure as a component of broader contracting revisions to be more heavily weighted toward fixed prices to healthcare providers (reflected as chargebacks in the table above) instead of rebates, resulting in a corresponding reduction in rebates and an increase in chargebacks, as noted in the table above.

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 primarily include amounts paid to payers in the United States 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 due to the time delay between the date of sale and the actual settlement of the liability, which could take up to one year. Those rebates totaled $1.5 billion, $1.5 billion and $1.8 billion for the years ended December 31, 2010, 2009 and 2008, 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. Based on our recent experience, changes in annual estimates related to prior annual periods have been less than 2% of the estimated rebate amounts charged against product sales for 2010 and 2009 and less than 3.5% for 2008. These changes in annual estimates relate substantially to sales made in the immediately preceding annual period. A 2% change in our rebate estimate attributable to rebates recognized in 2010 would have had an impact of approximately $30 million on our 2010 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

Table of Contents

purchase our products through wholesalers at these reduced prices, the wholesaler charges us for the difference between the prices it pays us and the prices it charges 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, $2.4 billion and $1.6 billion for the years ended December 31, 2010, 2009 and 2008, 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 provider, and we generally settle the liability for these deductions within a few weeks.

Included in other deductions in the table above are rebates and discounts paid to state Medicaid offices to participate in the Medicaid program. In 2010, healthcare reform legislation was enacted in the United States which has and will continue to significantly increase our Medicaid rebates and discounts. Certain provisions of this new legislation became effective in 2010, while others will become effective in later years. The provisions of this new legislation reduced our U.S. product sales in 2010 by approximately $200 million, and we anticipate that our U.S. product sales in 2011 will be negatively impacted by $250 million to $300 million by this legislation.

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.

Inventories produced in preparation for product launches

The Company capitalizes inventories produced in preparation for product launches when the related product candidates are considered to have a high probability of regulatory approval and the related costs are expected to be recoverable through the commercialization of the product. In connection with the decision to capitalize such inventory, we evaluate among other factors any identified risks or concerns with respect to the product candidate s safety and efficacy, the status of related discussions with regulatory authorities and the outlook for commercial success, including the existence of current or anticipated competitive products and any reimbursement concerns. In addition, we evaluate any risks associated with the manufacturing of the product candidate as well as consider the remaining shelf life of the inventory in relation to the expected launch date. Upon capitalization, we continue to monitor any changes in these factors. In the event of any significant negative developments, we may be required to impair previously capitalized costs. At December 31, 2009, we had capitalized approximately $258 million of inventory costs related to our then late-stage product candidate, denosumab. During 2010, we received various approvals for denosumab from regulatory authorities in the United States, the EU and various other countries and commenced selling the product in certain geographic markets.

Income taxes

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

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the financial statements on a particular tax position are measured based on the largest benefit that is more likely than not to be realized 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.

Table of Contents

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.

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 based on our projected cash flow, working capital and long-term investment requirements of our U.S. and foreign operations. If future events, including material changes in estimates of 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 U.S. and state marginal 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. For example, substantial reform of U.S. tax law regarding tax on certain foreign profits could result in an increase in our effective tax rate, which could have a material adverse effect on our financial results.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings such as intellectual property disputes, contractual disputes, governmental investigations and class action suits. Certain of these proceedings are discussed in Note 19, Contingencies and commitments to the Consolidated Financial Statements. We record accruals for such contingencies to the extent we conclude their occurrence is both probable and estimable. We consider all relevant factors when making assessments regarding these contingencies.

While it is not possible to accurately predict or determine the eventual outcome of these items, 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.

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 monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits, requiring letters of credit and obtaining credit insurance, as we deem appropriate. 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 type and issuer. We also enter into various types of foreign exchange and interest rate derivative hedging transactions with counterparties with investment grade credit ratings 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 led to historically low interest rates on corporate debt issuances during 2010. Short-term interest rates on U.S. Treasury instruments continued to decline as a result of

the Federal Reserve s monetary policy, which included a program to buy back U.S. Treasury instruments. 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, 2010 and 2009. Continued uncertainty surrounding European sovereign debt resulted in ongoing volatility in the foreign exchange markets, and we have consequentially assumed a hypothetical

Table of Contents

20% change in foreign exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2010 and 2009.

Interest rate sensitive financial instruments

Our investment portfolio of available-for-sale debt securities at December 31, 2010 and 2009 was comprised of: U.S. Treasury securities and other government obligations; corporate debt securities; mortgage and asset backed securities; money market mutual funds; and other short-term interest bearing securities, composed principally of commercial paper. The fair value of our investment portfolio of debt securities was $17.3 billion and $13.3 billion at December 31, 2010 and 2009, 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, 2010 and 2009, 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, 2010 and 2009 would not result in a material effect on the related income or cash flows in the respective ensuing year.

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. As of December 31, 2009 we had outstanding debt with a carrying value of $10.6 billion and a fair value of $11.6 billion. Our outstanding debt at December 31, 2010 and 2009 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, 2010 would have resulted in an increase of approximately $1.0 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, 2009 would have resulted in an increase of approximately $760 million in the aggregate fair value of our outstanding debt on this date.

To achieve a desired mix of fixed and floating interest rate debt, we have entered into interest rate swap agreements, which qualify and have been designated as fair value hedges, for certain of our fixed rate debt with notional amounts totaling $3.6 billion and $1.5 billion at December 31, 2010 and 2009, respectively. These derivative contracts effectively convert a fixed rate interest coupon to a floating 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, 2010 and 2009, would have resulted in a $213 million and $78 million, respectively, reduction in the fair value of our interest rate swap agreements on these dates and would not result in a material effect on the related income or cash flows in the respective ensuing year.

Foreign currency sensitive instruments

Our operating results are affected by fluctuations in the value of the U.S. dollar as compared to foreign currencies, predominately the Euro, as a result of the sale of our products in foreign markets. Increases and decreases in our international product sales from movements in foreign exchange rates are offset partially by the corresponding increases or decreases in our international operating expenses. To further reduce our net exposure to foreign exchange rate fluctuations on our results of operations, we enter into foreign currency forward and option contracts.

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, 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, 2009 we had open foreign currency forward and options contracts, primarily Euro based, with notional amounts of $3.4 billion and $376 million, respectively. As of December 31, 2010 the net unrealized gains and at December 31, 2009 the net unrealized losses on these contracts were not material. With regard

to foreign currency forward and option contracts that were open at December 31, 2010, a hypothetical 20% adverse movement in foreign 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

Table of Contents

$670 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, 2009 a hypothetical 20% adverse movement in foreign exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2009 would have resulted in a reduction in fair value of these contracts of approximately $720 million on this date and, in the ensuing year, a reduction in income and cash flows of approximately $330 million.

Also at December 31, 2010 and 2009, we had open foreign currency forward contracts with notional amounts totaling $670 million and $414 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, 2010 and 2009. With regard to these foreign currency forward contracts that were open at December 31, 2010 and 2009, a hypothetical 20% adverse movement in foreign exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2010 and 2009, would have resulted in a reduction in fair value of these contracts on these dates of $134 million and $83 million, respectively, and would not result in a material effect on the related income or cash flows in the respective ensuing year.

The analysis above does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions or on assets and liabilities that these foreign currency sensitive instruments were designed to offset.

Market price sensitive instruments

As of December 31, 2010 and 2009, 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 at December 31, 2010 and 2009 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. We attempt to mitigate that risk through credit monitoring procedures.

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 Form 10-K Annual Report.

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,

Table of Contents

the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2010.

Management determined that, as of December 31, 2010, 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, 2010. 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, 2010, 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 report appearing below, which expresses an unqualified opinion on the effectiveness of the Company s internal control over financial reporting as of December 31, 2010.

Table of Contents

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, 2010, 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, 2010, 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, 2010 and 2009, and the related Consolidated Statements of Income, Stockholders Equity, and Cash Flows for each of the three years in the period ended December 31, 2010 of Amgen Inc. and our report dated February 25, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California

February 25, 2011

Table of Contents

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 2011 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2010 (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 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 sections entitled EXECUTIVE COMPENSATION and CORPORATE GOVERNANCE in our Proxy Statement. Information about compensation committee matters is incorporated by reference from the sections entitled CORPORATE GOVERNANCE Compensation and Management Development Committee and CORPORATE GOVERNANCE Compensation Committee Report in our Proxy Statement.

Table of Contents

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, 2010 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, 2010 (including upon the exercise of options, pursuant to purchases of stock or upon vesting of awards of restricted stock units or performance units).

	(a)		(b)	(c)
Plan Category	**Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights**		**Weighted Average Exercise Price Outstanding Options and Rights**	**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]	20,820,542	$	54.61	69,964,716
Amended and Restated 1991 Equity Incentive Plan[2]	17,249,291	$	57.69	
Amended and Restated Employee Stock Purchase Plan[3]		$		6,316,000
Total Approved Plans	38,069,833	$	56.23	76,280,716
Equity compensation plans not approved by Amgen security holders:				
Amended and Restated 1993 Equity Incentive Plan[4]	69,625	$	49.06	
Amended and Restated 1999 Equity Incentive Plan[4]	11,667,851	$	61.62	
Amended and Restated 1997 Equity Incentive Plan[5]	1,280,822	$	52.35	
Amended and Restated 1997 Special Non-Officer Equity Incentive Plan[6]	5,618,035	$	63.44	
Amended and Restated 1996 Incentive Stock Plan[7]	311,000	$	68.81	
Amended and Restated 1999 Incentive Stock Plan[7]	1,681,339	$	65.66	
Amended and Restated Assumed Avidia Equity Plan[8]	13,186	$	2.03	
Total Unapproved Plans	20,641,858	$	61.84	
Total All Plans	58,711,691	$	58.66	76,280,716

(1) The number under column (a) with respect to this plan includes approximately 12.57 million shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $54.61, approximately 6.42 million shares issuable upon the vesting of outstanding restricted stock units and approximately 1.83 million shares issuable upon the vesting of outstanding performance units. The performance units awarded in 2009 and 2010 continue to be subject to performance goals and the maximum number of units that could be earned is 200% of the units awarded in 2009 and 2010. 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 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

Table of Contents

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 13.95 million shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $57.69, approximately 2.45 million shares issuable upon the vesting of outstanding restricted stock units and approximately 0.85 million shares issuable for outstanding performance units granted in 2008 based on a target performance. The maximum that could be earned would be 200% of the units granted in 2008.

(3) The purchases occurred on June 15, 2010 and December 15, 2010 (the Purchase Dates) with a purchase of 217,009 shares of Common Stock at a purchase price of $52.36 per shares on June 15, 2010 and 158,204 shares of Common Stock at a purchase price of $52.89 per share on December 15, 2010. 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 11.64 million shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $61.62 and approximately 27,000 shares issuable upon the vesting of outstanding restricted stock units.

(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 terminated as to future grants. The number under column (a) with respect to this plan includes approximately 5.49 million shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $63.44 and approximately 132,000 shares issuable upon the vesting of outstanding restricted stock units.

(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 311,000 shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $68.81. The number under column (a) with respect to the Amended and Restated 1999 Incentive Stock Plan includes approximately 1.42 million shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $65.66 and approximately 259,000 shares issuable upon the vesting of outstanding restricted stock units.

(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.

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.

Table of Contents

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.

Table of Contents

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)1. Index to Financial Statements

The following Consolidated Financial Statements are included herein:

	Page number
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Statements of Income for each of the three years in the period ended December 31, 2010	F-2
Consolidated Balance Sheets at December 31, 2010 and 2009	F-3
Consolidated Statements of Stockholders Equity for each of the three years in the period ended December 31, 2010	F-4
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2010	F-5
Notes to Consolidated Financial Statements	F-6 - F-51

(a)2. Index to Financial Statement Schedules

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

	Page number
II. Valuation Accounts	F-52

All other schedules are omitted because they are not applicable, not required or because the required information is included in the Consolidated Financial Statements or notes thereto.

(a)3. Exhibits

Exhibit No.	Description
3.1	Restated Certificate of Incorporation (As Restated December 6, 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 10, 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 Amended May 11, 2009). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 on August 10, 2009 and incorporated herein by reference.)
3.7	Certificate of Correction of the Restated Certificate of Incorporation (As Amended May 13, 2010). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2010 on August 9, 2010.)

Table of Contents

Exhibit No.	Description
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 4.16, 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	81/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.7	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 81/8% 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 0.125% Convertible Senior Note due 2011). (Filed as exhibit to Form 10-Q for the quarter ended June 30, 2006 on August 9, 2006 and incorporated herein by reference.)

Table of Contents

Exhibit No.	Description
4.17	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.)
4.18	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.)
4.19	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.)
4.20	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.)
4.21	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.)
4.22	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.)
4.23	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.)
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. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2010 on November 8, 2010 and incorporated herein by reference.)
10.3+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Equity Incentive Plan. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2010 on May 7, 2010 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. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2010 on May 7, 2010 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.)

Table of Contents

Exhibit No.	Description
10.9+	Amendment and Restatement of the Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010.) (Filed as an exhibit to Form 8-K on December 15, 2010 and incorporated herein by reference.)
10.10+	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.)
10.11+	Amgen Inc. Executive Nonqualified Retirement Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.12+	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.)
10.13+	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.)
10.14+	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.)
10.15+	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.)
10.16	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).
10.17	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.)
10.18	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.)
10.19	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.)
10.20	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.)

10.21 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.)

Table of Contents

Exhibit No.	Description
10.22	Amendment No. 13 to the Shareholders Agreement, dated June 28, 2007 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.23	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.)
10.24	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.)
10.25	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.)
10.26	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.)
10.27	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.)
10.28	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.)
10.29	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.)
10.30	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.)

10.31	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.)
10.32	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.)

Table of Contents

Exhibit No.	Description
10.33	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.)
10.34	Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International for warrants expiring in 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.35	Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International for warrants expiring in 2013. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.36	Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Morgan Stanley & Co. International Limited for warrants maturing in 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.37	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.)
10.38	Credit Agreement, dated November 2, 2007, among Amgen Inc., with Citicorp USA, Inc., as administrative agent, Barclays Bank PLC, as syndication agent, Citigroup Global Markets, Inc. and Barclays Capital, as joint lead arrangers and joint book runners, and the other banks party thereto. (Filed as an exhibit to Form 8-K filed on November 2, 2007 and incorporated herein by reference.)
10.39	Amendment No. 1, dated May 18, 2009, to the Credit Agreement dated November 2, 2007, among Amgen Inc., with Citicorp USA, Inc., as administrative agent, Barclays Bank PLC, as syndication agent, Citigroup Global Markets, Inc. and Barclays Capital, as joint lead arrangers and joint book runners, and the other banks party thereto. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 on August 10, 2009 and incorporated herein by reference.)
10.40	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.)
10.41	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.)
10.42	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.)

10.43	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.)
10.44	Master Services Agreement, dated October 22, 2008, between Amgen Inc. and International Business Machines Corporation (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)

Table of Contents

Exhibit No.	Description
10.45	Amendment, dated December 11, 2009, to Master Services Agreement, dated October 22, 2009, between Amgen Inc. and International Business Machines Corporation (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2009 on March 1, 2010 and incorporated herein by reference.)
10.46	Amendment Number 6, dated September 23, 2010, to Master Services Agreement, dated October 22, 2009, between Amgen Inc. and International Business Machines Corporation (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2010 on November 8, 2010 and incorporated herein by reference.)
10.47	Integrated Facilities Management Services Agreement, dated February 4, 2009 between Amgen Inc. and Jones Lang LaSalle Americas, Inc. (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
10.48	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.)
10.49	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.)
10.50	Amendment Number 1, dated September 20, 2010, to Expansion Agreement dated July 27, 2009 between Amgen Inc. and Glaxo Group Limited, a wholly-owned subsidiary of GlaxoSmithKline plc (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2010 on November 8, 2010 and incorporated herein by reference.)
10.51	Underwriting Agreement, dated March 12, 2010, by and among the Company and Banc of America Securities LLC, Barclays Capital Inc. and Morgan Stanley & Co. Incorporated, as representatives of the several underwriters named therein. (Filed as an exhibit to Form 8-K on March 15, 2010 and incorporated herein by reference.)
10.52	Underwriting Agreement, dated September 13, 2010, by and among the Company and Citigroup Global Markets Inc., Goldman, Sachs & Co. and Morgan Stanley & Co. Incorporated, as representatives of the several underwriters named therein. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)
21*	Subsidiaries of the Company.
23	Consent of the Independent Registered Public Accounting Firm. The consent is set forth on pages 105 and 106 of this Annual Report on Form 10-K.
24	

	Power of Attorney. The Power of Attorney is set forth on pages 103 and 104 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.

Table of Contents

Exhibit No.	Description
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.)

Table of Contents

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: 02/25/2011

By:
/s/ Jonathan m. peacock

Jonathan M. Peacock
Executive Vice President
and Chief Financial Officer

Table of Contents

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)	02/25/2011
/s/ Jonathan M. Peacock **Jonathan M. Peacock**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	02/25/2011
/s/ Thomas J.W. Dittrich **Thomas J.W. Dittrich**	Vice President Finance and Chief Accounting Officer (Principal Accounting Officer)	02/25/2011
/s/ David Baltimore **David Baltimore**	Director	02/25/2011
/s/ Frank J. Biondi, Jr. **Frank J. Biondi, Jr.**	Director	02/25/2011
/s/ Jerry D. Choate **Jerry D. Choate**	Director	02/25/2011
/s/ Vance D. Coffman **Vance D. Coffman**	Director	02/25/2011
/s/ François de Carbonnel **François de Carbonnel**	Director	02/25/2011

/s/ Frederick W. Gluck	Director	02/25/2011
Frederick W. Gluck		
/s/ Rebecca M. Henderson	Director	02/25/2011
Rebecca M. Henderson		
/s/ Frank C. Herringer	Director	02/25/2011
Frank C. Herringer		
/s/ Gilbert S. Omenn	Director	02/25/2011
Gilbert S. Omenn		

Table of Contents

Signature	Title	Date
/s/ Judith C. Pelham **Judith C. Pelham**	Director	02/25/2011
/s/ J. Paul Reason **J. Paul Reason**	Director	02/25/2011
/s/ Leonard D. Schaeffer **Leonard D. Schaeffer**	Director	02/25/2011
/s/ Ronald D. Sugar **Ronald D. Sugar**	Director	02/25/2011

Table of Contents

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 Statement (Form S-8 No. 333-81284) 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 Statement (Form S-3 No. 333-92450 and Amendment No. 1 thereto) pertaining to Amgen Inc. s Common Stock;

Registration Statement (Form S-8 No. 333-92424 and Amendment No. 1 thereto) pertaining to the Amgen Inc. Amended and Restated 1993 Equity Incentive Plan (formerly known as the Immunex Corporation 1993 Stock Option Plan), the Amgen Inc. Amended and Restated 1999 Equity Incentive Plan (formerly known as the Immunex Corporation 1999 Stock Option Plan);

Registration Statements (Form S-3 No. 333-107639 and Amendment 1 thereto) relating to debt securities, common stock and associated preferred share repurchase rights, preferred stock, warrants to purchase debt securities, common stock or preferred stock, securities purchase contracts, securities purchase units and depositary shares of Amgen Inc. and in the related Prospectuses;

Registration Statement (Form S-8 No. 333-118254) pertaining to the Amgen Inc. Amended and Restated 1997 Equity Incentive Plan (formerly known as the Tularik Inc. 1997 Equity Incentive Plan, as amended);

Table of Contents

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 Statement (Form S-3 No. 333-150290) 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.

of our reports dated February 25, 2011, 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, 2010.

/s/ Ernst & Young LLP

Los Angeles, California
February 25, 2011

Table of Contents

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, 2010 and 2009, and the related Consolidated Statements of Income, Stockholders Equity, and Cash Flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, 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, 2010, 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 25, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California
February 25, 2011

Table of Contents

AMGEN INC.

CONSOLIDATED STATEMENTS OF INCOME

Years ended December 31, 2010, 2009 and 2008

(In millions, except per share data)

	2010	2009	2008
Revenues:			
Product sales	$ 14,660	$ 14,351	$ 14,687
Other revenues	393	291	316
Total revenues	15,053	14,642	15,003
Operating expenses:			
Cost of sales (excludes amortization of certain acquired intangible assets presented below)	2,220	2,091	2,296
Research and development	2,894	2,864	3,030
Selling, general and administrative	3,983	3,820	3,789
Amortization of certain acquired intangible assets	294	294	294
Other charges	117	67	380
Total operating expenses	9,508	9,136	9,789
Operating income	5,545	5,506	5,214
Interest expense, net	604	578	551
Interest and other income, net	376	276	352
Income before income taxes	5,317	5,204	5,015
Provision for income taxes	690	599	963
Net income	$ 4,627	$ 4,605	$ 4,052
Earnings per share:			
Basic	$ 4.82	$ 4.53	$ 3.79
Diluted	$ 4.79	$ 4.51	$ 3.77
Shares used in calculation of earnings per share:			
Basic	960	1,016	1,070
Diluted	965	1,021	1,075

See accompanying notes.

Table of Contents

AMGEN INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2010 and 2009

(In millions, except per share data)

	2010	2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,287	$ 2,884
Marketable securities	14,135	10,558
Trade receivables, net	2,335	2,109
Inventories	2,022	2,220
Other current assets	1,350	1,161
Total current assets	23,129	18,932
Property, plant and equipment, net	5,522	5,738
Intangible assets, net	2,230	2,567
Goodwill	11,334	11,335
Other assets	1,271	1,057
Total assets	$ 43,486	$ 39,629
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 716	$ 574
Accrued liabilities	3,366	3,299
Current portion of convertible notes	2,488	
Total current liabilities	6,570	3,873
Convertible notes	2,296	4,512
Other long-term debt	8,578	6,089
Other non-current liabilities	2,098	2,488
Contingencies and commitments		
Stockholders equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750 shares authorized; outstanding 932 shares in 2010 and 995 shares in 2009	27,299	26,944
Accumulated deficit	(3,508)	(4,322)
Accumulated other comprehensive income	153	45
Total stockholders equity	23,944	22,667
Total liabilities and stockholders equity	$ 43,486	$ 39,629

See accompanying notes.

Table of Contents

AMGEN INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

Years ended December 31, 2010, 2009 and 2008

(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, 2007	1,087	$ 25,890	$ (7,431)	$ 53	$ 18,512
Comprehensive income:					
Net income			4,052		4,052
Other comprehensive income, net of tax				64	64
Comprehensive income					4,116
Issuance of common stock in connection with the Company s equity award programs	5	198			198
Stock-based compensation		267			267
Tax impact related to employee stock options		86			86
Repurchases of common stock	(45)		(2,294)		(2,294)
Balance at December 31, 2008	1,047	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	7	190			190
Stock-based compensation		324			324
Tax impact related to employee stock options		(11)			(11)
Repurchases of common stock	(59)		(3,254)		(3,254)
Balance at December 31, 2009	995	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	69			69
Stock-based compensation		357			357
Tax impact related to employee stock options		(71)			(71)
Repurchases of common stock	(67)		(3,800)		(3,800)
Other			(13)		(13)
Balance at December 31, 2010	932	$ 27,299	$ (3,508)	$ 153	$ 23,944

See accompanying notes.

Table of Contents

AMGEN INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2010, 2009 and 2008

(In millions)

	2010	2009	2008
Cash flows from operating activities:			
Net income	$ 4,627	$ 4,605	$ 4,052
Depreciation and amortization	1,017	1,049	1,073
Stock-based compensation expense	353	284	262
Deferred income taxes	(167)	47	(137)
Property, plant and equipment impairments	118	21	59
Dividend received from equity investee		110	8
Other items, net	140	111	244
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	(210)	(36)	65
Inventories	153	(134)	(59)
Other current assets	36	(3)	15
Accounts payable	142	71	95
Accrued income taxes	(656)	(142)	14
Other accrued liabilities	152	320	(30)
Deferred revenue	82	33	327
Net cash provided by operating activities	5,787	6,336	5,988
Cash flows from investing activities:			
Purchases of property, plant and equipment	(580)	(530)	(672)
Cash paid for acquisitions, net of cash acquired			(56)
Purchases of marketable securities	(14,602)	(12,418)	(10,345)
Proceeds from sales of marketable securities	10,485	8,252	6,762
Proceeds from maturities of marketable securities	642	1,443	1,018
Other	(97)	51	128
Net cash used in investing activities	(4,152)	(3,202)	(3,165)
Cash flows from financing activities:			
Repurchases of common stock	(3,786)	(3,208)	(2,268)
Repayment of debt		(1,000)	(2,000)
Net proceeds from issuance of debt	2,471	1,980	991
Net proceeds from issuance of common stock in connection with the Company s equity award programs	80	171	155
Other	3	33	49
Net cash used in financing activities	(1,232)	(2,024)	(3,073)

Increase (decrease) in cash and cash equivalents	403	1,110	(250)
Cash and cash equivalents at beginning of period	2,884	1,774	2,024
Cash and cash equivalents at end of period	$ 3,287	$ 2,884	$ 1,774

See accompanying notes.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2010

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 biotechnol medicines company that 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 primarily consist of sales of Aranesp® (darbepoetin alfa), EPOGEN® (Epoetin alfa), Neulasta® (pegfilgrastim), NEUPOGEN® (Filgrastim) and Enbrel® (etanercept). 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 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 end users and their usage.

Other revenues

Other revenues primarily consist of royalty income and corporate partner revenues. Royalties from licensees are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectability is reasonably assured. Royalty estimates are made in advance of amounts collected using historical and forecasted trends. Pursuant to the license agreement with J&J, noted

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

above, we earn a 10% royalty on net sales, as defined, of Epoetin alfa by J&J in the United States. For the years ended December 31, 2010, 2009 and 2008, we recognized royalty income from J&J of $111 million, $128 million and $126 million, respectively. Corporate partner revenues are comprised of amounts earned from Kirin-Amgen, Inc. (KA) for certain research and development (R&D) activities and are generally earned as the R&D activities are performed and the amounts become due. Corporate partner revenues also include license fees and milestone payments earned from KA and from collaborations with third parties. Revenue from non-refundable, upfront license fees where we have continuing involvement is recognized ratably over the estimated period of ongoing involvement. Revenue associated with at risk performance milestones is recognized based upon the achievement of the milestone, as defined in the respective agreements. See Note 6, Collaborative arrangements and Note 7, Related party transactions.

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 include costs incurred under R&D arrangements with our corporate partners, such as activities performed on behalf of KA, and costs and cost recoveries associated with collaborative R&D and in-licensing arrangements, including upfront fees and milestones paid to collaboration partners in connection with technologies which have not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs for arrangements with our corporate partners 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. 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 for collaborations is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 6, Collaborative arrangements.

Advertising costs are expensed as incurred. For the years ended December 31, 2010, 2009 and 2008, advertising costs were $98 million, $95 million and $81 million, respectively.

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 and performance units. The estimated fair values of stock option and restricted stock unit 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 over the period from the grant date to the end of the performance period based on the probable outcomes of the award s performance conditions. 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.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Collaborative arrangements

Certain arrangements we have entered into regarding the R&D, manufacture and/or commercialization of products and product candidates are considered collaborative arrangements. A collaborative arrangement is defined as 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. For collaborative arrangements where it is determined that we are the principal participant, revenue generated and costs incurred with third parties are recorded on a gross basis in our consolidated financial statements. See Note 6, Collaborative arrangements.

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 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 10, Available-for-sale securities and Note 17, 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 which approximates the first-in, first-out method. The Company capitalizes inventories produced in preparation for product launches when the related product candidates are considered to have a high probability of regulatory approval and the related costs are expected to be recoverable through the commercialization of the product. See Note 11, 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 17, Fair value measurement and Note 18, Derivative instruments.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 of buildings, equipment, furniture and fixtures is provided over their estimated 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. Useful lives by asset category are as follows:

Asset Category	Years
Buildings and improvements	10-40
Manufacturing equipment	5-12
Laboratory equipment	8-12
Furniture, fixtures and other assets	3-15

See Note 12, 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 13, Intangible assets.

The estimated fair values of in-process R&D projects acquired in a business combination which have not reached technological feasibility and were acquired on and after January 1, 2009 are capitalized and accounted for as indefinite-lived intangible assets subject to impairment testing until completion or abandonment of the project. Capitalized in-process R&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. The estimated fair values of in-process R&D projects acquired in a business combination prior to January 1, 2009, which had not reached technological feasibility at the date of acquisition and which did not have an alternative future use, were immediately expensed as required by accounting principles then in effect.

Goodwill principally relates to our 2002 acquisition of Immunex Corporation (Immunex). We perform an impairment test annually and whenever events or changes in circumstances indicate that the carrying amount of goodwill 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 2011 Convertible Notes and 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 15, Financing arrangements.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Recent accounting pronouncements

In January 2010, we adopted a newly issued accounting standard which requires additional disclosure about the amounts of and reasons for significant transfers between levels of the fair value hierarchy discussed in Note 17, Fair value measurement. This standard also clarifies existing disclosure requirements related to the level of disaggregation of fair value measurements for each class of assets and liabilities and disclosures about inputs and valuation techniques used to measure fair value for both recurring and nonrecurring Level 2 and Level 3 measurements. In addition, effective for interim and annual periods beginning after December 15, 2010, this standard requires additional disclosure and requires an entity to present disaggregated information about activity for Level 3 fair value measurements on a gross as opposed to a net basis. As this accounting standard only requires enhanced disclosure, its adoption did not impact our consolidated financial position, results of operations or cash flows.

In January 2011, we adopted a newly issued accounting standard which addresses the accounting for the annual fee due from the pharmaceutical manufacturing industry beginning January 1, 2011, mandated by 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 PPACA. We refer to these two laws collectively as the new healthcare reform law . The new healthcare reform law obligates a pharmaceutical manufacturer, upon the first gross receipt during a calendar year from prescription drug sales under any specified government program, to pay an annual fee to the U.S. government. The new accounting standard requires the liability for the annual fee to be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost established that is to be amortized and recognized as an operating expense over the calendar year that it is payable using a straight-line method of allocation unless another method better allocates the fee. We have elected to amortize this fee on a straight-line basis and it will be recorded in SG&A expense.

2. Acquisitions

Dompé Biotec, S.p.A

On January 4, 2008, we completed the acquisition of Dompé Biotec, S.p.A (Dompé), a privately held company that marketed certain of our products in Italy. This acquisition was accounted for as a business combination. The purchase price was approximately $168 million, which included the carrying value of our existing 49% ownership in Dompé. The purchase price paid was allocated to the net assets acquired of approximately $63 million, principally comprised of marketing rights to marketed products, based on their estimated fair values at the acquisition date and the excess of the purchase price over the fair values of net assets acquired of approximately $105 million was assigned to goodwill. There was no material gain or loss related to the reacquisition of marketing rights previously granted to Dompé as a result of this business combination. The results of Dompé s operations have been included in the consolidated financial statements commencing January 4, 2008. Pro forma results of operations for the year ended December 31, 2008 assuming the acquisition of Dompé had taken place at the beginning of 2008 would not differ significantly from the actual reported results.

3. Stock-based compensation

Our 2009 Equity Incentive Plan (the 2009 Plan) provides for the grant of equity-based awards, including stock options, restricted stock units 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 existing 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 restricted stock units and performance

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2010, the 2009 Plan provides for future grants and/or issuances of up to approximately 70 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, 2010, 2009 and 2008 (in millions):

	2010	2009	2008
Stock options	$ 124	$ 115	$ 103
Restricted stock units	182	134	105
Performance units	47	35	54
Total stock-based compensation expense, pre-tax	353	284	262
Tax benefit from stock-based compensation expense	(120)	(97)	(89)
Total stock-based compensation expense, net of tax	$ 233	$ 187	$ 173

Employee stock option and restricted stock unit grants

Eligible employees generally receive a grant of stock options and/or restricted stock units 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 stock options and/or restricted stock unit grants upon commencement of employment. Our stock option and restricted stock unit grants provide for accelerated or continued vesting in certain circumstances as defined in the plans, including upon death, disability, a change in control, or retirement of employees who meet certain service and/or age requirements. Grants of stock options and restricted stock units generally vest over a four year period.

Stock option grants

The exercise price for stock options granted under our 2009 Plan and Prior Plans is set at the closing price of our common stock on the date of grant and the related number of shares granted is fixed at that point in time. Awards granted to employees on and after April 26, 2010 expire 10 years from the date of grant; options granted to employees prior to that date expire seven years from the date of grant.

We use the Black-Scholes option valuation model to estimate the grant date fair value of our employee stock options. The weighted-average assumptions used in the Black-Scholes 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, 2010, 2009 and 2008:

	2010	2009	2008
Closing price of our common stock on grant date	$ 58.32	$ 50.65	$ 43.60
Fair value of stock options granted	$ 20.97	$ 18.35	$ 14.50
Expected volatility	28.0%	39.6%	31.6%
Expected life (in years)	6.6	4.6	4.6
Risk-free interest rate	3.2%	2.1%	2.9%
Expected dividend yield	0%	0%	0%

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

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 following summarizes select information regarding our stock options during the year ended December 31, 2010:

	Options (in millions)	Weighted-average exercise price	Weighted-average remaining contractual life (years)	Aggregate intrinsic value (in millions)
Balance unexercised at December 31, 2009	50.8	$ 59.50		
Granted	6.7	$ 58.32		
Exercised	(1.3)	$ 46.13		
Forfeited/expired	(9.4)	$ 64.72		
Balance unexercised at December 31, 2010	46.8	$ 58.66	3.6	$ 110
Vested or expected to vest at December 31, 2010	46.0	$ 58.71	3.5	$ 109
Exercisable at December 31, 2010	31.7	$ 61.05	2.1	$ 58

The total intrinsic value of options exercised during the three years ended December 31, 2010, 2009 and 2008 was $15 million, $57 million and $68 million, respectively.

Restricted stock unit grants

The fair value of a restricted stock unit is equal to the closing price of our common stock on the grant date. The weighted-average grant date fair values of restricted stock units granted in 2010, 2009 and 2008 were $58.19, $51.24 and $42.63, respectively. The following summarizes select information regarding our restricted stock units during the year ended December 31, 2010:

	Units (in millions)	Weighted-average grant date fair value
Balance nonvested at December 31, 2009	8.8	$ 50.00
Granted	4.1	$ 58.19
Vested	(3.2)	$ 52.50
Forfeited	(0.4)	$ 51.96

Balance nonvested at December 31, 2010	9.3	$ 52.67

The total fair values of shares of restricted stock units that vested during the year ended December 31, 2010, 2009 and 2008 was $184 million, $139 million and $77 million, respectively.

As of December 31, 2010, there was approximately $499 million of unrecognized compensation costs related to nonvested stock option and restricted stock unit awards, which is expected to be recognized over a weighted-average period of 1.7 years.

Performance award program

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 2010, 2009 and 2008, which are accounted for as equity awards, are based upon one or more of the

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

following, as defined in the program: (i) Amgen s standalone financial performance, (ii) Amgen s annual stockholder return and (iii) Amgen s annual stockholder return compared to a comparator group of companies. 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, or retirement of employees who meet certain service and/or age requirements.

The performance units granted in 2010, 2009 and 2008 include stockholder return performance goals, which are considered market conditions and are reflected in the grant date fair value of the units. The performance units granted in 2010 and 2009 also included performance goals based on the Company s standalone financial performance, which are considered performance conditions. 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 to be earned with respect to the performance conditions, net of estimated forfeitures. The expense recognized for the awards granted in 2008 is based on the grant date fair value of a unit multiplied by the number of units granted, net of estimated forfeitures.

We used a Monte Carlo simulation model to estimate the grant date fair value of performance units granted in 2010 and 2009. We used a lattice model to estimate the grant date fair value of performance units granted in 2008. The assumptions used in these models and the resulting grant date fair values of our performance units were as follows for the years ended December 31, 2010, 2009 and 2008:

	2010	2009	2008
Closing price of our common stock on grant date	$ 56.90	$ 47.63	$ 44.62
Fair value of unit	$ 62.06	$ 48.22	$ 36.91
Volatility	34.7%	34.3%	32.4%
Risk-free interest rate	1.3%	1.2%	2.0%
Expected dividend yield	0%	0%	0%

The valuation models also use terms based on the length of the performance period and compound annual growth rate goals for total stockholder return based on the terms of the award. For the years ended December 31, 2010 and 2009, the Monte Carlo simulation model also assumed correlations of returns of the stock prices of our common stock and the common stocks of a comparator group of companies and stock price volatilities of the comparator group of companies.

As of December 31, 2010 and 2009, a total of 2.7 million and 2.9 million performance units were outstanding with weighted-average grant date fair values of $49.49 and $53.46 per unit, respectively. During the year ended December 31, 2010, 1.0 million performance units with a grant date fair value of $62.06 were granted, 0.6 million performance units with a grant date fair value of $36.91 vested and 0.1 million performance units with a weighted-average grant date fair value of $47.97 were forfeited.

The total fair values of performance units that vested during 2010 and 2009 were $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 and 2008 aggregated $30 million and $70 million, respectively.

As of December 31, 2010, there was approximately $48 million of unrecognized compensation cost related to the 2010 and 2009 performance unit grants that is expected to be recognized over a weighted-average period of approximately 1 year.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Income taxes

The provision for income taxes for the years ended December 31, 2010, 2009 and 2008 includes the following (in millions):

	2010	2009	2008
Current provision:			
Federal	$ 636	$ 325	$ 866
State	52	85	82
Foreign	153	155	152
Total current provision	841	565	1,100
Deferred (benefit) provision:			
Federal	(196)	92	(86)
State	43	(59)	(43)
Foreign	2	1	(8)
Total deferred (benefit) provision	(151)	34	(137)
Total provision	$ 690	$ 599	$ 963

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.

Significant components of our deferred tax assets and liabilities as of December 31, 2010 and 2009 are as follows (in millions):

	2010	2009
Deferred tax assets:		
Intercompany inventory related items	$ 306	$ 351
Expense accruals	626	519
Acquired net operating loss and credit carryforwards	147	178
Expenses capitalized for tax	188	177
Stock-based compensation	269	229
Deferred revenue	117	128
Other	72	108
Total deferred tax assets	1,725	1,690

Valuation allowance	(80)	(92)
Net deferred tax assets	1,645	1,598
Deferred tax liabilities:		
Acquired intangibles	(739)	(882)
Fixed assets	(181)	(201)
Unremitted foreign earnings	(118)	(13)
Other	(142)	(125)
Total deferred tax liabilities	(1,180)	(1,221)
Total deferred taxes, net	$ 465	$ 377

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

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2010, we had net operating loss carryforwards of $303 million available to reduce future taxable income in various state taxing jurisdictions. We have provided a valuation allowance against $44 million of the state operating loss carryforwards. The state operating loss carryforwards expire between 2010 and 2018.

At December 31, 2010, we had $110 million of tax credit carryforwards available to reduce future state income taxes which have no expiration date, and $80 million of state tax credit carryforwards for which a full valuation allowance has been provided.

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, 2010, 2009 and 2008 is as follows (in millions):

	2010	2009	2008
Balance at beginning of year	$ 1,140	$ 1,113	$ 922
Additions based on tax positions related to the current year	305	302	382
Reductions for tax positions of prior years	(110)	(215)	
Settlements	(415)	(60)	(191)
Balance at end of year	$ 920	$ 1,140	$ 1,113

Substantially all of the UTBs as of December 31, 2010, if recognized, would affect our effective tax rate.

During the year ended December 31, 2010, we settled our examination with the Internal Revenue Service (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.

During the year ended December 31, 2008, we reached an agreement with the IRS as to the amount of certain transfer pricing adjustments for the years ended December 31, 2005 and 2006 which were covered by the closing agreement entered into in 2007.

As of December 31, 2010, we believe it is reasonably possible that our gross liabilities for UTBs may decrease by $200 million within the succeeding twelve months due to potential tax settlements.

Interest and penalties related to UTBs are included in our provision for income taxes. During 2010, 2009, and 2008, we accrued approximately $41 million, $57 million, and $71 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. At December 31, 2010 and 2009, accrued interest and penalties associated with UTBs totaled approximately $90 million and $125 million, respectively.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The reconciliation between the federal statutory rate and our effective tax rate for the years ended December 31, 2010, 2009 and 2008 is as follows:

	2010	2009	2008
Federal statutory rate applied to income before income taxes	35.0 %	35.0 %	35.0 %
Foreign earnings, including earnings invested indefinitely	(19.1) %	(19.6) %	(16.7) %
State taxes	1.6 %	1.1 %	1.4 %
Audit settlements	(3.1) %	(4.2) %	0.0 %
Credits, primarily research and experimentation	(0.9) %	(0.8) %	(1.1) %
Other, net	(0.5) %	0.0 %	0.6 %
Effective tax rate	13.0 %	11.5 %	19.2 %

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. At December 31, 2010, these earnings amounted to approximately $17.2 billion. If these earnings were repatriated to the United States, we would be required to accrue and pay approximately $6.1 billion of additional income taxes based on the current tax rates in effect. For the years ended December 31, 2010, 2009 and 2008, our total foreign income before income taxes was approximately $3.1 billion, $3.1 billion and $2.6 billion, respectively. These earnings include income from manufacturing operations in Puerto Rico under tax incentive grants that expire in 2020.

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, 2010, 2009 and 2008, totaled $1,344 million, $497 million and $673 million, respectively.

5. Earnings per share

The computation of basic earnings per share (EPS) is based upon the weighted-average number of our common shares outstanding. The computation of diluted EPS is based upon the weighted-average number of our common shares and dilutive potential common shares outstanding. Potential common shares outstanding, determined using the treasury stock method, principally include: shares that may be issued under our stock option, restricted stock and performance unit awards; our 2011 Convertible Notes and 2013 Convertible Notes, as discussed below; and our outstanding warrants (collectively dilutive securities). The convertible note hedges purchased in connection with the issuance of our 2011 Convertible Notes and 2013 Convertible Notes are excluded from the calculation of diluted EPS as their impact is always anti-dilutive. For further information regarding our convertible notes and warrants, see Note 15,

Financing arrangements.

Upon conversion of our 2011 Convertible Notes and 2013 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, 2010, 2009 and 2008, 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. For further information regarding our convertible notes, see Note 15, Financing arrangements.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table sets forth the computation for basic and diluted EPS for the years ended December 31, 2010, 2009 and 2008 (in millions, except per share data):

	2010	2009	2008
Income (Numerator):			
Net income for basic and diluted EPS	$ 4,627	$ 4,605	$ 4,052
Shares (Denominator):			
Weighted-average shares for basic EPS	960	1,016	1,070
Effect of dilutive securities	5	5	5
Weighted-average shares for diluted EPS	965	1,021	1,075
Basic EPS	$ 4.82	$ 4.53	$ 3.79
Diluted EPS	$ 4.79	$ 4.51	$ 3.77

For the years ended December 31, 2010, 2009 and 2008, there were employee stock options, calculated on a weighted average basis, to purchase 43 million, 42 million and 45 million shares of our common stock, respectively, with exercise prices greater than the average market prices of our common stock for these periods that are not included in the computation of diluted EPS as their impact would have been anti-dilutive. In addition, shares of our common stock which may be issued upon exercise of our warrants are not included in the computation of diluted EPS for any of the periods presented above as their impact would have been anti-dilutive.

6. Collaborative arrangements

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, R&D and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration agreements with third parties are performed on a best efforts basis with no guarantee of either technological or commercial success. Each collaboration is unique in nature and our significant arrangements are discussed below except for our arrangements with KA, which are discussed in Note 7, Related party transactions.

Pfizer Inc.

Amgen and Pfizer are in a collaboration agreement 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 and product pricing. 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 the annual gross profits on our ENBREL sales in the United States and Canada attributable to all approved indications for ENBREL on a scale that increases as gross profits increase; however, we maintain a majority share of ENBREL profits. After expiration of the collaboration agreement in the fourth quarter of 2013, we are required to pay Pfizer a percentage of net ENBREL sales in the United

States and Canada for three years. The annual amount of such payments is anticipated to be significantly less than the current ENBREL profit share.

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, 2010, 2009 and 2008, ENBREL sales aggregated $3.5 billion, $3.5 billion and $3.6 billion, respectively.

During the years ended December 31, 2010, 2009 and 2008, the ENBREL profit share expense was $1,184 million, $1,163 million and $1,195 million, respectively, and is included in Selling, general and

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

administrative expense in the Consolidated Statements of Income. In addition, cost recoveries from Pfizer for their share of the selling and marketing expense were $87 million, $75 million and $77 million for the years ended December 31, 2010, 2009 and 2008, respectively, and are included in Selling, general and administrative expense in the Consolidated Statements of Income.

Glaxo Group Limited

In July 2009, we entered into a collaboration agreement 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 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 do not currently have a commercial presence, including China, Brazil, India, Taiwan and South Korea (the Expansion Territories). In the Expansion Territories, Glaxo will be responsible for all development and commercialization costs and will purchase denosumab from us to meet demand. We will record product sales to Glaxo in the Expansion Territories. We have the option of expanding our role in the future 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 will also be 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.

We have determined that we are the principal participant in the Primary Territories. Accordingly, we will record related product sales to third parties net of estimated returns, rebates and other deductions. During the year ended December 31, 2010, product sales in the Primary Territories for osteoporosis indications were not material.

During the years ended December 31, 2010 and 2009, cost recoveries from Glaxo were $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. The 2010 payments were recognized as revenue upon the achievement of the related milestones and are included in 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 is being amortized and recognized as revenue over our estimated period of continuing involvement of approximately 13 years in Other revenue in our Consolidated Statements of Income.

Takeda Pharmaceutical Company Limited

In February 2008, we entered into a collaboration agreement with Takeda Pharmaceutical Company Limited (Takeda), which provides Takeda the exclusive rights to develop and commercialize for the Japanese market up to 12 clinical

stage molecules from our pipeline across a range of therapeutic areas, including oncology and inflammation, (collectively the products). The products include Vectibix® which received regulatory approval in Japan in 2010 for unresectable, advanced or recurrent colorectal cancer with wild-type *KRAS*, AMG 386, which is in a phase 3 trial in the United States for recurrent ovarian cancer, and ganitumab (AMG 479) which is expected to enter into a phase 3 trial in the United States for first-line metastatic pancreatic cancer in 2011. Under this agreement, Amgen received an upfront payment of $200 million in 2008 and may receive up to $307 million of additional amounts upon the achievement of various success-based development and regulatory approval

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

milestones. In addition, Takeda is obligated to pay Amgen up to an additional $120 million of future worldwide development costs for these products through 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 us royalties on future sales of these products in Japan. Amgen has the right to participate in the promotion of the products in Japan.

In February 2008, we also entered into a collaboration agreement with Takeda for the worldwide development and commercialization of our product candidate, motesanib, in the oncology area. Under this agreement, the parties will share responsibility for the development of motesanib outside Japan and Takeda shall be responsible for development in Japan. 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. Under this agreement, Amgen received an upfront payment of $100 million in 2008 and may receive up to $175 million of additional amounts upon the achievement of various success-based regulatory approval and sales milestones. In addition, 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.

During the years ended December 31, 2010, 2009 and 2008, cost recoveries from Takeda were $91 million, $112 million and $120 million, respectively, and are included in Research and development expense in the Consolidated Statements of Income. In addition, during 2010, we received payments aggregating $55 million for the achievement of certain regulatory milestones. The 2010 payments were recognized as revenue upon the achievement of the related milestones and are included in Other revenue in our Consolidated Statement of Income. The upfront payments, aggregating $300 million, are being amortized over our estimated period of continuing involvement of approximately 20 years and are recognized as revenue in Other revenues in our Consolidated Statements of Income. In 2010, royalties received on sales of Vectibix® in Japan were not material.

Daiichi Sankyo Company, Limited

In July 2007, we entered into a collaboration and license agreement with Daiichi Sankyo Company, Limited (Daiichi Sankyo), which provides Daiichi Sankyo the exclusive rights to develop and commercialize denosumab in Japan in postmenopausal 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. 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 and are being amortized over 11 years and the amortization expense is included in Cost of sales (excludes amortization of certain acquired intangible assets) expense in the Consolidated Statements of Income.

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

During the years ended December 31, 2010, 2009 and 2008, cost recoveries from Daiichi Sankyo were $3 million, $64 million and $60 million, respectively. The cost recoveries are included in Research and development expense in the Consolidated Statements of Income.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Other

We have various other collaborations in addition to those discussed above including our collaborations with Array BioPharma Inc. (Array), Kyowa Hakko Kirin Co. Ltd. (KHK) and Cytokinetics, Inc. (Cytokinetics), discussed below

We entered into our collaboration agreement with Array in December 2009, which granted us exclusive worldwide rights to Array s small-molecule glucokinase activator program, including ARRY-403 (AMG 151), which at the time of the agreement was and currently is being tested in a phase 1 clinical trial in patients with Type 2 diabetes. In connection with entering the agreement, we paid Array $60 million which we expensed when paid and included in Research and development expense in the Consolidated Statement of Income.

We entered into our collaboration agreement with KHK in March 2008, which granted us an exclusive license to develop and commercialize KHK s humanized monoclonal antibody KW-0761 (AMG 761) worldwide, except in Japan, Korea, China and Taiwan. KW-0761 (AMG 761) is being studied in inflammation and oncology settings and at the time the agreement was entered into was and currently is in a phase 1 clinical trial for both settings. In connection with entering the agreement, we paid KHK $100 million. In 2010, KHK paid us $20 million to reacquire our rights for KW-0761 (AMG 761) in the oncology setting. Both amounts were recognized when paid and included in Research and development expense in the Consolidated Statement of Income.

We entered into a collaboration agreement with Cytokinetics in December 2006, to discover, develop and commercialize novel small-molecule therapeutics that activate cardiac muscle contractility for potential applications in the treatment of heart failure. In addition, Amgen obtained an option to participate in future development and commercialization of Cytokinetics lead drug candidate arising from this program, Omecamtiv mecarbil (AMG 423), which at the time the agreement was entered into was in a phase 1 clinical trial and currently is in a phase 2 clinical trial. The collaboration is worldwide, excluding Japan. In connection with entering into the agreement, we paid Cytokinetics $42 million. In 2009, we exercised our option under the agreement and paid Cytokinetics an additional $50 million, to assume responsibility for development and commercialization of the lead drug candidate and related compounds, subject to certain participation rights of Cytokinetics. Both payments were expensed when paid and included in Research and development expense in the Consolidated Statements of Income.

Pursuant to the terms of these agreements, we may also be required to pay additional amounts upon the achievement of various development, regulatory and commercial milestones which in the aggregate are significant. In addition, if any products related to these collaborations are approved for sale, we would be required to pay 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 KA, a corporation formed in 1984 with Kirin Holdings Company, Limited (Kirin) for the development and commercialization of certain products based on advanced biotechnology. We account for our interest in KA under the equity method and include our share of KA s profits or losses in Selling, general and administrative expense in the Consolidated Statements of Income. For the years ended December 31, 2010, 2009 and 2008, our share of KA s profits was $71 million, $72 million and $72 million, respectively. At December 31, 2010 and 2009, the carrying value of our equity method investment in KA, net of dividends received, was $377 million and $306 million, respectively, and is included in non-current Other assets in the Consolidated Balance Sheets. The amount of dividends

received was $110 million and $8 million for the years ended December 31, 2009 and 2008, respectively. We did not receive any dividend payments in 2010. KA s revenues consist of royalty income related to its licensed technology rights. All of our rights to manufacture and market certain products including darbepoetin alfa, recombinant human erythropoietin, pegfilgrastim, granulocyte colony-stimulating factor, and romiplostim are pursuant to exclusive licenses from KA, which we currently market under

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the brand names Aranesp®, EPOGEN®, Neulasta®, NEUPOGEN® and Nplate®, respectively. KA receives royalty income from us, as well as from Kirin, J&J and F. Hoffmann-La Roche Ltd. (Roche) under separate product license agreements for certain geographic areas outside of the United States. During the years ended December 31, 2010, 2009 and 2008, KA earned royalties from us of $322 million, $327 million and $321 million, respectively. These amounts are included in Cost of sales (excludes amortization of certain acquired intangible assets) in the Consolidated Statements of Income. As of December 31, 2010 and 2009, we owed KA $62 million and $104 million, respectively, which are included in Accrued liabilities in the Consolidated Balance Sheets.

KA s expenses consist primarily of costs related to R&D activities conducted on its behalf by Amgen and Kirin. KA pays Amgen and Kirin for such services at negotiated rates. During the years ended December 31, 2010, 2009 and 2008, we earned revenues from KA of $96 million, $102 million and $124 million, respectively, for certain R&D activities performed on KA s behalf. These amounts are included in Other revenues in the Consolidated Statements of Income. During the years ended December 31, 2010, 2009 and 2008, we recorded cost recoveries from KA of $88 million, $96 million and $82 million, respectively, related to certain third-party costs. These amounts are included in Research and development expense in the Consolidated Statements of Income.

8. Cost savings initiatives and restructuring

As part of continuing efforts to optimize our network of manufacturing facilities and improve costs efficiencies, on January 18, 2011, we entered into an agreement whereby Boehringer Ingelheim (BI) will acquire all our rights in and substantially all assets at our manufacturing operations located in Fremont, California. The transaction was approved by Amgen s Board of Directors in December 2010 and is anticipated to close in March 2011. Upon the closing of this transaction, BI will assume our obligations under the facilities operating lease agreements and will enter into an agreement to manufacture certain quantities of our marketed product, Vectibix®, for us at this facility through December 31, 2012 (the supply agreement).

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 does not meet the accounting requirements to be treated as a sale involving real estate. As a result, the related assets will continue to be carried on our Consolidated Balance Sheet and will be depreciated over the period of the supply agreement.

We considered this transaction with BI to be a potential indicator of impairment and, accordingly, we performed an impairment analysis of the carrying values of the related 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. This impairment charge is included in Other charges in our Consolidated Statement of Income for the year ended December 31, 2010. The carrying values of the remaining assets, aggregating approximately $133 million, were determined to be fully recoverable.

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 agent (ESA) products, including our marketed ESA products Aranesp® and EPOGEN®, and the resulting impact on our operations. Key components of our restructuring plan initially included: (i) worldwide staff reductions, (ii) rationalization of our worldwide network of manufacturing facilities and, to a lesser degree, changes to certain R&D capital projects and (iii) abandoning leases primarily for certain R&D facilities that

will not be used in our operations. Subsequently, we identified certain additional initiatives designed to further assist in improving our cost structure, including outsourcing certain non-core business functions, most notably certain of our information systems infrastructure services, as well as abandoning leases for certain additional facilities that will no longer be used in 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

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2009, we recorded charges associated with these actions aggregating $70 million, primarily comprised of staff separation costs of $25 million, principally included in Other charges in the Consolidated Statement of Income, and integration related costs of $32 million, which were principally included in Selling, general and administrative expenses in the Consolidated Statement of Income. During the year ended December 31, 2008, we recorded charges associated with these actions aggregating $148 million, primarily comprised of loss accruals for certain leases that will not be used in our business of $59 million, asset impairment charges of $59 million and staff separation costs of $10 million, all of which were primarily included in Other charges in the Consolidated Statement of Income. The asset impairment charges principally represent the write-off of the total cost of the manufacturing-related assets as they were abandoned with no alternative future uses or residual value.

9. Other charges

For the years ended December 31, 2010, 2009 and 2008, we recorded charges associated with cost savings initiatives and/or restructuring totaling $118 million, $34 million and $92 million, respectively. Such expenses are included in Other charges in the Consolidated Statements of Income. (See Note 8, Cost savings initiatives and restructuring for further discussion.)

For the years ended December 31, 2009 and 2008, we recorded loss accruals for settlements of certain legal proceedings aggregating $33 million and $288 million, respectively. The loss accruals for 2008 principally related to the settlement of the Ortho Biotech Products L.P. antitrust suit. These amounts are included in Other charges in the Consolidated Statements of Income.

10. Available-for-sale investments

The fair values of available-for-sale investments by type of security, contractual maturity and classification in the Consolidated Balance Sheets were as follows as of December 31, 2010 and 2009 (in millions):

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 securities	17,057	256	(36)	17,277
Equity securities	50		(2)	48
	$ 17,107	$ 256	$ (38)	$ 17,325

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Type of security as of December 31, 2009	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. Treasury securities	$ 1,929	$ 12	$ (6)	$ 1,935
Obligations of U.S. government agencies and FDIC guaranteed bank debt	3,731	62	(1)	3,792
Corporate debt securities	4,193	96	(4)	4,285
Mortgage and asset backed securities	489	4	(2)	491
Money market mutual funds	2,784			2,784
Other short-term interest bearing securities	55			55
Total debt securities	13,181	174	(13)	13,342
Equity securities	63		(8)	55
	$ 13,244	$ 174	$ (21)	$ 13,397

Contractual maturity	2010	2009
Maturing in one year or less	$ 4,118	$ 3,444
Maturing after one year through three years	6,736	6,369
Maturing after three years through five years	5,812	3,207
Maturing after five years	611	322
Total debt securities	17,277	13,342
Equity securities	48	55
	$ 17,325	$ 13,397

Classification in the Consolidated Balance Sheets	2010	2009
Cash and cash equivalents	$ 3,287	$ 2,884
Marketable securities	14,135	10,558
Other assets noncurrent	48	55
	17,470	13,497
Less cash	(145)	(100)
	$ 17,325	$ 13,397

For the years ended December 31, 2010, 2009 and 2008, realized gains totaled $115 million, $104 million and $124 million, respectively, and realized losses totaled $25 million, $62 million and $49 million, respectively. The cost of securities sold is based on the specific identification method.

The primary objective of our investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits 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 type and issuer.

We review our available-for-sale investments for other-than-temporary declines in fair value below our cost basis on a quarterly basis 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 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 by a rating agency. As of December 31, 2010 and 2009, we believe the cost bases for our available-for-sale investments were recoverable in all material respects.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. Inventories

Inventories consisted of the following as of December 31, 2010 and 2009 (in millions):

	2010	2009
Raw materials	$ 128	$ 97
Work in process	1,382	1,683
Finished goods	512	440
	$ 2,022	$ 2,220

As of December 31, 2009, work in process included $258 million of denosumab inventory capitalized in preparation for its anticipated product launch upon regulatory approval. During 2010, we received various approvals for denosumab from regulatory authorities in the United States, the European Union and various other countries and commenced selling the product in certain geographic markets.

During 2008, we wrote-off $84 million of inventory resulting from a strategic decision to change manufacturing processes. This charge is included in Cost of sales (excludes amortization of certain acquired intangible assets) in our Consolidated Statement of Income.

12. Property, plant and equipment

Property, plant and equipment consisted of the following as of December 31, 2010 and 2009 (in millions):

	2010	2009
Land	$ 361	$ 450
Buildings and improvements	3,392	3,293
Manufacturing equipment	1,802	1,462
Laboratory equipment	955	892
Furniture, fixtures and other assets	3,547	3,369
Construction in progress	631	910
	10,688	10,376
Less accumulated depreciation and amortization	(5,166)	(4,638)
	$ 5,522	$ 5,738

During the years ended December 31, 2010, 2009 and 2008, we recognized depreciation and amortization charges associated with our property, plant and equipment of $594 million, $624 million and $648 million, respectively.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. Intangible assets

Amortization of finite-lived intangible assets is provided over their estimated useful lives ranging from 5 to 15 years on a straight-line basis (weighted average remaining amortization period of 6 years at December 31, 2010). Finite-lived intangible assets consisted of the following as of December 31, 2010 and 2009 (in millions):

Intangible assets subject to amortization	Weighted average amortization period	2010	2009
Acquired product technology rights:			
Developed product technology	15 years	$ 2,872	$ 2,872
Core technology	15 years	1,348	1,348
Trade name	15 years	190	190
Acquired R&D technology rights	5 years	350	350
Other intangible assets	10 years	627	541
		5,387	5,301
Less accumulated amortization		(3,157)	(2,734)
		$ 2,230	$ 2,567

Acquired product technology rights relate to the identifiable intangible assets acquired in connection with the 2002 Immunex acquisition and the amortization is included in Amortization of certain acquired intangible assets in the Consolidated Statements of Income. Intangible assets also include acquired R&D technology rights consisting of technology used in R&D with alternative future uses and the amortization is included in Research and development expense in the Consolidated Statements of Income. The amortization of other 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, 2010, 2009 and 2008, we recognized amortization charges associated with our intangible assets of $423 million, $425 million and $425 million, respectively. The total estimated amortization for each of the next five years for our intangible assets is $353 million, $331 million, $331 million, $316 million and $309 million in 2011, 2012, 2013, 2014 and 2015, respectively.

14. Accrued liabilities

Accrued liabilities consisted of the following as of December 31, 2010 and 2009 (in millions):

	2010	2009
Sales deductions	$ 1,144	$ 970
Employee compensation and benefits	764	751

Clinical development costs	230	361
Sales returns reserve	339	211
Other	889	1,006
	$ 3,366	$ 3,299

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. Financing arrangements

The following table reflects the carrying values and the fixed contractual coupon rates of our borrowings under our various financing arrangements as of December 31, 2010 and 2009 (dollar amounts in millions):

	2010	2009
0.125% convertible notes due 2011 (2011 Convertible Notes)	$ 2,488	$ 2,342
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,213	2,088
5.85% notes due 2017 (2017 Notes)	1,099	1,099
4.85% notes due 2014 (2014 Notes)	1,000	1,000
5.70% notes due 2019 (2019 Notes)	998	998
6.40% notes due 2039 (2039 Notes)	996	995
6.375% notes due 2037 (2037 Notes)	899	899
3.45% notes due October 2020 (October 2020 Notes)	897	
5.75% notes due 2040 (2040 Notes)	696	
4.95% notes due 2041 (2041 Notes)	595	
6.15% notes due 2018 (2018 Notes)	499	499
6.90% notes due 2038 (2038 Notes)	499	499
4.50% notes due March 2020 (March 2020 Notes)	300	
Other notes	183	182
Total borrowings	13,362	10,601
Less current portion	(2,488)	
Total non-current debt	$ 10,874	$ 10,601

Debt issuances

We issued debt securities in various offerings during the three years ended December 31, 2010, including: in 2010, $300 million principal amount of March 2020 Notes, $700 million principal amount of 2040 Notes, $900 million principal amount of October 2020 Notes and $600 million principal amount of 2041 Notes; in 2009, $1.0 billion principal amount of 2019 Notes and $1.0 billion principal amount of 2039 Notes; and in 2008, $500 million principal amount of 2018 Notes and $500 million principal amount of 2038 Notes. Debt issuance costs incurred in connection with these debt offerings totaled $17 million, $13 million and $6 million for debt issued in 2010, 2009 and 2008, respectively, and 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 these debt securities as well as the 2017 Notes and the 2037 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 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.

Debt repayments

We repaid $1.0 billion aggregate principal amount of notes with a fixed interest rate of 4.00% in 2009 and $2.0 billion aggregate principal amount of floating London Interbank Offered Rate (LIBOR) based notes in 2008. No debt was due or repaid in 2010.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2011 and 2013 Convertible Notes

In 2006, we issued $2.5 billion principal amount of convertible notes (the 2011 Convertible Notes) at par that became due and were repaid in February, 2011. While outstanding, the 2011 Convertible Notes were convertible into shares of our common stock at a conversion rate of 12.5247 shares per $1,000 principal amount of notes, which represents a conversion price of approximately $79.84 per share.

Concurrent with the issuance of the 2011 Convertible Notes, we issued $2.5 billion principal amount of convertible notes due in February 2013 (the 2013 Convertible Notes) at par. The 2013 Convertible Notes may be converted into shares of our common stock based on an initial conversion rate of 12.5814 shares per $1,000 principal amount of notes, which represents a conversion price of approximately $79.48 per share. This conversion rate will be adjusted if we make specified types of distributions or enter into certain other transactions with respect to our common stock. The 2013 Convertible Notes may only be converted: (i) during any calendar quarter if the closing price of our common stock exceeds 130% of the 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) 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. The 2011 Convertible Notes had similar conversion terms. As of December 31, 2010, the 2011 Convertible Notes and the 2013 Convertible Notes were not convertible.

Concurrent with the issuance of the 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 2013 Convertible Notes upon conversion. This convertible note hedge will terminate at the earlier of the maturity of the 2013 Convertible Notes or the first day none of these notes remain outstanding due to conversion or otherwise. We also purchased convertible note hedges with similar terms in connection with the issuance of the 2011 Convertible Notes which terminated when these notes were repaid.

Also concurrent with the issuance of the 2011 Convertible Notes and 2013 Convertible Notes, we sold warrants to acquire shares of our common stock at an exercise price of $107.90 per share. Pursuant to these transactions, warrants for approximately 31.3 million shares of our common stock may be settled in May 2011 and warrants for approximately 31.5 million shares of our common stock may be settled in May 2013 (the settlement dates). If the average price of our common stock during a defined period ending on or about the respective settlement dates exceeds the exercise price of the warrants, the warrants will be net settled, at our option, in cash or shares of our common stock.

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 2011 Convertible Notes and 2013 Convertible Notes were bifurcated and accounted for separately. While the notes are outstanding, their discounted carrying values resulting from the bifurcation are accreted back to their principal amounts over periods that end on the scheduled maturity dates, resulting in the recognition of non-cash interest expense. After

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

giving effect to this bifurcation, the effective interest rates on these borrowings are 6.24% for the 2011 Convertible Notes and 6.35% for the 2013 Convertible Notes. For the years ended December 31, 2010, 2009 and 2008, total interest expense for the 2011 Convertible Notes was $149 million, $140 million and $132 million, respectively, including non-cash interest expense of $146 million, $136 million and $128 million, respectively. For the years ended December 31, 2010, 2009 and 2008, total interest expense for the 2013 Convertible Notes was $134 million, $127 million and $120 million, respectively, including non-cash interest expense of $125 million, $118 million and $110 million, respectively. The difference between the total interest expense and non-cash interest expense for the 2011 Convertible Notes and the 2013 Convertible Notes in each year is the interest expense related to the contractual coupon rates.

The principal balances, unamortized discounts and net carrying amounts of the liability components and the equity components of our 2011 Convertible Notes and our 2013 Convertible Notes were as follows as of December 31, 2010 and 2009 (in millions):

	Liability component			Equity component
December 31, 2010	**Principal balance**	**Unamortized discount**	**Net carrying amount**	**Net carrying amount**
2011 Convertible Notes	$ 2,500	$ 12	$ 2,488	$ 643
2013 Convertible Notes	2,500	287	2,213	829
December 31, 2009				
2011 Convertible Notes	$ 2,500	$ 158	$ 2,342	$ 643
2013 Convertible Notes	2,500	412	2,088	829

Other

Other notes include zero coupon convertible notes due in 2032 with a carrying value of $83 million and $82 million at December 31, 2010 and 2009, 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 agreements 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. These interest rate swap agreements qualify and are designated as fair value hedges. The effective interest rates on these notes as of December 31, 2010 and 2009 after giving effect to the related interest rate swap agreements and the notional amounts of these interest rate swap agreements were as follows as of December 31, 2010 and 2009 (dollar amounts in millions):

		Notional amount	
	Effective interest rate	**2010**	**2009**

2017 Notes	LIBOR + 2.5%	$ 1,100	$
2014 Notes	LIBOR + 0.3%	1,000	1,000
2019 Notes	LIBOR + 2.6%	1,000	
2018 Notes	LIBOR + 1.8%	500	500
		$ 3,600	$ 1,500

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Shelf registration statements and other facilities

As of December 31, 2010, we have a commercial paper program that allows us to issue up to $2.3 billion of unsecured commercial paper to fund our working capital needs. At December 31, 2010, no amounts were outstanding under our commercial paper program.

As of December 31, 2010, we have a $2.3 billion syndicated, unsecured, revolving credit facility which matures in November 2012 and is available for general corporate purposes or as a liquidity backstop to our commercial paper program. Annual commitment fees for this facility are 0.05% based on our current credit rating. As of December 31, 2010, no amounts were outstanding under this facility.

We have filed a shelf registration statement with the SEC, which allows us to issue an unspecified amount 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 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 expires in April 2011.

As of December 31, 2010, we have $400 million remaining under a shelf registration statement that was established in 1997. In connection with this shelf registration, 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, 2010, no securities were outstanding under this medium-term note program.

Certain of our financing arrangements contain non-financial covenants and we were in compliance with all applicable covenants as of December 31, 2010. None of our financing arrangements contain any financial covenants.

Contractual maturities of long-term debt obligations

The aggregate contractual maturities of all long-term debt obligations due subsequent to December 31, 2010 are as follows (in millions):

Maturity date	**Amount**
2011[(1)]	$ 2,500
2012[(2)]	84
2013[(3)]	2,500
2014	1,000
2015	
Thereafter	7,600
Total	$ 13,684

(1) This amount represents the principal amount due for our 2011 Convertible Notes after full accretion of the debt discount.

(2) This amount represents the accreted value of our zero coupon convertible notes due in 2032 as of March 1, 2012, the next date on which holders may put the debt to us for repayment.

(3) This amount represents the principal amount due for our 2013 Convertible Notes after full accretion of the debt discount.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2010, 2009 and 2008 was $604 million, $578 million and $551 million, respectively. Interest costs capitalized for the years ended December 31, 2010, 2009 and 2008 were $33 million, $32 million and $22 million, respectively. Interest paid, net of interest rate swaps, during the years ended December 31, 2010, 2009 and 2008, totaled $323 million, $293 million and $303 million, respectively.

16. Stockholders equity

Stock repurchase program

The following table is a summary of activity under our stock repurchase program for the years ended December 31, 2010, 2009 and 2008 (in millions):

	2010		2009		2008	
	Shares	Dollars	Shares	Dollars	Shares	Dollars
First quarter	29.1	$ 1,684	37.5	$ 1,997		$
Second quarter	10.3	616			32.7	1,549[(1)]
Third quarter	6.6	364				19[(1)]
Fourth quarter	20.5	1,136	21.7	1,211	12.6	700
Total	66.5	$ 3,800	59.2	$ 3,208	45.3	$ 2,268

(1) The total cost of shares repurchased during the three months ended June 30, 2008 excludes approximately $19 million paid in July 2008 in connection with the final settlement of an accelerated share repurchase program entered into in May 2008.

In December 2009, the Board of Directors authorized us to repurchase up to an additional $5.0 billion of common stock of which a total of $2.2 billion remains available as of December 31, 2010. The manner of purchases, the amount we spend and the number of shares repurchased will vary based on a variety of factors, including the stock price, blackout periods in which we are restricted from repurchasing shares and the impact of repurchases on our credit rating, and may include private block purchases as well as market transactions.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accumulated other comprehensive income

The components of Accumulated Other Comprehensive Income (AOCI) are as follows for the years ended December 31, 2010, 2009 and 2008 (in millions):

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2007	$ 59	$ (45)	$ 39	$	$ 53
Other comprehensive income:					
Foreign currency translation adjustments	(43)				(43)
Unrealized gains		155	92		247
Reclassification adjustments to income			(75)		(75)
Other				(11)	(11)
Income taxes	9	(60)	(7)	4	(54)
Balance as of December 31, 2008	25	50	49	(7)	117
Other comprehensive income:					
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
Other comprehensive income:					
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

Other

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. At December 31, 2010 and 2009, no shares of preferred stock were issued or outstanding.

17. Fair value measurement

We use various valuation approaches in determining the fair value of our financial assets and liabilities within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down 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

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 to measure 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 following fair value hierarchy tables present information about each major class/category of the Company s financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2010 and 2009 (in millions):

Fair value measurement at 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

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Fair value measurement at December 31, 2009 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	$ 1,935	$	$	$ 1,935
Obligations of U.S. government agencies and FDIC guaranteed bank debt		3,792		3,792
Corporate debt securities		4,285		4,285
Mortgage and asset backed securities		491		491
Money market mutual funds	2,784			2,784
Other short-term interest bearing securities		55		55
Equity securities	55			55
Derivatives		153		153
Total assets	$ 4,774	$ 8,776	$	$ 13,550
Liabilities:				
Derivatives	$	$ 152	$	$ 152
Total liabilities	$	$ 152	$	$ 152

The fair value 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. Our other government related debt securities portfolio is comprised of securities with a weighted average credit rating of AAA or equivalent by Standard and Poor s (S&P), Moody s Investors Services, Inc. (Moody s) or Fitch, Inc. (Fitch), and our corporate debt securities portfolio has a weighted average credit rating of A equivalent by S&P, Moody s or Fitch. We estimate the fair value of these securities 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 and broker/dealer quotes of the same or similar securities, issuer credit spreads, benchmark securities and other observable inputs.

Our mortgage and asset backed securities portfolio is comprised entirely of senior tranches, with a credit rating of AAA or equivalent by S&P, Moody s or Fitch. We estimate the fair value of these securities 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 and broker/dealer quotes of 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 entered into with counterparties that have a minimum credit rating of A- or equivalent by S&P, Moody s or Fitch. We estimate the fair value of these contracts 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 quoted foreign currency

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

spot rates, forward points, LIBOR and swap curves 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, 2010 and December 31, 2009, we had open foreign currency forward contracts with notional amounts of $3.2 billion and $3.4 billion, respectively, and open foreign currency option contracts with notional amounts of $398 million and $376 million, respectively, that were primarily Euro-based and were designated as cash flow hedges. In addition, as of December 31, 2010 and December 31, 2009, we had $670 million and $414 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 18, Derivative instruments.)

Our interest rate swap contracts are entered into with counterparties that have a minimum credit rating of A- or equivalent by S&P, Moody s or Fitch. We estimate the fair value of these contracts using an income-based industry standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs include LIBOR and swap curves and obligor credit default swap rates. We had interest rate swap agreements with an aggregate notional amount of $3.6 billion and $1.5 billion as of December 31, 2010 and December 31, 2009, respectively, that were designated as fair value hedges. (See Note 18, Derivative instruments.)

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 year ended 2009 of assets and liabilities that are not measured at fair value on a recurring basis. See Note 8, Cost savings initiatives and restructuring for further discussion on an impairment that we recognized in 2010.

Summary of the fair value of other financial instruments

Short-term assets and liabilities

The estimated fair values of cash equivalents, accounts receivable and accounts payable approximate their carrying values due to the short-term nature of these financial instruments.

Borrowings

We estimate the fair value of our convertible notes 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 values of our convertible notes exclude their equity components and 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 value of our other long-term notes 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 and broker/dealer quotes of the same or similar securities, credit spreads, benchmark yields and other observable inputs (Level 2). The

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

following tables present the carrying values and estimated fair values of our borrowings as of December 31, 2010 and 2009 (in millions):

	2010		2009	
	Carrying value	Fair value	Carrying value	Fair value
2011 Convertible Notes	$ 2,488	$ 2,501	$ 2,342	$ 2,487
2013 Convertible Notes	2,213	2,479	2,088	2,374
2017 Notes	1,099	1,280	1,099	1,207
2014 Notes	1,000	1,101	1,000	1,075
2019 Notes	998	1,139	998	1,077
2039 Notes	996	1,149	995	1,102
2037 Notes	899	1,027	899	988
October 2020 Notes	897	857		
2040 Notes	696	734		
2041 Notes	595	564		
2018 Notes	499	584	499	551
2038 Notes	499	607	499	582
March 2020 Notes	300	311		
Other notes	183	214	182	206
Total	$ 13,362	$ 14,547	$ 10,601	$ 11,649

18. Derivative instruments

The Company is exposed to risks related to its business operations, certain of which are managed through derivative instruments. The risks that we manage by using derivative instruments are foreign exchange rate risk and interest rate risk. We use financial instruments including foreign currency forward, foreign currency option, forward interest rate and interest rate swap contracts, to reduce our risk to these exposures. We do not use derivatives for speculative trading purposes.

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Consolidated Balance Sheets. (See Note 17, Fair value measurement.) 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.

Cash flow hedges

We are exposed to possible changes in values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, associated primarily with our international product sales denominated in Euros. Increases or decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are partially offset 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 successive periods. As of December 31, 2010 and 2009, we had open foreign currency forward contracts with notional amounts of $3.2 billion and $3.4 billion, respectively, and open foreign currency option contracts with notional amounts of $398 million and $376 million, respectively. These foreign currency forward and

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 in the Consolidated Balance Sheets and reclassified to earnings in the same periods during which the hedged transactions affect 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 recorded in Other Comprehensive Income (OCI) and amortized into earnings over the lives of the associated debt issuances.

The following table reflects the effective portion of the unrealized gain/(loss) recognized in OCI for our cash flow hedge contracts for the years ended December 31, 2010 and 2009 (in millions):

Derivatives in cash flow hedging relationships	**2010**	**2009**
Foreign currency contracts	$ 191	$ (202)
Forward interest rate contracts	(5)	(11)
Total	$ 186	$ (213)

The following table reflects the location in the Consolidated Statements of Income and the effective portion of the gain/(loss) reclassified from AOCI into earnings for our cash flow hedge contracts for the years ended December 31, 2010 and 2009 (in millions):

Derivatives in cash flow hedging relationships	**Statements of Income location**	**2010**	**2009**
Foreign currency contracts	Product sales	$ 47	$ (7)
Forward interest rate contracts	Interest expense, net	(1)	(1)
Total		$ 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 expense for the years ended December 31, 2010 and 2009. As of December 31, 2010, the amounts expected to be reclassified from AOCI into earnings over the next 12 months are approximately $8 million of losses on foreign currency forward and option 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 rate debt, we have entered into interest rate swap agreements, which qualify and have been designated as fair value hedges. The terms of these interest rate swap agreements

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%. We had interest rate swap agreements with aggregate notional amounts of $3.6 billion and $1.5 billion as of December 31, 2010 and 2009, respectively. The interest rate swap agreements as of December 31, 2010 were for our notes due in 2014, 2017, 2018 and 2019 and, as of December 31, 2009 for our notes due in 2014 and 2018. For derivative instruments that are designated and qualify as a fair value hedge, 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 are recognized in current earnings. For the year ended December 31, 2010, we included the unrealized loss on the hedged debt of $105 million in the same line item, Interest expense, net in the Consolidated Statement of Income, as the offsetting unrealized gain of $105 million on the related interest rate swap agreements. For the year ended December 31, 2009, we included the unrealized gain on the hedged debt of

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

$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 agreements.

Derivatives not designated as hedges

We enter into foreign currency forward contracts to reduce our exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies which are not designated as hedging transactions. These exposures are hedged on a month-to-month basis. As of December 31, 2010 and 2009, the total notional amounts of these foreign currency forward contracts, primarily Euro-based, were $670 million and $414 million, respectively.

The following table reflects 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 for the years ended December 31, 2010 and 2009 (in millions):

Derivatives not designated as hedging instruments	Statements of Income location	2010	2009
Foreign currency contracts	Interest and other income, net	$ 32	$ (24)

The following tables reflect the fair values of both derivatives designated as hedging instruments and not designated as hedging instruments included in the Consolidated Balance Sheets as of December 31, 2010 and 2009 (in millions):

	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 non-current assets	$ 195	Accrued liabilities/ Other non-current liabilities	$
Foreign currency contracts	Other current assets/ Other non-current assets	154	Accrued liabilities/ Other non-current 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

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Derivative assets		Derivative liabilities	
December 31, 2009	**Balance Sheet location**	**Fair value**	**Balance Sheet location**	**Fair value**
Derivatives designated as hedging instruments:				
Interest rate swap contracts	Other current assets/Other non-current assets	$ 90	Accrued liabilities/ Other non-current liabilities	$
Foreign currency contracts	Other current assets/Other non-current assets	63	Accrued liabilities/ Other non-current liabilities	152
Total derivatives designated as hedging instruments		153		152
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets		Accrued liabilities	
Total derivatives not designated as hedging instruments				
Total derivatives		$ 153		$ 152

Our derivative contracts that were in a liability position as of December 31, 2010 contain certain credit risk related contingent provisions that are 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 are included within Net cash provided by operating activities in the Consolidated Statements of Cash Flows.

19. 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, which are complex in nature and have outcomes that are difficult to predict. We record accruals for such contingencies to the extent that we conclude that it is probable that a liability will be incurred and the amount

of the related loss can be reasonably estimated. While it is not possible to accurately predict or determine the eventual outcome of these items, one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain of our legal proceedings and other matters are discussed below:

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 (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

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 United States 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. The ITC has not yet issued a decision on Amgen s motion.

Teva Matters

Sensipar® Abbreviated New Drug Application (ANDA) Litigation

On July 25, 2008, Amgen, NPS Pharmaceuticals (NPS) and Brigham and Women s Hospital (BWH), filed a lawsuit against Teva Pharmaceuticals USA, Inc. (Teva USA), Teva Pharmaceutical Industries Ltd. (Teva Ltd. , and together with Teva USA, Teva) and Barr Laboratories, Inc. (Barr) in the U.S. District Court for the District of Delaware (the Delaware District Court) for infringement of four patents U.S. Patent Nos. 6,001,068 (the 068 Patent); 6,031,003 (the 003 Patent); 6,313,146 (the 146 Patent) and 6,211,244 (the 244 Patent). The lawsuit is based on ANDAs filed by Teva and Barr which seek approval to market generic versions of Sensipar® (cinacalcet hydrochloride). Amgen s filing of the lawsuit stays any U.S. Food and Drug Administration (FDA) approval of the Teva or Barr ANDA until September 2011.

Trial in this action commenced on November 30, 2010 on Teva s and Barr s invalidity and inequitable conduct defenses. Prior to commencement of trial and based on agreement between the parties, the Delaware District Court entered an order that Teva and Barr infringe the 068, 003 and 244 patents and dismissed all claims relating to the 146 patent. The Delaware District Court issued its Memorandum Decision and Order on January 7, 2011 rejecting Teva s and Barr s defenses, finding the 068, 003 and 244 patents valid, enforceable and infringed, and enjoining Teva and

Barr from the commercial manufacture, use, import or sale of their generic version of cinacalcet hydrochloride until the last of the three patents expires. On February 4, 2011, Teva and Barr filed a notice of appeal of the Delaware District Court s Memorandum Decision and Order.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Teva v. Amgen, the 603 Patent Litigation

On May 20, 2009, Teva Ltd. filed a lawsuit against Amgen in the U.S. District Court for the Eastern District of Pennsylvania (the Pennsylvania District Court) alleging infringement of Teva s U.S. Patent No. 7,449,603 by its manufacture, importation, use, sale and/or offer for sale of Sensipar® (cinacalcet hydrochloride). Amgen filed an answer and counterclaims of noninfringement and patent invalidity. Pretrial discovery is ongoing.

Teva v. Amgen, the G-CSF Patent Litigation

On November 30, 2009, Teva USA filed a lawsuit in the Pennsylvania District Court requesting that Amgen s U.S. Patent Nos. 5,580,755 and 5,582,823 (the 755 patent and the 823 patent , respectively) relating to human G-CSF and methods for its use, be declared invalid and/or not infringed by Teva USA s G-CSF product, a filgrastim molecule. Also on November 30, 2009, Teva Ltd. announced that it had filed a biologics license application with the FDA seeking approval to market its G-CSF product in the United States. On January 15, 2010, Amgen filed an answer and brought counterclaims against Teva USA and Teva Ltd. seeking a declaration that Amgen s patents are valid and will be infringed by Teva s G-CSF product. On May 4, 2010, Teva withdrew its non-infringement affirmative defense and Teva USA withdrew its non-infringement counterclaim. On September 10, 2010, the Pennsylvania District Court issued its claim construction ruling. On September 24, 2010, Amgen moved for summary judgment of infringement of certain claims of the 755 patent and the 823 patent, and on September 29, 2010, Teva USA sought leave to amend its pleadings to re-allege non-infringement of the patents-in-suit. The Court denied both motions on November 19, 2010. Teva announced on September 30, 2010 that it received a complete response letter from the FDA for its G-CSF product Neutroval™, indicating that the FDA wanted further information but that Teva believed that no further pre-marketing clinical trials would be necessary. Discovery is ongoing and no trial date has yet been set.

Simonian v. Amgen Inc.

On March 9, 2010, Thomas A. Simonian filed a lawsuit in the U.S. District Court for the Northern District of Illinois alleging that Amgen violated a false marking statute by marking product packaging or product inserts of its NEUPOGEN® product with U.S. Patent Nos. 4,810,643 and 4,999,291, now both expired. After a three month stay, plaintiff s amendment of its complaint, and denial of Amgen s motion to dismiss, Amgen filed an answer to the complaint on December 7, 2010 denying the allegation that Amgen violated the false marking statute. Pretrial proceedings are ongoing.

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 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.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. Plaintiffs continue to file for extensions for the final approval hearing of the Track II settlement due to continued deficiencies in executing notices, and the final approval hearing is now expected to occur in the spring of 2011.

Certain AWP litigation cases are not a part of the MDL Proceeding. These cases are:

County of Erie v. Abbott Laboratories, Inc., et al. This case was filed against Amgen and Immunex, along with several other pharmaceutical manufacturers, on March 8, 2005 in the Supreme Court of New York, Erie County. On August 11, 2010, Amgen and Immunex reached a settlement with the County of Erie, and on November 19, 2010, the county discontinued proceedings against the companies with prejudice.

County of Schenectady v. Abbott Laboratories, Inc., et al. This case was filed against Amgen and Immunex, along with several other pharmaceutical manufacturers, on May 9, 2006 in the Supreme Court of New York, Schenectady County. On August 11, 2010, Amgen and Immunex reached a settlement with the County of Schenectady, and on November 19, 2010, the county discontinued proceedings against the companies with prejudice.

County of Oswego v. Abbott Laboratories, Inc., et al. This case was filed against Amgen and Immunex, along with several other pharmaceutical manufacturers, on May 9, 2006 in the Supreme Court of New York, Oswego County. On August 11, 2010, Amgen and Immunex reached a settlement with the County of Oswego, and on November 19, 2010, the county discontinued proceedings against the companies with prejudice.

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. 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.

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,

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Gilbert S. Omenn and Franklin P. Johnson, Jr., (the Federal Defendants) in the U.S. District Court for the Central District of California (the California Central District Court) on April 17, 2007 (Kairalla v. Amgen Inc., et al.), May 1, 2007 (Mendall v. Amgen Inc., et al., & Jaffe v. Amgen Inc., et al.), May 11, 2007 (Eldon v. Amgen Inc., et al.), May 21, 2007 (Rosenfield v. Amgen Inc., et al.) and June 18, 2007 (Public Employees Retirement Association of Colorado v. Amgen Inc., et al.) were consolidated by the California Central District Court into one action captioned *In re Amgen Inc. Securities Litigation*. The consolidated complaint was filed with the California Central District Court on October 2, 2007. The consolidated complaint alleges that Amgen and these officers and directors made false statements that resulted in: (i) deceiving the investing public regarding Amgen s prospects and business; (ii) artificially inflating the prices of Amgen s publicly traded securities and (iii) causing plaintiff and other members of the class to purchase Amgen publicly traded securities at inflated prices. The complaint also makes off-label marketing allegations that, throughout the class period, the Federal Defendants improperly marketed Aranesp® and EPOGEN® for off-label uses while aware that there were alleged safety signals with these products. The plaintiffs seek class certification, compensatory damages, legal fees and other relief deemed proper. The Federal Defendants filed a motion to dismiss on November 8, 2007. On February 4, 2008, the California Central District Court granted in part, and denied in part, the Federal Defendants motion to dismiss the consolidated amended complaint. Specifically, the California Central District Court granted the Federal Defendants motion to dismiss as to individual defendants Fritzky, Omenn, Johnson, Fenton and McNamee, but denied the Federal Defendants motion to dismiss as to individual defendants Sharer, Nanula, Perlmutter and Morrow.

A class certification hearing before the California Central District Court, was held on July 17, 2009 and on August 12, 2009, the California Central District Court granted plaintiffs motion for class certification. On August 28, 2009, Amgen filed a petition for permission to appeal with the U.S. Court of Appeals for the Ninth Circuit (the Ninth Circuit) under Rule 23(f), regarding the Order on Class Certification and the Ninth Circuit granted Amgen s appeal on December 11, 2009. Amgen filed its brief on March 29, 2010 and plaintiff filed its brief on April 27, 2010. No date has been set for oral argument before the Ninth Circuit. On February 2, 2010, the lower court granted Amgen s motion to stay the underlying action pending the outcome of the Ninth Circuit 23(f) appeal.

State Derivative Litigation

Larson v. Sharer, et al.

The three state stockholder derivative complaints filed against Amgen Inc., Kevin W. Sharer, George J. Morrow, Dennis M. Fenton, Brian M. McNamee, Roger M. Perlmutter, David Baltimore, Gilbert S. Omenn, Judith C. Pelham, Frederick W. Gluck, Jerry D. Choate, J. Paul Reason, Frank J. Biondi, Jr., Leonard D. Schaeffer, Frank C. Herringer, Richard D. Nanula, Willard H. Dere, Edward V. Fritzky, Franklin P. Johnson, Jr. and Donald B. Rice as defendants (the State Defendants) on May 1, 2007 (*Larson v. Sharer, et al.*, & *Anderson v. Sharer, et al.*), and August 13, 2007 (*Weil v. Sharer, et al.*) in the Superior Court of the State of California, Ventura County (the Superior Court) were consolidated by the Superior Court under one action captioned *Larson v. Sharer, et al*. The consolidated complaint was filed on July 5, 2007. The complaint alleges that the State Defendants breached their fiduciary duties, wasted corporate assets, were unjustly enriched and violated the California Corporations Code. Plaintiffs allege that the State Defendants failed to disclose and/or misrepresented results of Aranesp® clinical studies, marketed both Aranesp® and EPOGEN® for off-label uses and that these actions or inactions caused stockholders to suffer damages. The complaints also allege insider trading by the State Defendants. The plaintiffs seek treble damages based on various causes of action, reformed corporate governance, equitable and/or injunctive relief, restitution, disgorgement of profits, benefits and other compensation, and legal costs.

An amended consolidated complaint was filed on March 13, 2008, adding Anthony Gringeri as a State Defendant and removing the causes of action for insider selling and misappropriation of information, violation of California Corporations Code Section 25402 and violation of California Corporations Code Section 25403. On July 14, 2008, the Superior Court dismissed without prejudice the consolidated state derivative class action. The

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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,

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Stockholder Demand

On August 20, 2010, Amgen received a stockholder demand on the Board of Directors to take action to remedy alleged breaches of fiduciary duty and related violations by the Board and certain officers of the Company. The stockholder, Dr. Mark Victor, alleged that the directors and certain executive officers caused the Company to issue false or misleading statements regarding the safety of EPOGEN® and Aranesp® and promotional practices regarding these drugs. The Board of Directors undertook an investigation into the allegations made by the stockholder and on October 11, 2010, the Board of Directors notified Dr. Victor that it had rejected his demand.

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, which remains pending before the Ninth Circuit. 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

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Fiduciary Committee. 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 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 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 on December 16, 2009. Plaintiffs filed their opposition on January 19, 2010. The motion to dismiss was argued on February 11, 2010. 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. Petitioner s opening brief was served on December 20, 2010 and Amgen s answering brief was filed on February 2, 2011. No date has been set for oral argument.

Third-Party Payers Litigation

On June 5, 2007, the *United Food & Commercial Workers Central Pennsylvania and Regional Health & Welfare Fund v. Amgen Inc.* (the United Food Matter), on June 7, 2007 the *Vista Healthplan Inc. v. Amgen Inc.* (the Vista Healthplan Matter), on June 14, 2007, the *Painters District Council No. 30 Health & Welfare Fund v. Amgen. Inc.* (the Painters Matter), on August 8, 2007, the *Ironworkers v. Amgen Inc.* (the Ironworkers Matter), on August 15, 2007, *Watters (State of Michigan) v. Amgen Inc.* (the Watters Matter), and on August 28, 2007, *Sheet Metal v. Amgen Inc.* (the Sheet Metal Matter), putative class action lawsuits, were filed by third-party payers against Amgen in the California Central District Court. In each action, the plaintiff alleges that Amgen marketed its anemia medicines, EPOGEN® and Aranesp®, for off-label uses, or uses that are not approved by the FDA, and claims that, as a result, the plaintiff paid for unwarranted prescriptions. Specifically, the complaints allege that Amgen promoted EPOGEN® and Aranesp® for: treating cancer patients who are not on chemotherapy; treating quality of life symptoms associated with anemia, such as fatigue; and reaching hemoglobin targets above the FDA-approved level. Each plaintiff asserts claims under California s consumer protection statutes and for breach of implied warranty and unjust enrichment and plaintiffs seek to represent a nationwide class of individuals and entities.

On October 29, 2007, in the United Food Matter, the Vista Healthplan Matter and the Painters Matter, a motion to dismiss and a motion to transfer each of the three cases were heard before California Central District Court. On November 13, 2007, the United Food Matter was transferred to the U.S. District Court for the Middle District of Pennsylvania, the Vista Healthplan Matter was transferred to the U.S. District Court for the Southern District of Florida and the Painters Matter was transferred to the U.S. District Court for the Northern District of Illinois. On December 4, 2007, the Watters Matter was transferred to the U.S. District Court for the Eastern District of Michigan. On January 25, 2008, the Ironworkers Matter was transferred back to the U.S. District Court for the District of New Jersey (the New Jersey District Court). On February 4, 2008, the California Central District Court heard defendants motion to dismiss and motion to transfer the Sheet Metal Matter back to the U.S. District Court for the Middle District of Pennsylvania.

On January 10, 2008, plaintiffs in the United Food Matter brought a motion before the Judicial Panel on MDL seeking to have the five third-party payer lawsuits consolidated into one MDL case and assigned to the U.S. District Court for the Northern District of Illinois. Defendants filed an opposition to the MDL consolidation motion on February 3, 2008.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On January 11, 2008, the Vista Healthplan Matter was voluntarily dismissed. On April 8, 2008, the Judicial Panel on MDL granted plaintiffs motion in the United Food Matter to centralize the five third-party payer lawsuits into one MDL case for the purpose of consolidated pre-trial proceedings and the five cases were transferred back to the California Central District Court. On December 17, 2008, the Judicial Panel on MDL granted defendants motion to dismiss without prejudice and, on January 30, 2009, plaintiffs filed an Amended Consolidated Class Action Complaint, which is predicated on similar underlying allegations. Amgen filed its motion to dismiss the amended and consolidated MDL complaint on March 6, 2009. On June 17, 2009, the California Central District Court granted Amgen s motion and dismissed the entire action with prejudice.

On July 17, 2009, plaintiffs filed a notice of appeal with the Ninth Circuit. On October 8, 2010, oral argument was heard before the Ninth Circuit and on October 21, 2010, the Ninth Circuit affirmed the California Central District Court s decision dismissing the action with prejudice.

Qui Tam Actions

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 states that the relator in the Massachusetts Qui Tam Action is a former Amgen employee. Further, the filing represents that, in addition to the Massachusetts Qui Tam Action, there are currently nine other actions under the False Claim Act (Qui Tam Actions) 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. While the Massachusetts Qui Tam Action has been partially unsealed, the other nine Qui Tam Actions remain under seal and have not been provided to Amgen. In the filing made public on May 7, 2009, the U.S. government represents that these ten Qui Tam Actions allege that Amgen engaged in a wide variety of illegal marketing practices with respect to various Amgen products and that these are joint civil and criminal investigations being conducted by a wide variety and large number of federal and state agencies.

On September 1, 2009, the U.S. government filed a notice of non-intervention and 14 states and the District of Columbia filed notices of intervention. 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 allege 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 alleges that Amgen retaliated against and wrongfully terminated 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

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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). On June 11, 2010, the Massachusetts District Court held a scheduling conference related to the relator s fourth amended complaint and ordered that a jury trial be set for the running trial list starting on July 5, 2011.

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 October 22, 2010, the states of New York, Massachusetts, Michigan, California, Illinois and Indiana, on behalf of the states of Georgia and New Mexico, and the relator filed opening briefs with the First Circuit. On January 10, 2011, Amgen and co-defendant INN filed response briefs with the First Circuit. Oral argument has been scheduled for April 6, 2011.

Warren General Hospital v. Amgen

On September 25, 2009, Warren General Hospital of Warren, Pennsylvania (on its behalf and all others similarly situated) filed a class action in the New Jersey District Court against Amgen alleging federal antitrust violations under Section 1 of the Sherman Act and Section 3 of the Clayton Act based on Amgen s contracting practices. The complaint seeks damages including treble damages, attorneys fees and costs. Amgen filed a motion to dismiss the complaint on December 9, 2009. Following briefing by the parties, Amgen s motion to dismiss was granted by the New Jersey District Court on June 7, 2010 and plaintiffs filed their notice of appeal to the motion to dismiss on June 14, 2010 with the U.S. Court of Appeals for the Third Circuit (the Third Circuit). Plaintiff filed their opening brief on August 23, 2010 and Amgen s response brief was filed on September 22, 2010. Plaintiff filed its reply brief on October 6, 2010. Oral argument before the Third Circuit was held on January 25, 2011.

Other

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 continues to fully cooperate in responding to the subpoena.

Beginning in October 2007, Amgen has received a number of subpoenas from the U.S. Attorney s Office, Eastern District of New York, 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. The government is allowed to use materials produced in response to a section 3486 administrative subpoena in both criminal and civil investigations. Amgen continues to cooperate with the government s document requests. Additionally, numerous current and former Amgen employees have and continue to receive civil and grand jury subpoenas to provide testimony on a wide variety of subjects.

Beginning in November 2007, Amgen has received a number of subpoenas from the U.S. Attorney s Office, 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. The government is allowed to use materials produced in response to a section 3486 administrative subpoena in both criminal and civil investigations. Amgen continues to cooperate with the government s document requests. Also in 2010, a former Amgen employee was notified by the U.S. Attorney s Office of the Western District of Washington that the former employee was a target of

the investigation. Amgen continues to cooperate with the government s document requests. Additionally, numerous current and former Amgen employees, including some executive vice presidents and other officers of the Company, have and continue to receive grand jury subpoenas to provide testimony on a wide variety of subjects.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 has completed its response per the terms of the subpoena.

Commitments

We lease certain administrative, R&D, sales and marketing and manufacturing facilities and equipment 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, 2010 (in millions):

	2010
2011	$ 140
2012	127
2013	119
2014	101
2015	88
Thereafter	434
Total minimum operating lease commitments	$ 1,009

Included in the table above are future rental commitments for abandoned leases in the amount of $284 million. Rental expense on operating leases for the years ended December 31, 2010, 2009 and 2008 was $115 million, $114 million and $120 million, respectively.

In addition, we have minimum contractual purchase commitments with third party manufacturers through 2012 that total $121 million. Amounts purchased under these contractual purchase commitments for the years ended December 31, 2010, 2009 and 2008 were $68 million, $207 million and $196 million, respectively.

20. 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.

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenues

Revenues for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in millions):

	2010	2009	2008
Product sales:			
Aranesp® U.S.	$ 1,103	$ 1,251	$ 1,651
Aranesp® International	1,383	1,401	1,486
EPOGEN® U.S.	2,524	2,569	2,456
Neulasta® U.S.	2,654	2,527	2,505
NEUPOGEN® U.S.	932	901	896
Neulasta® International	904	828	813
NEUPOGEN® International	354	387	445
ENBREL U.S.	3,304	3,283	3,389
ENBREL Canada	230	210	209
Sensipar® U.S.	459	429	412
Mimpara® International	255	222	185
Vectibix® U.S.	115	97	108
Vectibix® International	173	136	45
Nplate® U.S.	129	78	13
Nplate® International	100	32	4
Prolia® U.S.	26		
Prolia® International	7		
XGEVA™ U.S.	8		
Other U.S.			30
Other International			40
Total product sales	14,660	14,351	14,687
Other revenues	393	291	316
Total revenues	$ 15,053	$ 14,642	$ 15,003

Geographic information

Outside the United States, we principally sell products in Europe and Canada. Information regarding revenues and long-lived assets (consisting of property, plant and equipment) attributable to the United States and to all international countries collectively is stated below. Information regarding long-lived assets for Puerto Rico is also stated below. 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 is as follows (in millions):

	Years ended December 31,		
	2010	2009	2008
Revenues:			
United States	$ 11,636	$ 11,421	$ 11,772
International countries	3,417	3,221	3,231
Total revenues	$ 15,053	$ 14,642	$ 15,003

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	December 31, 2010	2009
Long-lived assets:		
United States	$ 3,248	$ 3,525
Puerto Rico	2,079	1,920
International countries	195	293
Total long-lived assets	$ 5,522	$ 5,738

Major customers

In the United States, we sell primarily to wholesale distributors of pharmaceutical products. We utilize these wholesale distributors as the principal means of distributing our products to healthcare providers, such as physicians or their clinics, dialysis centers, hospitals and pharmacies. In Europe, our products are sold principally to healthcare providers and/or wholesalers depending upon the distribution practice in each country. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits, requiring letters of credit and obtaining credit insurance, as we deem appropriate. We had product sales to three large wholesaler customers each accounting for more than 10% of total revenues for the years ended December 31, 2010, 2009 and 2008. On a combined basis, these distributors accounted for 71% and 88% of worldwide gross revenues and U.S. gross product sales, respectively, for 2010, as noted in the table below. Certain information with respect to these distributors for the years ended December 31, 2010, 2009 and 2008 is as follows (dollar amounts in millions):

	2010	2009	2008
AmerisourceBergen Corporation:			
Gross product sales	$ 7,678	$ 7,179	$ 7,099
% of total gross revenues	38%	37%	37%
% of U.S. gross product sales	47%	46%	46%
McKesson Corporation:			
Gross product sales	$ 3,913	$ 3,694	$ 3,594
% of total gross revenues	19%	19%	19%
% of U.S. gross product sales	24%	24%	23%
Cardinal Health, Inc.:			
Gross product sales	$ 2,813	$ 2,841	$ 2,823
% of total gross revenues	14%	15%	15%
% of U.S. gross product sales	17%	18%	18%

At December 31, 2010 and 2009, amounts due from these three large wholesalers each exceeded 10% of gross trade receivables, and accounted for 54% and 53%, respectively, of net trade receivables on a combined basis. At December 31, 2010 and 2009, 44% and 45%, 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, 2010 and

2009 was not material.

21. Subsequent event

On January 24, 2011, we announced that we had entered into an agreement to acquire BioVex Group, Inc. (BioVex), a privately held biotechnology company developing treatments for cancer and the prevention of infectious disease, including OncoVEX^{GM-CSF}, a novel oncolytic vaccine in phase 3 clinical development for the treatment of melanoma and head and neck cancer. In connection with this acquisition, which will be accounted for as a business combination, we will make an upfront payment of $425 million and will be obligated to pay up to an additional $575 million contingent upon the achievement of certain regulatory and sales milestones with regard

Table of Contents

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

to OncoVEX^{GM-CSF}. Upon its acquisition, BioVex will become a wholly owned subsidiary of Amgen. This acquisition will provide us with an opportunity to expand our development efforts to bring novel therapeutics to market. BioVex will be included in our consolidated financial statements commencing on the acquisition date. The contingent consideration obligations regarding OncoVEX^{GM-CSF} regulatory and sales milestones will be recorded at their fair values on the acquisition date and will be subsequently remeasured to their fair values through earnings each reporting period until the contingencies are resolved. The acquisition, which is subject to customary closing conditions, is expected to close during the three months ended March 31, 2011.

22. Quarterly financial data (unaudited)

	2010 Quarters ended			
(In millions, except per share data)	**December 31[1]**	**September 30[2]**	**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

	2009 Quarters ended			
(In millions, except per share data)	**December 31**	**September 30[3]**	**June 30[4]**	**March 31[5]**
Product sales	$ 3,743	$ 3,736	$ 3,634	$ 3,238
Gross profit from product sales	3,205	3,191	3,103	2,761
Net income	931	1,386	1,269	1,019
Earnings per share:				
Basic	$ 0.93	$ 1.36	$ 1.25	$ 0.99
Diluted	$ 0.92	$ 1.36	$ 1.25	$ 0.98

(1) 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.

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

(3) We recorded $100 million of income tax benefit, net due to the favorable resolution of certain prior years matters with tax authorities, net of a $28 million tax provision associated with certain prior period transfer pricing matters.

(4) We recorded $115 million of income tax benefit as the result of resolving certain transfer pricing issues with the IRS for prior periods.

(5) We recorded $25 million of income tax benefit, net resulting from adjustments to previously established deferred taxes, primarily related to prior acquisitions and stock option expense, due to changes in California tax law effective for future periods.

See Notes 4 and 8 for further discussion of the items described above.

Table of Contents

Schedule

SCHEDULE II

AMGEN INC.

VALUATION ACCOUNTS

Years ended December 31, 2010, 2009 and 2008

(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, 2010	$ 32	$ 10	$	$	$ 42
Year ended December 31, 2009	$ 38	$ (6)	$	$	$ 32
Year ended December 31, 2008	$ 39	$ 1	$	$ 2	$ 38