AMGEN INC
Form 10-K
March 01, 2010
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington D.C. 20549**

# Form 10-K

**(Mark One)**

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

**For the fiscal year ended December 31, 2009**

**OR**

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

**Commission file number 000-12477**

# Amgen Inc.

(Exact name of registrant as specified in its charter)

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

**(805) 447-1000**

(Registrant s telephone number, including area code)

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

**Common stock, $0.0001 par value**

(Title of class)

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

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

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

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

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

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

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company ¨

(Do not check if a smaller reporting company)

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

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $53,667,437,634 as of June 30, 2009(A)

(A) Excludes 1,036,665 shares of common stock held by directors and officers, and any stockholders whose ownership exceeds five percent of the shares outstanding, at June 30, 2009. 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.

**979,301,627**

(Number of shares of common stock outstanding as of February 12, 2010)

**DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of the registrant s Proxy Statement with respect to the 2010 Annual Meeting of stockholders to be held May 12, 2010 are incorporated by reference into Part III of this annual report.

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**PART I**

**Item 1. BUSINESS**

**Overview**

Amgen Inc. (including its subsidiaries, referred to as Amgen, the Company, we, our and us ) is the world s largest independent biotechnolog 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 Amgen has filed electronically with 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, 2009, we had 17,200 staff members worldwide. Approximately 6,600 of our staff members work in our research and development ( R&D ) function; approximately 4,700 work in manufacturing; approximately 3,900 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), erythropoietic-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 93%, 94% and 95% of our sales in 2009, 2008 and 2007, respectively. Our other marketed products include: Sensipar®/Mimpara® (cinacalcet), a small molecule calcimimetic that lowers serum calcium levels; Vectibix® (panitumumab), a fully human 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 to our marketed products, we have products in mid-to-late stage development in various therapeutic areas, including oncology, hematology, inflammation, bone, nephrology and general medicine, which includes cardiology and neurology. Denosumab, our leading late-stage product candidate, is a fully human monoclonal antibody that specifically targets a ligand known as RANKL (that binds to a receptor known as RANK), an essential regulator of osteoclasts (the cells that break down bone) that is under regulatory review and is being studied across a range of conditions. Our R&D organization has expertise in multiple treatment modalities, including large molecules (such as proteins, antibodies and peptibodies) and small molecules.

We maintain sales and marketing forces primarily in the United States, Europe and Canada. 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 is evolving with greater emphasis on cost containment and in demonstrating the economic value of products.

Drug development in our industry is complex, challenging and risky. Product development cycles are very long approximately 10 to 15 years from discovery to market and failure rates are high. A new medicine must undergo many years of preclinical and clinical testing to establish safety and efficacy for use in humans at appropriate dosing levels with an acceptable benefit-risk profile. Biotechnology 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

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generally face substantial competition. Our industry is also highly regulated, and various U.S. and international regulatory bodies have substantial authority over how we develop, manufacture and commercialize our products as well as conduct our business. The regulatory environment is evolving and there is increased scrutiny on drug safety and increased authority being granted to regulatory bodies, in particular the U.S. Food and Drug Administration ( FDA ), to assist in ensuring safety of therapeutic products, which may lead to fewer products being approved by the FDA or other regulatory bodies, delays in receiving approvals or additional safety-related requirements or restrictions on the use of our products, including expanded safety labeling, required risk management activities, including a risk evaluation and mitigation strategy ( REMS ), and/or additional or more extensive clinical trials as part of post-marketing commitments ( PMCs ), post-marketing requirements ( PMRs ) or pharmacovigilance programs.

**Key Developments**

The following is a list of selected key developments that occurred during 2009 and early 2010 affecting our business, including regulatory and reimbursement developments associated with certain of our marketed products and product candidates. A more detailed discussion of each key development follows in the appropriate sections.

*Denosumab*

We received Complete Response Letters from the FDA on our biologics license application ( BLA ) for Prolia in the treatment and prevention of postmenopausal osteoporosis ( PMO ) in women and bone loss in patients undergoing hormone ablation therapy ( HALT ) for either prostate or breast cancer. These Complete Response Letters requested additional information to support approval of the treatment of the PMO indication and the HALT indication, and requested a new clinical program to support approval of the prevention of the PMO indication. (The FDA has provisionally approved the trade name Prolia in the indications noted above, for which the drug is administered twice yearly subcutaneously at a 60 milligram ( mg ) dose. The trade name is only for these indications and may not apply for other indications of denosumab.)

On February 19, 2010, we announced that the FDA has evaluated the content of our Complete Response submission for Prolia in the treatment of PMO, which we submitted on January 25, 2010, and classified it as a Class 2 resubmission. With the Class 2 designation, the FDA set a corresponding Prescription Drug User Fee Act ( PDUFA ) action date of July 25, 2010.

We received a positive opinion from the Committee for Medicinal Products for Human Use ( CHMP ) of the European Medicines Agency ( EMA ) (formerly known as the EMEA) for marketing authorization for the treatment of osteoporosis in postmenopausal women at increased risk of fractures and bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures.

We announced positive results from the following three phase 3 head-to-head trials evaluating denosumab versus Zometa® (zoledronic acid) in the treatment of bone metastases:

- in patients with advanced breast cancer, in which denosumab was superior to Zometa® in delaying the time to the first skeletal-related event ( SRE ) and delaying the time to the first-and-subsequent SREs,
- in advanced cancer patients with solid tumors or multiple myeloma, in which denosumab was non-inferior to Zometa® in delaying the time to the first SRE,
- in men with advanced prostate cancer, in which denosumab was superior to Zometa® in delaying the time to the first SRE and delaying the time to the first-and-subsequent SREs.

These three studies will form the basis of the clinical evidence package for denosumab in advanced cancer, which will be submitted to regulatory authorities later in 2010.

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*ESAs*

On February 16, 2010, we announced that the FDA approved a REMS program for our ESAs.

We published detailed results from the Trial to Reduce Cardiovascular Endpoints with Aranesp® Therapy ( TREAT ) and updated the ESA labels to incorporate certain of the trial results regarding the increased risk of stroke and to reinforce the need to follow the approved label guidance to maintain appropriate hemoglobin ( Hb ) levels.

The FDA announced that it will call an advisory committee meeting in 2010 to re-evaluate the use of ESAs to treat anemia in patients with chronic kidney disease ( CKD ) and could consider lowering targeted Hb levels and reducing approved dosing for ESAs.

The Centers for Medicare & Medicaid Services ( CMS ) has scheduled a Medicare Evidence Development & Coverage Advisory Committee ( MEDCAC ) meeting on March 24, 2010 to examine currently available evidence on the use of ESAs to manage anemia in patients who have CKD, which may consider the results of the TREAT study.

The CMS released its proposed rule to implement the bundled prospective payment system for end stage renal disease ( ESRD ), which could impact reimbursement for EPOGEN®.

*U.S. healthcare reform*

Healthcare reform, focused on expanding healthcare coverage to millions of uninsured Americans and reducing the rate of increase in the costs of healthcare, remains a priority for President Obama, U.S. Congress and a number of states. Developments in this area have been highly dynamic and difficult to predict. As recently as February 23, 2010, President Obama released a new proposal for healthcare reform which includes a combination of provisions from both the Senate and House of Representatives bills passed in late 2009. Certain healthcare reform proposals being considered, which may or may not be adopted into law, could:

- restrict the coverage and reimbursement of our products by Medicare, Medicaid and other government programs;
- reduce the number of years of data exclusivity for innovative biological products potentially leading to earlier biosimilar competition; and/or
- require additional healthcare reform costs be borne by pharmaceutical and biotechnology companies.

At this time, we cannot predict which or whether any reform measures will be adopted into law.

*Other pipeline developments*

We announced detailed results from two key phase 3 trials evaluating Vectibix® as a first- and second-line treatment in patients with *KRAS* wild-type metastatic colorectal cancer ( mCRC ).

We announced plans to initiate a phase 3 trial for AMG 386 in ovarian cancer.

**Marketed Products and Selected Product Candidates**

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

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patents, or a reduction in the price we receive from selling our products. For example, we are facing increasing competition from biosimilars in the European Union ( EU ), which has an established regulatory pathway for biosimilars. In addition, lawmakers in the United States have proposed bills to create a regulatory pathway for the abbreviated approval of biosimilars and several companies have recently announced plans to pursue development of biosimilars in the United States. Further, the development of new treatment options or standards of care may require less use of our products, particularly in supportive cancer care, or limit the utility and application of ongoing clinical trials for our product candidates.

In addition to challenges presented by competition, our existing products and product candidates are also subject to increasing regulatory compliance requirements which can be imposed as a condition of approval or after a product has been approved. This is increasingly true of new therapies with novel mechanisms of action. While these therapies may offer important benefits and/or better treatment alternatives, they may also involve a relatively new or higher level of scientific complexity and, therefore, generate increased safety concerns. For example, as a condition of approval or due to safety concerns after the product has been approved, we may be required to perform additional clinical trials or studies, such as observational epidemiological studies. Such trials or studies are called PMCs or PMRs. We currently have PMCs or PMRs for some of our marketed products. In addition, we may be required to implement a REMS for a product to ensure that the benefits of the drug outweigh the risks. This requirement, too, may 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 other elements the FDA deems are necessary to assure safe use of the product. While the elements of a REMS may vary, all REMS are required to have a timetable for assessments.

*ESAs*

Aranesp® is our registered trademark for one of our ESAs, a protein that stimulates 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 where insufficient oxygen is delivered to the body s organs and tissues. Anemia can be associated with chronic renal failure ( CRF ), both in patients on dialysis and not on dialysis. Anemia can also result from chemotherapy treatments for patients with non-myeloid malignancies.

EPOGEN® is our other ESA and is our registered trademark for our recombinant human erythropoietin product, a protein that stimulates red blood cell production. A reduced red blood cell count can result in anemia (see *Aranesp® (darbepoetin alfa)* ). Individuals with CRF suffer from anemia because they do not produce sufficient amounts of erythropoietin, which is normally produced in healthy kidneys.

Our ESA products have and will continue to face challenges. For example, based on adverse safety results observed beginning in late 2006 in various ESA studies, performed by us and others, that explored the use of ESAs in settings different from those outlined in the FDA approved label, the product labeling of our ESA products has been updated several times to reflect these safety concerns in the United States and the EU, including, most recently, label updates in the United States in August 2008 and in December 2009 to reflect certain results of our TREAT study, as discussed below. 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.

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

On February 16, 2010, Amgen and Centocor Ortho Biotech Products, L.P. ( Centocor Ortho Biotech Products ), a subsidiary of Johnson & Johnson ( J&J ), announced that the FDA approved a REMS for ESAs which includes Aranesp®, EPOGEN® and Procrit® (Epoetin alfa). The FDA has determined that a REMS is necessary for ESAs to ensure the benefits of these drugs outweigh the risks of shortened overall survival ( OS ) and/or increased tumor progression or recurrence as identified in clinical studies in

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patients with breast, non-small cell lung, head and neck, lymphoid and cervical cancers. As part of the REMS, a medication guide explaining the risks and benefits of ESAs must be provided to all patients receiving ESAs. To ensure continued access to ESAs for healthcare providers who prescribe, or prescribe and dispense, ESAs to patients with cancer, providers are required to train and enroll in the ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs) Oncology Program and 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. The ESA APPRISE Oncology Program will be launched on March 24, 2010. Direct patient registration or approval prior to ESA administration is not required through the ESA APPRISE Oncology Program.

On December 16, 2009, after consultation with the FDA, Amgen and Centocor Ortho Biotech Products updated the safety information in the ESA product labeling to reflect certain results of our TREAT study. These changes include a revision to the BOXED WARNINGS section to include the increased risk of stroke and to reinforce the need to follow the approved label guidance to maintain Hb levels within the range of 10 to 12 grams per deciliter ( g/dL ). (See discussion of Aranesp® TREAT study results in *Research and Development and Selected Product Candidates.* )

The FDA has announced that it will call an advisory committee meeting in 2010 to re-evaluate the use of ESAs to treat anemia in patients with CKD and could consider lowering targeted Hb levels and reducing approved dosing for ESAs.

The CMS has scheduled a MEDCAC meeting for March 24, 2010 to examine currently available evidence on the use of ESAs to manage anemia in patients who have CKD, which may consider the results of the TREAT study. In February 2010, the CMS released the voting questions the MEDCAC will address, including whether the available evidence in both CKD not on dialysis and ESRD clearly (i) demonstrates benefits and risks of ESA therapy, (ii) supports a baseline Hb range or (iii) justifies a dose response or maximum dose. The CMS will decide whether more evidence is needed to determine whether ESA treatment is reasonable and necessary to support continued Medicare coverage. (See *Reimbursement.* )

On September 15, 2009, the CMS released its proposed rule to implement a bundled prospective payment system for ESRD, which becomes effective in 2011 and could impact EPOGEN®. (See *Reimbursement.* )

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 may evaluate 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 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. These studies were subsequently designated by the FDA as PMCs. Of the five studies, one was sponsored by Amgen while the remaining four were investigator-sponsored. Results of certain of these 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 while final results of the other two are expected in 2010 or 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. In addition, J&JPRD s EPO-ANE-3010 study in breast cancer is ongoing and is designated as a FDA PMC.

Based on our ongoing 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 these discussions, we have initiated a randomized, double-blind, placebo-controlled, phase 3

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non-inferiority study evaluating OS when comparing advanced non-small cell lung cancer ( NSCLC ) patients on Aranesp® to patients receiving placebo ( Study 782 ) as part of our Aranesp® pharmacovigilance program. 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 initially 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, 2009, 2008 and 2007 were $2.65 billion, $3.14 billion and $3.61 billion, respectively. For the years ended December 31, 2009, 2008 and 2007, U.S. Aranesp® sales were $1.25 billion, $1.65 billion and $2.15 billion, respectively and international Aranesp® sales were $1.40 billion, $1.49 billion and $1.46 billion, respectively.

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

| Territory | General Subject Matter | Expiration |
|---|---|---|
| U.S. | Glycosylation analogs of erythropoietin proteins | 5/15/2024 |
| Europe[(1)] | Glycosylation analogs of erythropoietin proteins | 10/12/2010 |
| Europe[(1)] | Glycosylation analogs of erythropoietin proteins | 8/16/2014 |

(1) In some cases, these European patents 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 on December 12, 2004. Although we do not market EPOGEN® in Europe, upon expiration of this patent, some companies have received approval to market biosimilars or other products that compete with Aranesp® in Europe, presenting additional competition, as further discussed below.

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Any products or technologies that are directly or indirectly successful in addressing anemia associated with chemotherapy and renal failure could negatively impact product sales of Aranesp® . 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 discussion below of competitor marketed products and potential products may not be exhaustive.

| Territory | Competitor Marketed Product | Competitor |
|---|---|---|
| U.S. | PROCRIT®(1) | Centocor Ortho Biotech Products(2) |
| Europe | EPREX®/ERYPO® | Janssen-Cilag(2) |
| Europe | NeoRecormon® | F. Hoffmann-La Roche Ltd. ( Roche ) |
| Europe | Retacrit (3)/Silapo®(3) | Hospira Enterprises B.V. ( 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 | Biopoin® | CT Arztneimittel GmbH ( CT Arztneimittel ) |

(1) In the United States, Aranesp® competes with PROCRIT® in the supportive cancer care and pre-dialysis settings.
(2) A subsidiary of J&J.
(3) Biosimilar product approved and launched in certain EU countries.
(4) Competes with Aranesp® in the nephrology segment only.

In the United States, Aranesp® also competes with EPOGEN®, primarily in the U.S. hospital dialysis clinic setting. In addition to competition from the above-noted marketed products, the following product candidates could compete with Aranesp® in the future. Affymax Inc. and Takeda Pharmaceutical Company Limited ( Takeda ) are co-developing Hematide an ESA for the treatment of anemia in renal patients and they have announced plans to file for regulatory approval in 2010. FibroGen Inc. is developing FG-2216 and FG-4592, orally active ESAs, for the treatment of anemia and is also studying FG-4592 for the treatment in anemia of CKD. Additionally, in December 2008, Merck & Company, Inc. ( Merck ) announced the formation of a new biotech division, Merck Bioventures, which is developing a late-stage pegylated ESA (MK-2578), which they have announced they expect to launch in 2012.

*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 Ortho Biotech Products), a license to commercialize recombinant human erythropoietin as a human therapeutic in the United States in all markets 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 for 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, 2009, 2008 and 2007 were $2.6 billion, $2.5 billion and $2.5 billion, respectively.

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Our outstanding material patents for Epoetin alfa are described in the table below.

| 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 |

Amgen and Roche reached a settlement of litigation in December 2009, and on December 22, 2009, the U.S. District Court for the District of Massachusetts entered final judgment and a permanent injunction against Roche prohibiting Roche from infringing our patents. The judgment was accompanied by Roche s admission that our five patents involved in the lawsuit are valid, enforceable and infringed by Roche s Peg-EPO, and by us allowing Roche to begin selling Peg-EPO in the United States in mid-2014 under terms of a limited license agreement. Peg-EPO has been approved by the FDA for the treatment of anemia associated with CKD.

Any products or technologies that are directly or indirectly successful in addressing anemia associated with CRF could negatively impact product sales of EPOGEN®. 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 in the United States from those product candidates noted in the Aranesp® section above that may be used in dialysis.

*Neulasta® (pegfilgrastim)/NEUPOGEN® (Filgrastim)*

Neulasta® is our registered trademark for a pegylated protein, based on the Filgrastim molecule, that selectively stimulates production of certain white blood cells known as neutrophils. Neutrophils defend against infection. NEUPOGEN® is our registered trademark for our recombinant-methionyl human G-CSF, a protein that selectively stimulates production of neutrophils. 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 effects of cytotoxic chemotherapy, resulting in neutropenia with an increased risk of severe infection. Very often, neutropenia is the dose limiting side effect of chemotherapy and can thus be responsible for a reduction in the amount of chemotherapy that can be administered safely. Such reductions in chemotherapy dose can compromise the effectiveness of chemotherapy on the cancer it is being used to treat, with the result of a higher treatment failure rate. As mentioned above, the pegfilgrastim molecule is 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 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* ).

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 initially launched in the United States and Europe in 2002 and is indicated for reducing the incidence of infection associated with chemotherapy-induced 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 at least a 17% risk of febrile neutropenia. NEUPOGEN® was initially launched in the United States and Europe in 1991. NEUPOGEN® is indicated for reducing the incidence of infection as manifested by febrile neutropenia for

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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® sales for the years ended December 31, 2009, 2008 and 2007 were $3.4 billion, $3.3 billion and $3.0 billion, respectively. Worldwide NEUPOGEN® sales for each of the three years ended December 31, 2009 were $1.3 billion.

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

| 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 table below.

| 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 on August 22, 2006. Upon expiration of this patent, some companies have received approval to market biosimilar products that compete with Neulasta® and NEUPOGEN® in Europe, presenting additional competition, as further discussed below.

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

The following table reflects companies and their currently marketed products that primarily compete with Neulasta® and NEUPOGEN® in the United States and Europe in the supportive cancer care setting. The table and discussion below of competitor marketed products and potential competitor products 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) | Ratiopharm GmbH |
| Europe | Biograstim®(1) | CT Arztneimittel |
| Europe | Tevagrastim®(1) | Teva Pharmaceutical Industries Ltd. ( Teva Pharmaceutical ) |
| Europe | Zarzio®(1)/Filgrastim Hexal®(1) | Sandoz/Hexal |

(1) Biosimilar product approved and launched in certain EU countries.

In February 2010, Teva Pharmaceutical announced that the FDA has accepted for review its BLA seeking U.S. approval to market XM02 to boost white blood cells under the brand name Neutroval. XM02 is already

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being sold under the brand name Tevagrastim® in several European countries. If approved in the United States, this drug could 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 Teva Pharmaceutical s XM02 and on January 15, 2010, we filed an answer and counterclaims seeking a declaratory judgment that our patents are valid and infringed. (See Note 20, *Contingencies and commitments* to the Consolidated Financial Statements.) In addition, in September 2009, Hospira announced it acquired worldwide rights to a biogeneric version of Filgrastim from Teva Pharmaceutical. If approved in Europe, this drug could compete with NEUPOGEN® and Neulasta®.

*Enbrel® (etanercept)*

ENBREL is our registered trademark for 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 ).

We market ENBREL under a co-promotion agreement with Pfizer Inc. ( Pfizer ) in the United States and Canada (see *Business Relationships Pfizer Inc.* ). The rights to market and sell ENBREL outside of the United States and Canada are reserved to Pfizer. ENBREL was initially launched in November 1998 by Immunex 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.

ENBREL sales for the years ended December 31, 2009, 2008 and 2007 were $3.5 billion, $3.6 billion and $3.2 billion, respectively.

Our outstanding material patent for etanercept is described in the table below.

| Territory | General Subject Matter | Expiration |
|---|---|---|
| U.S. | TNFR DNA vectors, cells and processes for making proteins | 10/23/2012 |

Any products or technologies that are directly or indirectly successful in treating rheumatology, which includes moderate to severe RA, moderate to severe polyarticular juvenile idiopathic arthritis, ankylosing spondylitis and psoriatic arthritis; and dermatology, which includes moderate to severe plaque psoriasis, could negatively impact product sales of ENBREL. Current treatments for these indications include generic methotrexate and other products, as further discussed below.

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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 discussion below of competitor marketed products and potential competitor products may not be exhaustive.

| Territory | Therapeutic Area | Competitor Marketed Product | Competitor |
|---|---|---|---|
| U.S. & Canada | Rheumatology & Dermatology | REMICADE® | Centocor Ortho Biotech Inc. ( Centocor Ortho Biotech [1])/Merck |
| U.S. & Canada | Rheumatology & Dermatology | HUMIRA® | Abbott Laboratories ( Abbott ) |
| U.S. & Canada | Rheumatology & Dermatology | Trexall | Duramed Pharmaceuticals, Inc.[2] |
| U.S. & Canada | Rheumatology & Dermatology | Simponi® | Centocor Ortho Biotech[1] |
| U.S. & Canada | Rheumatology | Cimzia® | UCB/ Nektar Therapeutics |
| U.S. & Canada | Rheumatology | Orencia® | Bristol-Myers Squibb Corporation ( BMS ) |
| U.S. & Canada | Rheumatology | Arava® | Sanofi-Aventis |
| U.S. & Canada | Rheumatology | Rheumatrex® | DAVA Pharmaceuticals, Inc. |
| U.S. & Canada | Rheumatology | Rituxan® | Roche |
| U.S. | Rheumatology | Actemra® | Roche |
| U.S. & Canada | Dermatology | Stelara® | Centocor Ortho Biotech[1] |
| U.S. & Canada | Dermatology | Amevive® | Biogen IDEC Inc. |

(1) A subsidiary of J&J.
(2) A subsidiary of Teva Pharmaceutical.

In addition to competition from the above-noted marketed products, various companies are developing products which may compete with ENBREL in the future, including Abbott, which is developing ABT-874 in phase 3 trials for the treatment of psoriasis. Abbott has announced that they are planning to submit this indication for regulatory approval in 2010. In addition, a number of companies have JAK kinase inhibitors in development for RA, including Pfizer and Incyte Corporation.

*Other*

Our other marketed products are principally comprised of Sensipar® (cinacalcet), Vectibix® (panitumumab) and Nplate® (romiplostim).

*Sensipar® (cinacalcet)*

Sensipar® is our registered trademark in the United States and Mimpara® is our registered trademark in Europe for our first 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 (through an extension of the marketing authorization for Mimpara®) for the reduction of hypercalcemia in patients with primary hyperparathyroidism where a parathyroidectomy is not clinically appropriate or is contraindicated. We market Sensipar®/Mimpara® primarily in the United States and Europe.

Worldwide Sensipar® sales for the years ended December 31, 2009, 2008 and 2007 were $651 million, $597 million and $463 million, respectively.

On September 15, 2009, the CMS released its proposed rule to implement a bundled prospective payment system for ESRD. The proposed rule also includes in the bundled payment oral drugs that are not equivalent to separately billable Part B drugs, which could impact reimbursement for Sensipar®. (See *Reimbursement.* )

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

| Territory | General Subject Matter | Expiration |
|---|---|---|
| U.S.[1] | Calcium receptor-active molecules | 10/23/2015 |
| U.S.[1] | Calcium receptor-active molecules | 12/14/2016 |
| U.S.[1] | Methods of treatment | 12/14/2016 |
| Europe[2] | Calcium receptor-active molecules | 10/23/2015 |

(1) An application for patent term extension has been submitted and is currently pending in the United States.

(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 could negatively impact product sales of Sensipar®/Mimpara®.

The following table reflects companies and their currently marketed products that primarily compete with Sensipar® in the United States and Mimpara® in Europe in the nephrology segment for patients with CKD on dialysis. The table and discussion below of competitor marketed products and potential competitor products 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 Inc |
| U.S. & Europe | Zemplar® | Abbott |
| U.S. & Europe | Renagel® | Genzyme |
| U.S. & Europe | Renvela® | Genzyme |
| U.S. & Europe | PhosLo®/Rephoren® | Fresenius Medical Care AG & Co. KGaA ( Fresenius Medical Care ) |
| U.S. & Europe | OsvaRen® | Fresenius Medical Care |
| U.S. & Europe | Fosrenol® | Shire Pharmaceuticals Group Plc |

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 is based on the Abbreviated New Drug Application filed by Teva and Barr which seeks approval to market generic versions of Sensipar®. (See Note 20, *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 our first fully human 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® is a fully human monoclonal antibody that binds with high affinity to EGFrs and interferes with signals that might otherwise stimulate growth and survival of the cancer cell. The goal of developing fully human monoclonal antibodies is to offer effective targeted therapies with lessened risk of immune response against these agents. We acquired full ownership of Vectibix® with our acquisition of Abgenix, Inc. ( Abgenix ) in April 2006 and Vectibix® received FDA approval in September 2006. 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* after failure of standard chemotherapy regimens was received in December 2007 and is reviewed annually by the CHMP. In December 2008 and 2009, the conditional marketing authorization was renewed with an additional specific obligation to conduct a clinical trial in the existing approved indication. In 2009, the CHMP approved the protocol for this additional

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clinical trial which will compare the effect of Vectibix® versus Erbitux® (cetuximab) on OS for chemorefractory mCRC patients with wild-type *KRAS* tumors.

Worldwide Vectibix® sales for the years ended December 31, 2009, 2008 and 2007 were $233 million, $153 million and $170 million, respectively.

In July 2009, we announced that the FDA approved certain revisions to the U.S. prescribing information ( PI ) for the EGFr class of antibodies, including Vectibix®. The INDICATIONS AND USAGE section of the PI has been updated to include that retrospective subset analyses of mCRC trials have not shown a treatment benefit for Vectibix® in patients whose tumors had *KRAS* mutations in codon 12 or 13 and that use of Vectibix® is not recommended for the treatment of colorectal cancer with these mutations. The CLINICAL STUDIES section of the PI has been updated to reflect results from retrospective analyses across seven randomized clinical trials with agents in this class. This includes the first phase 3 analysis that showed mCRC patients with mutated *KRAS* tumors do not respond to monotherapy with an EGFr-inhibiting antibody (the Vectibix® 408 trial). This decision follows the FDA s December 2008 ODAC meeting where the clinical utility of the *KRAS* gene as a predictive biomarker in patients with mCRC treated with anti-EGFr antibody was discussed.

In 2009, we announced that the primary endpoint of extending progression-free survival ( PFS ) was met in the phase 3 clinical trial evaluating Vectibix® in combination with FOLFOX as a first-line treatment in patients with *KRAS* wild-type mCRC, while the secondary endpoint of OS was not met. In patients with mutated *KRAS*, PFS was significantly inferior for patients who received Vectibix® as compared to patients that did not receive Vectibix®. We also announced in 2009 that the co-primary endpoint of extending PFS was met in the phase 3 clinical trial evaluating Vectibix® in combination with FOLFIRI as compared to patients who received FOLFIRI alone as a second line treatment in patients with *KRAS* wild-type mCRC, while the co-primary endpoint of OS was not met. In patients with mutated *KRAS*, no difference was seen in PFS for patients who received Vectibix® as compared to patients that did not receive Vectibix®. For more information, see *Research and Development and Selected Product Candidates.* Based on the results of these studies, we are planning to file for regulatory approval in the United States and EU for first- and second- line treatment in patients with *KRAS* wild-type mCRC.

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

| Territory | General Subject Matter | Expiration |
|---|---|---|
| U.S. | Human monoclonal antibodies EGFr | 4/8/2020 |
| Europe | Human monoclonal antibodies EGFr | 12/4/2022 |

Any products or technologies that are directly or indirectly successful in treating mCRC after disease progression on, or following fluoropyrimidine-, oxaliplatin- and irinotecan- containing chemotherapy regimens could negatively impact product sales for Vectibix®. The following table reflects companies and their currently marketed products that primarily compete with Vectibix® in the United States and Europe. The table below of competitor marketed products 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®, the first platelet producer for the treatment of thrombocytopenia in splenectomized (spleen removed) and non-splenectomized adults with chronic immune thrombocytopenic purpura ( ITP ). Nplate®, the first FDA approved peptibody protein, 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 European Commission granted marketing authorization for Nplate® for the treatment of splenectomized adult chronic ITP patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). In the EU, Nplate® may

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also be considered as second-line treatment for adult non-splenectomized ITP patients where surgery is contraindicated.

Worldwide Nplate® sales for the years ended December 31, 2009 and 2008 were $110 million and $17 million, respectively.

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

| Territory | General Subject Matter | Expiration |
|---|---|---|
| U.S.[1] | Thrombopoietic compounds | 10/22/2019 |
| Europe[2] | Thrombopoietic compounds | 10/22/2019 |

(1) An application for patent term extension has been submitted and is currently pending in the United States.

(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.

We currently have an approved REMS for Nplate®, which includes a medication guide, a healthcare provider communication plan and certain elements to ensure safe use (including restricted distribution, registry and healthcare provider and patient enrollment).

Promacta®, GlaxoSmithKline plc s ( GSK ) registered trademark in the United States, is indicated for the treatment of thrombocytopenia in patients with chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy, and competes with Nplate®. In December 2009, Revolade® , GSK s proposed registered trademark in Europe, received a positive opinion from the CHMP for marketing authorization for the treatment of adult chronic ITP splenectomized patients who are refractory to other treatments, and may compete with Nplate® in the EU, if approved by the European Commission.

*Product candidates*

We are currently studying new product candidates, including denosumab, and currently marketed products for new indications, which, if approved, we expect will enter into highly competitive markets. If successful, these product candidates will face substantial competition from products currently marketed as well as those under development by other biotechnology and pharmaceutical companies.

*Denosumab Developments*

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 an essential regulator of osteoclasts. Denosumab is under regulatory review and is being studied across a range of conditions, including osteoporosis, treatment-induced bone loss, bone metastases, multiple myeloma and RA.

The following is a summary of certain key developments that occurred in 2009 and early 2010 with respect to denosumab:

*Prolia (denosumab) for the Prevention and Treatment of PMO and the Prevention and Treatment of Bone Loss in Patients Undergoing HALT for either Prostate Cancer or Breast Cancer*

In late 2008, we submitted the BLA to the FDA for Prolia in the treatment and prevention of PMO in women and bone loss in patients undergoing HALT for either prostate or breast cancer.

On August 13, 2009, we announced the results of our meeting with the FDA s Advisory Committee for Reproductive Health Drugs ( ACRHD ) to review the potential use of Prolia for the treatment and prevention of PMO in women and the treatment and prevention of bone loss in patients undergoing HALT for either prostate cancer or breast cancer. The Committee recommended approval of Prolia for the treatment of PMO and for the treatment of bone loss in patients undergoing HALT for prostate cancer. The Committee recommended against approval of Prolia to treat or prevent bone loss in women with breast cancer undergoing HALT until additional data are available. The Committee also recommended against approval of Prolia to prevent bone loss in

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low-risk patients in all three populations. Finally, the Committee recommended that Prolia have a REMS. The ACRHD is an advisory committee of external experts who advise the FDA about the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology and related specialties. This committee is advisory only and FDA officials are not bound to or limited by their recommendations.

In October 2009, the FDA issued Complete Response Letters for our BLA for Prolia for the above-noted indications. The FDA issues Complete Response Letters to request additional information needed to complete the review of applications for product approval.

The Complete Response Letter related to the Prolia application for the treatment and prevention of PMO in women requested several items, including further information on the design and background adverse event rates that will inform the methodology of our previously submitted post-marketing surveillance program, although the letter did not require additional pre-marketing clinical trials to complete the review of the treatment indication. The FDA has also requested a new clinical program to support approval of Prolia for the prevention of PMO indication. In addition, the FDA has determined that a REMS is necessary for Prolia and must include a medication guide and a healthcare provider communication plan. The FDA acknowledged receipt of our previously submitted proposed REMS materials. The FDA also requested all updated safety data related to Prolia. On February 19, 2010, we announced that the FDA has evaluated the content of our Complete Response submission for Prolia in the treatment of PMO, which we submitted on January 25, 2010, and classified it as a Class 2 resubmission. With the Class 2 designation, the FDA set a corresponding PDUFA action date of July 25, 2010.

The Complete Response Letter related to the Prolia HALT application 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 ( ADT ). Specifically, the FDA has requested results from additional adequate and well-controlled clinical trials demonstrating that Prolia has no detrimental effects on either time-to-disease progression or OS. We continue to work with the FDA to determine the appropriate next steps regarding our application for the HALT indication.

*Prolia Received Positive Opinion from CHMP in the EU*

In December 2009, the CHMP announced a positive opinion for the marketing authorization of 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. If approved by the European Commission, we would receive marketing authorization for Prolia in all EU Member States. The timing of actual launch dates would vary by country based on reimbursement authority approval of pricing which could follow the EMA approval by many months. While the European Commission generally follows the CHMP s opinion, it is not bound to do so.

Prolia is also under regulatory review in Switzerland, Australia and Canada for the treatment and prevention of PMO and the treatment of bone loss in patients undergoing HALT for breast and prostate cancer. We are working closely with regulatory agencies in each of these countries.

*Denosumab Phase 3 Bone Metastases Clinical Trials*

In 2009, we announced that the phase 3 head-to-head trial evaluating denosumab versus Zometa® in the treatment of bone metastases in patients with advanced breast cancer met its primary endpoint of non-inferiority in time to first SRE and its secondary endpoints (superiority compared to Zometa® for both delaying the time to the first on-study SRE and delaying the time to the first-and-subsequent SREs). We also announced that the phase 3 head-to-head trial evaluating denosumab versus Zometa® in the treatment of bone metastases in advanced cancer patients with solid tumors (not including breast and prostate cancer) or multiple myeloma met its primary endpoint of non-inferiority in time to first SRE. On February 8, 2010, we announced that the phase 3 head-to-head trial evaluating denosumab versus Zometa® in the treatment of bone metastases in advanced cancer patients with prostate cancer met its primary endpoint of non-inferiority in time to first SRE and its secondary endpoints (superiority compared to Zometa® for both delaying the time to the first on-study SRE and delaying

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the time to the first-and-subsequent SREs). These three studies will form the basis of the clinical evidence package for denosumab in advanced cancer, which will be submitted to regulatory authorities later in 2010. For more information, see *Research and Development and Selected Product Candidates*.

*Patents and Competition*

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

| Territory | General Subject Matter | Expiration[1] |
|---|---|---|
| U.S. | RANKL antibodies | 12/22/2017 |
| U.S. | Methods of treatment | 11/11/2018 |
| U.S. | RANKL antibodies | 11/28/2023 |
| Europe | RANKL antibodies | 12/22/2017 |
| Europe | Methods of treatment | 4/15/2018 |
| Europe | RANKL antibodies | 2/23/2021 |

(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.

The following table and discussion reflect other companies and their currently marketed products that will compete with denosumab, if approved. This table and discussion of competitor marketed products and potential competitor products may not be exhaustive. 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 ( ALN ) became available from Teva and other companies, which competes with FOSAMAX®

| Therapeutic Area | Competitor Marketed Product | Potential Competitor |
|---|---|---|
| PMO | FOSAMAX® | Merck |
| PMO | Actonel® | Warner Chilcott/Aventis |
| PMO | Boniva®/Bonviva® | Roche/GSK |
| PMO | Evista® | Eli Lilly |
| PMO | Forteo®/Forsteo | Eli Lilly |
| PMO | Miacalcin® | Novartis AG ( Novartis ) |
| PMO | Aclasta®/Reclast® | Novartis |
| PMO | Conbriza® | Pfizer |
| PMO | Fablyn® | Pfizer |
| Oncology | Zometa® | Novartis |
| Oncology | Aredia® | Novartis |

**Marketing and Distribution**

We maintain sales and marketing forces primarily in the United States, Europe and Canada to support our currently marketed products and in preparation of the launch of Prolia. 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.

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. In early 2008, ENBREL s distribution model was converted from primarily being shipped directly to pharmacies to a wholesale distribution model similar to our other products. In Europe, Aranesp®, Neulasta® and NEUPOGEN® are principally sold 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.

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We had product sales to three large wholesaler customers each accounting for more than 10% of total revenues for the years ended December 31, 2009, 2008 and 2007. On a combined basis, these distributors accounted for 71% and 88% of worldwide gross revenues and U.S. gross product sales, respectively, for 2009, as noted in the following table (dollar amounts in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| AmerisourceBergen Corporation: | | | |
| Gross product sales | $ 7,179 | $ 7,099 | $ 6,124 |
| % of total gross revenues | 37% | 37% | 31% |
| % of U.S. gross product sales | 46% | 46% | 39% |
| McKesson Corporation: | | | |
| Gross product sales | $ 3,694 | $ 3,594 | $ 2,398 |
| % of total gross revenues | 19% | 19% | 12% |
| % of U.S. gross product sales | 24% | 23% | 15% |
| Cardinal Health, Inc.: | | | |
| Gross product sales | $ 2,841 | $ 2,823 | $ 2,715 |
| % of total gross revenues | 15% | 15% | 14% |
| % of U.S. gross product sales | 18% | 18% | 17% |

We have entered into certain co-promotion agreements to market our products in certain geographic areas. These agreements generally require us to share profits on product sales. Under a co-promotion agreement, we and Pfizer market ENBREL in the United States and Canada for all approved indications. Under a co-promotion agreement with GSK, we and GSK will commercialize Amgen s Prolia in Europe, Australia, New Zealand and Mexico, and GSK will commercialize denosumab, for all indications in countries where we do not currently have a commercial presence (see *Business Relationships GlaxoSmithKline plc* ). Additionally, we have entered into agreements with third-parties to market certain of our products, including Aranesp®, Neulasta® and NEUPOGEN® in certain geographic areas outside of the United States and to assist in marketing ENBREL in the United States. In addition, we have granted J&J a license to commercialize recombinant human erythropoietin as a human therapeutic in the United States in all markets other than dialysis (see *Business Relationships Johnson & Johnson* ). We have also granted Daiichi Sankyo Company, Limited ( Daiichi Sankyo ) a license to develop and commercialize denosumab in Japan in PMO, oncology and certain other indications (see *Business Relationships Daiichi Sankyo Company, Limited* ).

See *Government Regulation FDA Regulation of Product Marketing and Promotion* for a discussion of the government regulation over product marketing and promotion.

**Reimbursement**

Sales of all of our principal products are dependent, in 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, we believe that ongoing healthcare reform efforts will include long-term changes to the coverage and reimbursement of our products which may have a significant impact on our business.

*U.S. Reimbursement System*

Our principal products are predominantly sold in the United States and healthcare providers, including doctors, hospitals and other healthcare professionals and providers are reimbursed for their services by the

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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 from 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 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 national coverage decisions ( NCD ) as well as manual policy issuances and updates and codes for drugs and other items. Local Medicare contractors have authority to issue Local Coverage Determinations. Generally, a NCD issued by CMS is a national policy statement granting, limiting or excluding Medicare coverage for a specific medical item or service.

*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 only if they satisfy certain criteria, including that they are of the type that is not usually self-administered by the patient and they are reasonable and necessary for a medically accepted diagnosis or treatment. Medicare Part B also covers some 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, including EPOGEN®Aranesp®, Neulasta® and NEUPOGEN®, 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.

*Medicare Part D.* Medicare Part D provides a voluntary prescription drug benefit for Medicare eligible beneficiaries. This 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 Part D plans have at least two drugs in each unique therapeutic category, 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 these 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 our products covered and reimbursed by state Medicaid programs. (See *Government Regulation* and *Item 1A. Risk Factors Our sales depend on coverage and reimbursement from third-party payers.* )

*Private Health Insurance*

*Employer-sponsored insurance.* Employer-sponsored insurance represents the main pathway by which Americans receive private health insurance. Many employers provide health insurance as part of the benefits package for employees. 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.

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*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 employer. In contrast to the employer-sponsored insurance, the individual market allows health insurance companies to deny people coverage based on pre-existing conditions although a newly enacted law prohibits denial of coverage based on genetic discrimination. The plans are administered by private insurance companies. Individuals pay an out-of-pocket insurance premium for coverage and benefits vary widely according to plan specifications.

*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 Aranesp®, Neulasta® and NEUPOGEN®, under Part B, when administered in the physician clinic setting and the hospital outpatient and dialysis settings and 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. 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, dialysis facility or hospital outpatient setting. 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 January 1, 2005, in the physician office setting under Part B, our products have been reimbursed at 106% of its ASP (sometimes referred to as ASP+6% ). As of January 1, 2009, Medicare payment in the hospital outpatient setting reimbursed each product ASP+4% which is lower than the payment rate was in 2008 (ASP+5%) or from 2006-2007 (ASP+6%). In 2010, the payment methodologies in both the hospital outpatient and physician office settings are at the same levels from 2009 (ASP+6% in the physician office setting and ASP+4% in the hospital outpatient setting), pursuant to the 2010 Medicare Physician Fee Schedule Final Rule and the 2010 Hospital Outpatient Prospective Payment Final Rule. CMS has the regulatory authority to further adjust the outpatient hospital payment formula in future years. The extent to which commercial payers adopt the use of ASP as a payment methodology is still evolving and is often based on the relationship between the provider and the insurer.

*Dialysis Reimbursement.* Currently, dialysis providers in the United States are primarily reimbursed for EPOGEN® by Medicare through the ESRD Program. 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. The ESRD Program reimbursement methodology is established by federal law and is implemented by CMS. Medicare reimburses for separately billable dialysis drugs administered in both freestanding and hospital-based dialysis centers, including EPOGEN® and Aranesp®, at ASP+6%, using the same payment amount methodology used in the physician clinic setting under Part B. On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 (the MIPPA ) became law and contained a number of Medicare and Medicaid reforms, including a broader payment bundle for dialysis services and drugs which will require CMS, beginning in 2011, to establish a bundled Medicare payment rate that includes dialysis services and drug/labs that are currently separately billed. On September 15, 2009, CMS released its proposed rule to implement the bundled prospective payment system for ESRD. Under the proposed rule, the bundled payment system will include dialysis services covered under the current composite rate, as well as drugs and biologicals furnished for treatment of ESRD that are currently billed separately, including ESAs, intravenous iron and intravenous vitamin D, as well as oral equivalent forms of these intravenous drugs. In addition, the proposed rule also includes in the bundled payment oral drugs that are not equivalent to separately billable Part B drugs, specifically Sensipar® and phosphate binders. The public

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comment period ended on December 16, 2009. The bundled reimbursement rate will be phased in over a four year period in equal increments starting in 2011. Providers have the option to move to a full Medicare bundled payment system in 2011 or may elect to adopt certain components of the bundled payment system beginning in 2010. CMS will also be required to establish a quality incentive program that begins concurrently with bundling in 2011. Beginning in 2012, facilities would be subject to up to a 2% annual reduction in Medicare reimbursement for failure to meet or exceed CMS quality performance standards, including performance standards related to anemia management and dialysis adequacy. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment.

*ESA Reimbursement Developments.* Since April 1, 2006, Medicare reimbursement for ESAs administered to dialysis patients has been subject to a revised 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 a national coverage analysis ( NCA ), which is generally CMS first step toward developing a NCD. Subsequently, on May 14, 2007, CMS issued a proposed NCD that was open for public comment through June 13, 2007. On July 30, 2007, CMS issued a NCD which was substantially altered from the proposed NCD. On January 14, 2008, CMS issued changes to its Medicare NCD Manual, adding the ESA NCD, effective for claims with dates of service on and after July 30, 2007 with an implementation date of April 7, 2008. The 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 that the restrictions in the 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 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 NCD and we believe many healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage.

On September 11, 2007, the FDA held a joint meeting of the Cardiovascular-Renal Drug Advisory Committee ( CRDAC ) and the Drug Safety and Risk Management Advisory Committee ( DSaRMAC ) to evaluate the safety data on ESA use in renal disease. On July 31, 2008, CMS issued a listing of potential topics for future NCDs as a step to increase transparency in the NCD process, which included as potential topics the use of ESAs in ESRD and CKD. CMS has not announced whether it will proceed to a NCD for ESAs in ESRD or CKD and we cannot predict whether ESAs in the renal setting will be the subject of a future NCD, however, any final NCD for ESAs in the renal setting, which may include non-coverage and/or new dosing and treatment restrictions similar to those in the NCD for treatment of anemia in oncology with ESAs, would negatively affect use, reduce coverage and reimbursement, negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations. In addition, the CMS has scheduled a meeting on March 24, 2010 of the MEDCAC to review the available evidence on the use of ESAs to manage anemia in patients who have CKD, which may consider the results of the TREAT study. In February 2010, the CMS released the voting questions the MEDCAC will address, including whether the available evidence in both CKD not on dialysis and ESRD clearly (i) demonstrates benefits and risks of ESA therapy, (ii) supports a baseline Hb range or (iii) justifies a dose response or maximum dose. The CMS will decide whether more evidence is needed to determine whether ESA treatment is reasonable and necessary to support continued Medicare coverage. The CMS may consider initiating a NCA or a NCD following the MEDCAC. While the MEDCAC provides advice and recommendations to CMS about the adequacy of scientific evidence and votes on certain questions proposed by CMS, it functions as an independent advisory body and its advice and recommendations to CMS are advisory only.

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*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 then 10% of all ENBREL U.S. prescriptions are reimbursed by Medicare.

*Healthcare Reform.* Healthcare reform, focused on expanding healthcare coverage to millions of uninsured Americans and reducing the rate of increase in the costs of healthcare, remains a priority for President Obama, U.S. Congress and a number of states. Developments in this area have been highly dynamic and difficult to predict. As recently as February 23, 2010, President Obama released a new proposal for healthcare reform which includes a combination of provisions from both the Senate and House of Representatives bills passed in late 2009. Certain healthcare reform proposals being considered, which may or may not be adopted into law, could:

- restrict the coverage and reimbursement of our products by Medicare, Medicaid and other government programs
- reduce the number of years of data exclusivity for innovative biological products potentially leading to earlier biosimilar competition and/or
- require additional healthcare reform costs to be borne by pharmaceutical and biotechnology companies.

At this time, we cannot predict which or whether any reform measures will be adopted into law.

*Reimbursement Outside the United States*

Generally, in Europe and other countries outside the United States, the government-sponsored healthcare system has traditionally been the primary payer for 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 (e.g., National Institute for Health and Clinical Excellence ( NICE ) in the United Kingdom) that make recommendations and/or determinations of coverage and reimbursement based upon both the clinical as well as the economic value of a product. Although the methods employed by different HTA agencies differ 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.

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 in which the ceiling price of a pharmaceutical or biological product is set based to the price in particular benchmark countries. These price referencing rules are increasing in complexity as prices are more transparent and payers seek lower-price benchmarks against which to compare themselves. Additional cost-containment measures can include therapeutic reference pricing, including setting the reimbursement rate for a given class of agents at the lowest price within the class, generic substitution and government-mandated price cuts. 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 pricing mechanisms (e.g., payment caps) that facilitate greater predictability of payer budgets and require manufacturers to assume some financial risk.

**Manufacturing, Distribution and Raw Materials**

*Manufacturing*

Biotechnology 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 for Aranesp®, Epoetin alfa, Neulasta®, NEUPOGEN®, ENBREL, Vectibix®, Nplate® and other products and product candidates, including denosumab, for both commercial and clinical purposes. 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 dispenses the formulated bulk protein into vials or syringes. Finally, in the finish process, our products are packaged for distribution.

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We operate commercial and clinical manufacturing facilities in several locations throughout the United States, Puerto Rico and the Netherlands (see *Item 2. Properties*). Manufacturing of Sensipar®, our small molecule product, is performed entirely by third-party contract manufacturers. 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 and Nplate®, and a number of our clinical product candidates, including denosumab.

The global supply of our principal products is dependent on actively managing the inventory produced at our facilities and by third-party contract manufacturers and the uninterrupted and efficient operation of our manufacturing facilities. During the manufacturing scale-up process, and even after achieving sustainable commercial manufacturing, we may encounter difficulties or disruptions due to defects in raw materials or equipment, contamination or other factors which may impact product availability. (See *Item 1A. Risk Factors Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*)

We have obtained from various parties licenses that we deem to be necessary or desirable for the manufacture of our products. These 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*). Other than for ENBREL, we perform all of the commercial bulk manufacturing for our proteins. We supplement our own bulk manufacturing of ENBREL with a third-party contract manufacturer.

In addition to producing our own commercial quantities of bulk Epoetin alfa, we also supply bulk Epoetin alfa in the United States to J&J under a supply agreement (see *Business Relationships Johnson & Johnson*).

*Commercial Formulation, Fill and Finish Manufacturing*

Our primary commercial formulation, fill and finish manufacturing facility is located in Puerto Rico. In addition, we operate a commercial formulation, fill and finish manufacturing facility in California for Vectibix® and conduct certain finish activities in the Netherlands (see *Item 2. Properties*). Other than for Nplate®, we perform substantially all of our commercial formulation, fill and finish activities for our proteins in Puerto Rico. 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 (see *Item 1A. Risk Factors We manufacture and formulate, fill and finish substantially all our products at our Puerto Rico manufacturing facility; if significant natural disasters or production failures occur at this facility, we may not be able to supply these products*).

*Clinical Manufacturing*

Clinical bulk, formulation, fill and finish manufacturing facilities are operated in several locations throughout the United States and in Puerto Rico (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.

*Distribution*

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

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*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 these manufacturing and distribution activities are highly regulated by the FDA and other international regulatory agencies (see *Government Regulation FDA Regulation of Manufacturing Standards* ).

In preparation for the anticipated launch of Prolia, we have performed bulk manufacturing at our Boulder, Colorado manufacturing facility and formulation, fill and finish manufacturing activities in Puerto Rico. We also have an agreement with a third-party contract manufacturer that allows us to supplement, if necessary, our own bulk manufacturing activities of denosumab. In addition, in order to assist in meeting anticipated future demand, we are expanding our Puerto Rico bulk protein facilities to manufacture denosumab, as discussed below.

*Manufacturing Initiatives*

We have certain key ongoing initiatives to assist in meeting our future manufacturing needs. To maintain supply, mitigate risks associated with the majority of our formulation, fill and finish operations being performed in a single facility, and to satisfy anticipated future demand for a number of our late-stage product candidates, in particular denosumab, we are completing the construction and qualification of a new formulation and filling facility at our Puerto Rico site and the expansion and qualification of our existing bulk protein facilities at our Puerto Rico site. Upon completion, these facilities will require licensure by the various regulatory authorities. In addition to these projects, we have initiatives designed to operate our facilities at appropriate production capacity over the next few years, 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 manufacturing of our products are provided by single-source unaffiliated third-party suppliers. Also, certain medical devices and components necessary for the formulation, fill and finish of our products are provided by single-source unaffiliated third-party suppliers. Certain of these raw materials, medical devices and components are the proprietary products of these unaffiliated third-party suppliers and, in some cases, such proprietary products are specifically cited in our drug application with regulatory agencies so that they must be obtained from the specific sole source 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 sole-sourced suppliers by inventory management, relationship management and evaluating alternate 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.

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 includes bovine serum and human serum albumin ( HSA ). We continue to investigate alternatives to biological sources and alternative manufacturing processes that do not require the use of biologically-sourced raw materials as such raw materials may be subject to contamination and/or recall. Also, some countries in which we market our products may restrict the use of certain biologically derived substances in the manufacture of drugs. 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, 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 single-source third-party suppliers for certain of our raw materials, medical devices and components.* )

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

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**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 rights and have established R&D collaborations with third-parties to enhance our R&D capabilities and internally developed product pipeline. These arrangements may 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.

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 Central Asian, African and Middle East countries. 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, (ii) pegfilgrastim and G-CSF in Japan, China, Taiwan and Korea and (iii) 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 8, *Related party transactions* to the Consolidated Financial Statements).

*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.

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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 co-promotion agreement, Pfizer and Amgen each pay a defined percentage of all selling and marketing expenses approved by the joint management committee. In addition, we 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.

*GlaxoSmithKline plc*

In July 2009, we entered into a collaboration agreement with GSK for the commercialization of our late-stage product candidate, denosumab, in Europe, Australia, New Zealand and Mexico (the Primary Territories ) for osteoporosis indications. We will commercialize denosumab for all indications in the United States and Canada and for oncology indications in the Primary Territories. GSK will commercialize denosumab for all indications in countries where we do not currently have a commercial presence, including China, Brazil, India, Taiwan and South Korea (the Expansion Territories ). In the Expansion Territories, GSK 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 commercialization of denosumab in the Primary Territories and certain of the Expansion Territories in the future. In the Primary Territories, we will share equally in 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 that will decline as certain sales thresholds are met. GSK will also be responsible for bearing a portion of the cost of certain specified development activities.

*Takeda Pharmaceutical Company Limited*

In February 2008, we entered into a collaboration agreement with Takeda Pharmaceutical Company Limited ( Takeda ), which provides them the exclusive rights to develop and commercialize for the Japanese market up to 12 clinical stage molecules, including Vectibix®, from our pipeline across a range of therapeutic areas, including oncology and inflammation. We have the right to participate in the promotion of these 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 them the exclusive rights to develop and commercialize our late-stage product candidate, denosumab, in Japan in 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.

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*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 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 and subject to the terms and conditions of the agreement.

**Government Regulation**

Regulation by governmental 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, and other federal and state statutes and regulations govern, among other things, the raw materials and components used in the production of, research, development, testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising and promotion, and distribution of our products on a product-by-product basis. The failure to comply with the applicable regulatory requirements may subject us to a variety of administrative and/or judicially imposed sanctions. These 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 this 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 ( IND ) application with the FDA to begin human testing. The IND application 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 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™ were large and required substantial time and resources to recruit patients and significant expense to execute. Historically, our products have required smaller, shorter trials. Foreign studies performed under an IND must meet the same requirements that apply to U.S. studies. The FDA will accept a foreign clinical study not conducted under an IND only if the study is well-designed, well-conducted, performed by qualified investigators, and conforms to good clinical practice. Phase 1, 2 and 3 testing may not be completed successfully within any specified time period, if at all. (See *Item 1A. Risk Factors We may not be able to develop commercial products.* ) The FDA monitors the progress of each trial conducted under an IND and may, at its discretion, re-evaluate, alter, suspend, or terminate the testing based upon 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

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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 these 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. These additional trials may include, among other things, 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 may 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, they may require us to conduct further clinical trials to assess a known or potential serious risk. If required to conduct 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.

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

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

- distribution of a medication guide or a patient package insert to patients
- communication plan for the healthcare provider, such as a Dear Healthcare Professional Letter
- elements to ensure 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
- enrollment of patients in a registry.

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Each REMS is unique and varies depending on the specific factors required. Failure to comply with a REMS, including the submission of a required assessment or any modification to a REMS, may result in substantial civil or criminal penalties. We currently have approved REMS for our ESAs, ENBREL and Nplate®. Additionally, in response to the FDA s request, under authority prescribed by the FDAAA, we are currently in discussions with the FDA regarding an update to the existing REMS for ENBREL and a REMS for our product candidate Prolia™.

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 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 gain or maintain regulatory approval.* )

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 ACRHD, among others, to address certain issues related to Aranesp®, EPOGEN® and Prolia™, respectively. The FDA has also announced that it will call an advisory committee meeting in 2010 to re-evaluate the use of ESAs to treat anemia in patients with CKD and the advisory committee could consider lowering targeted Hb levels and reducing approved dosing for ESAs.

*FDA Regulation of Product Marketing and Promotion*. The FDA closely reviews and regulates the marketing and promotion of products. We are required to gain 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 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 clearance 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 these 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 the suspension of our manufacturing operations.

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*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. The specific requirements of each track differ depending upon the type of drug being reviewed. In the centralized procedure, 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 European Commission for final approval of the marketing authorization. While the European Commission generally follows the CHMP s opinion, it is not bound to do so. Although not all medicines have to undergo the centralized procedure, it is required of products derived from biotechnology. After evaluation and marketing authorization, various parties, including the national competent authorities, the EMA, the European Commission 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 the product labels be updated with safety data or warnings, that safety data or warnings be provided to healthcare professionals, or recommend the temporary suspension or complete withdrawal of a product from the market.

*Other*. We are also subject to various federal and state laws, as well as foreign laws, pertaining to healthcare fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug that is reimbursed by a state or federal program. The federal government and the states have published regulations that identify safe harbors or exemptions for certain arrangements that do not violate the anti-kickback statute. We seek to comply with the safe harbors wherever possible. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from 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 relating 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 was to allege against or convict us of violating these laws or 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 these laws and the increasing attention being given to them by law enforcement authorities.

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. Related to our participation in this program is a requirement that we extend comparable discounts under the Public Health Service ( PHS ) drug pricing program. Under the Medicaid drug rebate program, we pay a rebate for each unit of our product reimbursed by Medicaid. The amount of the rebate for each of our products is currently set by law as a minimum 15.1% 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-exempt customer. The rebate amount also includes an inflation adjustment if AMP increases faster than inflation. The PHS pricing program requires that we extend discounts comparable to the Medicaid rebate 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. 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 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

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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. There are also proposals related to both the Medicaid drug rebate program and the PHS drug pricing program as part of healthcare reform which could significantly alter the programs.

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 these four federal agencies and certain federal grantees. FSS pricing to these four federal agencies must be equal to or less than the Federal Ceiling Price ( FCP ), which is 24% below the Non-Federal Average Manufacturer Price ( Non-FAMP ) for the prior fiscal year. The accuracy of our reported Non-FAMPs, FCPs and our FSS contract prices may be audited by the government under applicable federal procurement laws and the terms of our FSS contract. Among the remedies available to the government for inaccuracies in calculation of Non-FAMPs and FCPs is recoupment of any overcharges to the four specified Federal agencies based on those inaccuracies. Also, if we were found to have knowingly reported a false Non-FAMP, in addition to other penalties available to the government, the VHC Act provides for civil monetary penalties of $100,000 per item that is incorrect. Finally, we are required to disclose in our FSS contract proposal all commercial pricing that is equal to or less than our proposed FSS pricing, and subsequent to award of an FSS contract, we are required to monitor certain commercial price reductions and extend commensurate price reductions to the government, under the terms of the FSS contract Price Reductions Clause. Among the remedies available to the government for any failure to properly disclose commercial pricing and/or to extend FSS contract price reductions is recoupment of any FSS overcharges that may result from such omissions.

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 that 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 would include 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 and general medicine, which includes cardiology and 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.

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

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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.* )

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* ).

In addition to product candidates and marketed products generated from our internal R&D efforts, we acquire companies, acquire and license certain product and technology rights and establish R&D collaborations with third parties, which 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. (See *Business Relationships* and Note 3, *Acquisitions* to the Consolidated Financial Statements.)

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

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.

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The following table is a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 5, 2010. Each target indication for product candidates in phase 3 is listed separately. For products in phase 1 and 2, the most advanced indication is shown. 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** | | |
| Sensipar® (cinacalcet) | Cardiovascular disease in patients with secondary hyperparathyroidism and chronic kidney disease undergoing maintenance dialysis | Nephrology |
| Aranesp® (darbepoetin alfa) | Anemia in heart failure | Nephrology |
| Prolia (denosumab) | Postmenopausal osteoporosis | Bone |
| Denosumab | Male osteoporosis | Bone |
| Denosumab | Cancer-related bone damage (skeletal-related events) from advanced malignancies in breast cancer, prostate cancer and solid tumors including multiple myeloma | Hematology/Oncology |
| Denosumab | Prevention of bone metastases in prostate cancer | Hematology/Oncology |
| Denosumab | Prevention of bone metastases in breast cancer | Hematology/Oncology |
| Prolia (denosumab) | Bone loss induced by hormone ablation therapy in breast cancer or prostate cancer | Hematology/Oncology |
| Motesanib | First-line non-small cell lung cancer | Hematology/Oncology |
| Vectibix® (panitumumab) | First- and second-line colorectal cancer | Hematology/Oncology |
| Vectibix® (panitumumab) | Metastatic and/or recurrent head and neck cancer | Hematology/Oncology |
| **Phase 2 Programs** | | |
| AMG 102 | Various cancer types | Hematology/Oncology |
| AMG 108 | Rheumatoid arthritis | Inflammation |
| AMG 222 | Type 2 diabetes | General Medicine |
| AMG 223 | Hyperphosphatemia | Nephrology |
| AMG 386 | Various cancer types | Hematology/Oncology |
| 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 (AMG 655) | Various cancer types | Hematology/Oncology |
| Denosumab | Rheumatoid arthritis | Inflammation |
| Dulanermin (rhApo2L/TRAIL) | Various cancer types | Hematology/Oncology |
| Motesanib | First-line breast cancer | Hematology/Oncology |
| Omecamtiv mecarbil (AMG 423) | Heart failure | General Medicine |
| Vectibix® (panitumumab) | Locally advanced head and neck cancer | Hematology/Oncology |
| Nplate® (romiplostim) | Chemotherapy-induced thrombocytopenia in non-small cell lung cancer and lymphoma | Hematology/Oncology |
| Nplate® (romiplostim) | Myelodysplastic syndromes | Hematology/Oncology |
| **Phase 1 Programs** | | |
| AMG 145 | Hypercholesterolemia | General Medicine |
| AMG 151 | Type 2 diabetes | General Medicine |
| AMG 157 | Asthma | Inflammation |
| AMG 167 | Bone-related conditions | Bone |
| AMG 191 | Inflammatory diseases | Inflammation |
| AMG 208 | Various cancer types | Hematology/Oncology |
| AMG 221 | Type 2 diabetes | General Medicine |
| AMG 557 | Systemic lupus erythematosus | Inflammation |
| AMG 745 | Muscle-wasting disorders | General Medicine |
| AMG 747 | Neuroscience | General Medicine |
| AMG 761 | Asthma | Inflammation |
| 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 |

**Phase 1** clinical trials investigate safety and proper dose ranges of a product candidate in a small number of human subjects.

**Phase 2** clinical trials investigate side effect profiles and efficacy of a product candidate in a large number of patients who have the disease or condition under study.

**Phase 3** clinical trials investigate the safety and efficacy of a product candidate in a large number of patients who have the disease or condition under study.

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

*AMG 102*

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.

Phase 2 studies of single agent AMG 102 for renal cell carcinoma ( RCC ) and glioblastoma multiforme ( GBM ) were completed in 2009. Limited efficacy was seen in GBM and RCC when AMG 102 was administered in monotherapy, and the effect size was not large enough to warrant moving forward with late-stage studies in these monotherapy indications.

Phase 2 combination studies with AMG 102 in the gastric, prostate, mCRC and small cell lung cancer settings continue. We expect data from the phase 2 study in mCRC to be available in 2010.

*AMG 108*

AMG 108 is a fully human monoclonal antibody that targets inhibition of the action of interleukin-1 ( IL-1 ).

*AMG 222*

AMG 222 is an orally-administered small molecule antagonist of DPP-IV. It is being investigated as a treatment of type 2 diabetes. AMG 222 is being developed in partnership with Servier.

In July 2009, we received results from a phase 2a study of AMG 222 in patients with type 2 diabetes. The results support continued phase 2 development of AMG 222.

*AMG 223*

AMG 223 is an orally-administered polymer which binds phosphate. It is being investigated as a treatment of hyperphosphatemia in CKD patients on hemodialysis.

*AMG 386*

AMG 386 is a peptibody that binds to and inhibits angiopoietin 1 and 2. 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 RCC, metastatic breast cancer, ovarian cancer, gastric cancer and colorectal cancer, and numerous other supportive studies. Based on study results, we plan to initiate a phase 3 trial in ovarian cancer. We expect the results from these other randomized phase 2 studies to be available in 2010 and 2011.

*AMG 479*

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 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 received the results from the phase 2 pancreatic cancer study in the second half of 2009 and we plan to present the results at an upcoming medical meeting. We expect the results from the phase 2 Ewing s sarcoma, metastatic breast cancer and mCRC studies to be available in 2010.

*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.

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

*AMG 827*

AMG 827 is a fully human monoclonal antibody that binds to and blocks signaling via the interleukin-17 ( IL-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. We expect data from the phase 2 study in psoriasis to be available in 2010.

*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.

*Aranesp® (darbepoetin alfa)*

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

In 2009, we announced the results from TREAT, the large, randomized, double-blind, placebo-controlled, phase 3 study of patients with CKD (not requiring dialysis), anemia and type-2 diabetes. Treatment of anemia with Aranesp® to a Hb target of 13 g/dL failed to meet either of two primary endpoints compared with placebo treatment with Aranesp® when the Hb level was less than 9 g/dL. The two primary endpoints were a composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke or hospitalization for myocardial ischemia) and a composite of time to all-cause mortality or chronic renal replacement therapy. Among the components of the TREAT outcomes measures, stroke was more likely to occur in the patients who received Aranesp® (101 patients [5.0%] versus 53 patients [2.6%]; Hazard Ratio ( HR ): 1.92 [95% Confidence Interval ( CI ) 1.38 to 2.68; P<0.001]). Although stroke has been noted in the Aranesp® label since 2001, the risk of stroke observed in TREAT was of a higher magnitude than that seen in previous clinical trials in CKD patients not on dialysis. Further, among patients who reported a history of cancer, there were 60 deaths from any cause in the 188 patients assigned to Aranesp® and 37 deaths in the 160 patients assigned to placebo (P=0.13 by the log-rank test). In this subgroup, 14 of the 188 patients assigned to Aranesp® died from cancer, as compared with 1 of the 160 patients assigned to placebo (P=0.002 by the log-rank test). Aranesp® treatment was associated with a statistically significant reduction in blood transfusions.

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), 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. On December 8, 2009, the RED-HF Trial Data Monitoring Committee ( DMC ) reviewed approximately 43% of the target number of primary endpoints. After careful review of outcomes and adverse events, including the results of TREAT (which was conducted in subjects with CKD, anemia and type 2 diabetes who were not receiving dialysis), the RED-HF Trial DMC recommended that the study continue as designed.

*Conatumumab (AMG 655)*

Conatumumab is a fully human monoclonal antibody agonist that targets death receptor 5 ( DR5 ) and induces apoptosis in sensitive tumor cells. It is being investigated as a cancer treatment.

We received the results from the phase 2 NSCLC and the soft tissue sarcoma studies in the second half of 2009 and we continue to analyze the data. We also received results from the phase 2 pancreatic cancer study and we plan to present the results at an upcoming medical meeting. We expect data from an on-going phase 2 study in mCRC to be available in 2010.

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*Dulanermin (rhApo2L/TRAIL)*

Dulanermin is a recombinant human protein that targets death receptors 4 ( DR4 ) and DR5 and induces apoptosis in sensitive tumor cells. It is being investigated as a cancer treatment. We are developing this molecule in collaboration with Genentech, Inc., a wholly owned member of the Roche Group.

Phase 2 data from the non-Hodgkin s Lymphoma and NSCLC studies have been analyzed and we plan to present the results at an upcoming medical meeting.

*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, bone metastases, multiple myeloma and RA.

The overall denosumab program remains on track with all completed phase 3 trials for denosumab having met all primary endpoints. The following chart is an overview of the phase 3 clinical development program for denosumab:

| Program Area | Indication | Enrollment Status | Projected Data Availability |
|---|---|---|---|
| Osteoporosis | PMO Treatment (versus placebo) | Complete | Received |
| Osteoporosis | PMO Treatment (versus ALN) | Complete | Received |
| Osteoporosis | PMO Prevention | Complete | Received |
| Osteoporosis | PMO Transition (from ALN) | Complete | Received |
| Osteoporosis | Male Osteoporosis | Enrolling | 2012 |
| Oncology | Treatment-Induced Bone Loss-Prostate Cancer | Complete | Received |
| Oncology | Treatment-Induced Bone Loss-Breast Cancer | Complete | Received |
| Oncology | Bone Metastases-Prostate Cancer | Complete | 2010[(1)] |
| Oncology | Bone Metastases-Breast Cancer | Approved | TBD[(2)] |
| Oncology | Skeletal-Related Events-Breast Cancer | Complete | Received |
| Oncology | Skeletal-Related Events-Solid Tumors/multiple myeloma | Complete | Received |
| Oncology | Skeletal-Related Events-Prostate Cancer | Complete | Received |

(1) Event-driven study and consequently data availability may vary as a result

(2) TBD = to be determined

In 2009, we announced that a pivotal, phase 3, head-to-head trial evaluating denosumab versus Zometa® in the treatment of bone metastases in 2,046 patients with advanced breast cancer met its primary endpoint (non-inferiority compared to Zometa®) and secondary endpoints (superiority compared to Zometa®). Superior efficacy compared to Zometa® was demonstrated for both delaying the time to the first on-study SREs (fracture, radiation to bone, surgery to bone or spinal cord compression) (HR: 0.82 [95% CI 0.71 - 0.95]), and delaying the time to the first-and-subsequent SREs (HR: 0.77 [95% CI 0.66 - 0.89]). Both results were statistically significant in this 34 month study. The median time to first on-study SRE was not reached for denosumab and therefore could not be estimated. The median time to first on-study SRE was 26.5 months for Zometa®, the current standard of care. Overall, the incidence of adverse events and serious adverse events was consistent with what has previously been reported for these two agents. Of note, osteonecrosis of the jaw ( ONJ ), which had not been observed in previously reported phase 3 studies with denosumab, was seen infrequently in both treatment groups (20 patients receiving denosumab as compared with 14 patients receiving Zometa®). There was no statistically significant difference in the rate of ONJ between the two treatment arms. Infectious adverse events were balanced between the two treatment arms, as was OS and the time to cancer progression.

In 2009, we also announced that a pivotal, phase 3, head-to-head trial evaluating denosumab administered subcutaneously versus Zometa® administered as an intravenous infusion in the treatment of bone metastases in 1,776 advanced cancer patients with solid tumors (not including breast and prostate cancer) or multiple myeloma

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met its primary endpoint. For the primary endpoint of this study, the median time to first on-study SRE (fracture, radiation to bone, surgery to bone or spinal cord compression) was 20.6 months for those patients receiving denosumab and 16.3 months for those patients receiving Zometa® (HR: 0.84, 95% CI: 0.71-0.98), which is statistically significant for non-inferiority (p=0.0007). Although numerically greater, the delay in the time to first SRE associated with denosumab was not statistically superior compared to Zometa® based upon the statistical testing strategy (adjusted p=0.06) (secondary endpoint). The time to first-and-subsequent SRE was also numerically greater but not statistically superior compared to Zometa® (HR: 0.90 [95% CI 0.77 - 1.04]) (secondary endpoint). Overall, the incidence of adverse events and serious adverse events was consistent with what has previously been reported for these two agents. Rates of ONJ were balanced and infrequent in both treatment groups (10 patients receiving denosumab as compared with 11 patients receiving Zometa®). Infectious adverse events were balanced between the two treatment arms, as was OS and the time to cancer progression.

On February 8, 2010, we announced that a pivotal, phase 3, head-to-head trial evaluating denosumab versus Zometa® in the treatment of bone metastases in 1,901 men with advanced prostate cancer met its primary endpoint of non-inferiority in time to first SRE and its secondary endpoints (superiority compared to Zometa® for both delaying the time to the first on-study SRE and delaying the time to the first-and-subsequent SREs). Denosumab demonstrated superiority over Zometa® for both delaying the time to the first on-study SREs (fracture, radiation to bone, surgery to bone or spinal cord compression) (HR: 0.82 [95% CI 0.71 - 0.95]), and delaying the time to the first-and-subsequent SREs (HR: 0.82 [95% CI 0.71 - 0.94]). Both results were statistically significant. Overall rates of adverse events and serious adverse events, including infections, were generally similar between the two arms. ONJ was infrequent (22 patients receiving denosumab as compared with 12 patients receiving Zometa®) and there was no statistically significant difference between treatment arms. As with previous studies in advanced cancer patients, hypocalcemia was more frequent in the denosumab arm. Both OS and the time to cancer progression were balanced between treatment arms.

The phase 3 147 study evaluating denosumab in patients with non-metastatic prostate cancer to prevent bone metastases is ongoing. We expect to receive the results from this study the second half of 2010.

*Motesanib*

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

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 nearly complete. Based on current event rates, we anticipate completion of the study in 2011.

In April 2009, Amgen and Millennium announced the phase 2 trial in metastatic breast cancer has been completed and the results support continued development.

*Nplate® (romiplostim)*

Nplate® is a peptibody agonist of the TPO receptor.

Nplate® is the first FDA-approved agent that acts directly to increase platelet production for the treatment of thrombocytopenia in splenectomized (spleen removed) and non-splenectomized adults with chronic ITP, who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.

In December 2009, we announced results from its first phase 1/2 study evaluating the safety and efficacy of Nplate® in children with chronic ITP. Results of the study showed that treatment with Nplate® appeared to be generally well-tolerated compared to placebo in children (aged 12 months to less than 18 years old) with chronic ITP (treatment related adverse events = 18% versus 20%, respectively).

In addition, we announced results from three studies on the safety and efficacy of Nplate® in adult patients with myelodysplastic syndromes ( MDS ). Data from two separate phase 2 studies showed that patients with low

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and intermediate risk MDS currently receiving either decitabine or lenalidomide showed reduced incidence of clinically significant thrombocytopenic events and platelet transfusions with the addition of Nplate® treatment.

We are also evaluating Nplate® 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 ).

In May 2009, Cytokinetics and Amgen Inc. announced that Amgen had exercised its option to obtain an exclusive license, worldwide (excluding Japan), to Cytokinetics cardiac contractility program, which includes omecamtiv mecarbil.

*Sensipar® (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® on mortality and cardiovascular morbidity in patients with CKD undergoing maintenance dialysis. The E.V.O.L.V.E. study completed enrollment in January 2008. Based on current event rates, we anticipate completion of the study in dialysis patients in 2011.

*Vectibix® (panitumumab)*

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

In September 2009, we announced detailed results from the phase 3 181 trial evaluating Vectibix® in combination with FOLFIRI (an irinotecan-based chemotherapy), as a second-line treatment for mCRC. The 181 trial is a global, multicenter, randomized phase 3 study. Patients enrolled in the study were randomized to receive either 6.0 milligram/kilogram of Vectibix® and FOLFIRI once every two weeks or FOLFIRI alone once every two weeks. The independently tested co-primary endpoints were PFS and OS. Secondary endpoints included objective response rate, time to progression, duration of response and safety by *KRAS* status. Originally designed to compare the treatment effect in the overall population, the study was amended to analyze outcomes with respect to the presence or absence of activating mutations in *KRAS*. Tumor *KRAS* status was ascertained in 91% of the 1,186 patients enrolled in this trial, the highest number ever reported for a second-line trial. In this trial, Vectibix® significantly improved PFS in patients with *KRAS* wild-type mCRC. The addition of Vectibix® to FOLFIRI significantly improved median PFS (co-primary endpoint) by two months (5.9 months versus 3.9 months for patients treated with FOLFIRI alone, HR: 0.73, p=0.004) in patients with *KRAS* wild-type mCRC. Although numerically greater (14.5 months versus 12.5 months, HR: 0.85), the improvement in median OS (co-primary endpoint) in the Vectibix® arm did not achieve statistical significance (p=0.115) in the same patient population. Further, the addition of Vectibix® to FOLFIRI resulted in greater than a three-fold improvement (35% versus 10%) in response rate in the *KRAS* wild-type patient population as measured by a blinded central review. In general, adverse events rates were comparable across arms with the exception of known toxicities associated with anti-EGFr therapy such as rash, diarrhea and hypomagnesemia. Vectibix®-related grade 3/4 infusion reactions were reported in less than 1% of patients. There were no differences in PFS, OS and response rates among patients with mutated *KRAS* who received Vectibix®. Tumor *KRAS* tests were finalized after the completion of enrollment and prior to the primary analysis.

Also in September 2009, we announced detailed results from the phase 3 203 trial evaluating Vectibix® administered in combination with FOLFOX (an oxaliplatin-based chemotherapy) as the first-line treatment of

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mCRC. In this trial, Vectibix® significantly improved median PFS by 1.6 months (9.6 months versus 8.0 months for patients treated with FOLFOX alone, (HR: 0.80; p=0.02)) in patients with *KRAS* wild-type mCRC (primary endpoint). Further, the addition of Vectibix® to chemotherapy also increased the response rate in the *KRAS* wild-type patient population as measured by blinded central review (55% versus 48% in the FOLFOX only arm). Importantly, in patients with tumors harboring activating *KRAS* mutations, PFS was significantly inferior in the Vectibix® arm. For patients with mutant *KRAS* tumors, median PFS was 7.3 months with Vectibix® in combination with FOLFOX versus 8.8 months with FOLFOX alone (HR: 1.29, p=0.02). These data confirm previous findings when oxaliplatin-based chemotherapy and an anti-EGFr antibody are combined in patients bearing tumors with activating *KRAS* mutations. Adverse event rates were comparable across arms with the exception of known toxicities associated with anti-EGFr therapy such as rash, diarrhea and hypomagnesemia. Vectibix®-related grade 3 infusion reactions were reported for two patients (less than 1%). Originally designed to compare the treatment effect in the overall population, the study was amended to analyze outcomes with respect to the presence or absence of activating mutations in *KRAS* in the tumor itself. Tumor *KRAS* status was ascertained in 93% of the 1,183 patients enrolled in the trial, the highest percentage ever reported. Tumor *KRAS* tests were finalized after the completion of enrollment and prior to the primary analysis.

In November 2009, we announced that the phase 3 203 trial evaluating Vectibix® administered in combination with FOLFOX (an oxaliplatin-based chemotherapy) as a first-line treatment of mCRC failed to meet a secondary endpoint of OS. The prospective analysis of the 203 study showed that Vectibix®, when added to a FOLFOX chemotherapy regimen in patients with *KRAS* wild-type mCRC, resulted in a median OS of 23.9 months compared to 19.7 months for patients treated with FOLFOX alone. The median OS difference of 4.2 months in the Vectibix® arm did not reach statistical significance (HR: 0.83, p=0.072). OS appeared to be reduced in patients with *KRAS* mutant tumors receiving Vectibix®. Although not statistically significant, this result emphasizes the importance, as described in product labeling, of ensuring that patients receiving Vectibix® do not bear tumors containing *KRAS* mutations.

In 2007, we initiated a phase 3 study for the first-line treatment of metastatic squamous cell carcinoma of the head and neck ( SCCHN ) as well as two randomized phase 2 studies in locally advanced SCCHN testing Vectibix® in combination with chemoradiotherapy or with radiotherapy alone. We expect the results from this study to be available in 2010. Vectibix® is also being investigated in combination with other investigational anti-cancer therapies.

**Human Resources**

As of December 31, 2009, we had approximately 17,200 staff members, which include approximately 200 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 the commencement of employment or the 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 January 31, 2010 are as follows:

Mr. Kevin W. Sharer, age 61, has served as a director of the Company since November 1992. Chief Executive Officer and President of the Company and has also been Chairman of the Board of Directors since January 2001. 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

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Communications Corporation ( MCI ). 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 a trustee of the California Institute of Technology, or Caltech.

Mr. David W. Beier, age 61, 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 63, 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 47, became Executive Vice President and Chief Financial Officer in April 2007. He joined the Company in 2006 as Vice President, Operations Strategy. Previously, Mr. Bradway had an 18 year career at Morgan Stanley in New York and London where he was a managing director in investment banking. Mr. Bradway led Morgan Stanley s healthcare practice in Europe for several years and also ran Morgan Stanley s European banking department.

Mr. Thomas J. Flanagan, age 60, became Senior Vice President and Chief Information Officer in October 2006. From June 2004 to October 2006, Mr. Flanagan served as Vice President, Information Systems. From December 1995 to May 2004, Mr. Flanagan served in a variety of executive positions including Chief Information Officer and Vice President, Global Service Delivery at MCI.

Mr. Brian McNamee, age 53, 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. George J. Morrow, age 57, became Executive Vice President of Worldwide Sales and Marketing in January 2001 and became Executive Vice President, Global Commercial Operations in April 2003. From January 1999 to December 2000, Mr. Morrow was President and Chief Executive Officer of Glaxo Wellcome Inc. ( Glaxo ), a subsidiary of GlaxoSmithKline. From January 1997 to December 1998, Mr. Morrow was Managing Director of Glaxo Wellcome U.K., also a subsidiary of GlaxoSmithKline. From May 1993 to December 1996, Mr. Morrow was Group Vice President for Commercial Operations of Glaxo. Mr. Morrow currently serves on the Board of Directors of Align Technology, Inc.

Dr. Roger M. Perlmutter, age 57, 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 49, 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

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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 57, 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 21, *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. Information related to the operation of the SEC s public reference room may be obtained by calling the SEC at 1-800-SEC-0330.

**Item 1A. RISK FACTORS**

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

*Our current products and products in development cannot be sold if we do not gain or maintain 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, regulatory agencies could add new regulations or change existing regulations at any time, which could affect our ability to obtain or maintain approval of our products. Regulatory reform efforts currently under discussion by U.S. policymakers may include changes to applicable laws and regulations that could have a significant impact on our business. 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 stud -

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ies; (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. We are unable to predict when and whether any changes to regulatory policy affecting our business could occur, and such changes could have a material adverse impact on our business.

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 our late-stage product candidate Prolia™ in the treatment and prevention of PMO and in the treatment and prevention of bone loss due to 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 that will inform the methodology of our previously submitted post-marketing surveillance program. The FDA also requested a new clinical program to support 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 ADT. 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 OS. On February 19, 2010, we announced that the FDA has evaluated the content of our Complete Response submission for Prolia™ in the treatment of PMO, which we submitted on January 25, 2010, and classified it as a Class 2 resubmission. With the Class 2 designation, the FDA set a corresponding PDUFA action date of July 25, 2010. A significant delay in regulatory approval to market and sell Prolia™ for the treatment of PMO could have a material adverse affect on our business and results of operations.

In addition, 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 final approval conditioned on conducting additional clinical trials of the use of Vectibix® as a therapy in treating mCRC. Our conditional approval of Vectibix® in the EU was received in December 2007 and is reviewed annually by the CHMP and in December 2008 and 2009 we received renewal of the conditional approval subject to us completing an additional clinical trial in the existing approved indication. In 2009, the CHMP approved our protocol for this additional clinical trial, which will compare the effect of Vectibix® versus Erbitux® on OS for chemorefractory mCRC patients with wild-type *KRAS* tumors. 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 these 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, 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, 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 significant 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

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an increased rate or number of previously-identified safety-related events

the discovery of significant problems or safety signals or trends with a similar product that implicates an entire class of products

subsequent concerns about the sufficiency of the data or studies underlying the label or changes to the underlying safety/efficacy analysis related to results from clinical trials, including sub-analyses, or meta-analysis (a meta-analysis is the review of studies using various statistical methods to combine results from previous separate but related studies) of clinical trials or clinical data performed by us or others

new legislation or rules by regulatory agencies

For example, 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. (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 could also lead to:

requirement of risk management activities (including a REMS) related to the promotion and sale of our products

mandated PMCs or pharmacovigilance programs for our approved products

product recalls of certain of our approved products

revocation of approval for our products from the market completely, or within particular therapeutic areas, and/or

delay in or fewer treatments being approved by the FDA or other 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 and implement. 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

place administrative burdens on healthcare providers in prescribing our products, or

affect our ability to compete against products that do not have a REMS or similar risk management activities

We currently have approved REMS for our ESAs, ENBREL and Nplate® and are currently in discussions with the FDA regarding an update to the existing REMS for ENBREL and a REMS for our product candidate Prolia™.

Further, if new medical data or product quality issues suggest an unacceptable safety risk or previously unidentified side-effects, we may withdraw some or all affected product either voluntarily or by regulatory mandate in certain therapeutic areas, or completely recall a product presentation from the market for some period or permanently. For example, in September 2009, we initiated a voluntary recall of a limited number of ENBREL SureClick® lots due to a defect in the glass syringe barrel which resulted in a small number of broken syringes following assembly of the autoinjector device. We may experience the same or other problems in the future resulting in broader product recalls or adverse event trends, which may adversely affect the sales of our products. Additionally, if other parties (including our licensees, such as J&J and Pfizer, or independent investigators) 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

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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 that result in revised safety-related labeling or restrictions on the use of our approved products could negatively impact healthcare provider prescribing behavior, use of our products, regulatory or private health organization medical guidelines and reimbursement for our products all of which would 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 from regulatory authorities. 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, and since that time have experienced a 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. In an editorial published in the *New England Journal of Medicine* in January 2010, the FDA announced that it will call an advisory committee meeting in 2010 to re-evaluate the use of ESAs to treat anemia in patients with CKD and could consider lowering targeted Hb levels. In addition, CMS has scheduled a MEDCAC meeting for March 24, 2010 to examine currently available evidence on the use of ESAs to manage anemia in patients who have CKD, which may consider the results from the TREAT study. The FDA may also require that we update the REMS for ESAs based on the TREAT results. Although we cannot predict what impact all of these activities could have on our business, the revised ESA labeling or any future labeling changes, including any required in connection with the scheduled advisory committee meeting, our ongoing discussions with the FDA regarding the conversion of the format of our ESA U.S. labels in accordance with the PLR or other changes required by the FDA, the outcome from the MEDCAC meeting or the impact of the approved REMS for ESAs could have a material adverse impact on the coverage, reimbursement and 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 gain or maintain regulatory approval*. and *Our sales depend on coverage and reimbursement from third-party payers.* )

We also have ongoing PMC studies for our ESAs which 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 OS when comparing NSCLC patients on Aranesp® to patients receiving placebo. We are currently identifying clinical sites for Study 782 and have begun enrolling patients in the study. Further, in 2008 the FDA and 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.

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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 European Commission 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 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.

*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 these clinical trials are used as the basis to obtain regulatory approval from regulatory authorities such as the FDA. (See *Our current products and products in development cannot be sold if we do not gain or maintain 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. If we fail to adequately manage the design, execution and regulatory aspects of our large, complex and regulatory diverse clinical trials, 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.)

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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 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 are moving forward with 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.

*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. 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. (See *Item 1. Business Reimbursement* ) The government-sponsored healthcare systems in Europe and other foreign countries are the primary payers of healthcare costs in those regions. 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 cannot predict the availability or level of coverage and reimbursement for our approved products or product candidates and a reduction in coverage and/or reimbursement for our products could have a material adverse effect on our product sales and results of operations.

Healthcare reform, focused on expanding healthcare coverage to millions of uninsured Americans and reducing the rate of increase in the cost of healthcare, remains a priority for President Obama, U.S. Congress and a number of states. Developments in this area have been highly dynamic and difficult to predict. As recently as February 23, 2010, President Obama released a new proposal for healthcare reform which includes a combination of provisions from both the Senate and House of Representatives bills passed in late 2009. Certain healthcare reform proposals being considered, which may or may not be adopted into law, could:

- restrict the coverage and reimbursement of our products by Medicare, Medicaid and other government programs

reduce the number of years of data exclusivity for innovative biological products potentially leading to earlier biosimilar competition and/or

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require additional healthcare reform costs to be borne by pharmaceutical and biotechnology companies.

We cannot predict whether these or any future proposed reform measures will be adopted into law. Healthcare cost-containment measures or other healthcare system reforms that are adopted could have a material adverse effect on our industry generally and any changes to the current U.S. healthcare system that reduce the coverage and reimbursement of our products, or restrict the way our products are used or prescribed, could have a material adverse impact on our business. (See *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval.* )

Public and private insurers have pursued, and continue to pursue, aggressive cost containment initiatives, which could result in lower reimbursement rates for our products. For example, 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. The ASP payment rate for most of our products furnished in the hospital outpatient setting has been reduced twice since 2007. 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 2010, 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.

Other initiatives reviewing the coverage or reimbursement of our products could result in less extensive coverage or lower reimbursement rates. For example, in March 2007, CMS announced a review of all Medicare coverage policies related to the administration of ESAs in non-renal disease applications which is a precursor to a NCD. In July 2007, CMS issued a 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. We believe the restrictions in the NCD on the coverage and reimbursement of ESAs has had a material adverse effect on the use, reimbursement and sales of Aranesp®, which has had a significant impact to our business. We believe that the NCD may continue to impact us in the future.

In the dialysis setting, the reimbursement rates for our products may also be subject to downward pressure. In the United States, dialysis providers are primarily reimbursed for EPOGEN® 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 monitored and implemented by CMS. Since April 2006, the Medicare reimbursement for ESAs administered to dialysis patients has 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.

In addition, on July 30, 2008, CMS issued a listing of potential topics for future NCDs as a step to increase transparency in the NCD process, which included as potential topics the use of ESAs in ESRD and CKD. Medicare currently does not have a NCD for the use of ESAs for anemia in patients who have CKD and CMS has not announced whether it will proceed with a NCD for ESAs in ESRD or CKD. However, CMS announced it had scheduled a MEDCAC meeting for March 24, 2010 to review the use of ESAs to manage anemia in patients who have CKD, which may consider the results of the TREAT study. In February 2010, CMS released the voting questions the MEDCAC will address, including whether the available evidence in both CKD not on dialysis and

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ESRD clearly (i) demonstrates the benefits and risks of ESA therapy, (ii) supports a baseline Hb range or (iii) justifies a dose response or maximum dose. CMS will decide whether more evidence is needed to determine whether ESA treatment is reasonable and necessary to support continued Medicare coverage. CMS may consider initiating a NCA or a NCD following the MEDCAC and a NCD for ESAs in the renal setting, which may include non-coverage and/or new dosing and treatment restrictions, could negatively affect use, reimbursement and coverage, and product sales of our ESA products. Also included in the initial potential future NCD topic list is the category of thrombopoiesis stimulating agents (platelet growth factors), the category of drugs that includes Nplate® although CMS has not announced whether it will proceed with a NCD related to thrombopoiesis stimulating agents.

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, on September 15, 2009, CMS released its proposed rule to implement a bundled prospective payment system for ESRD facilities as required by the MIPPA. Although we cannot predict what the final rule on the bundled payment system for ESRD facilities will include, implementation of the rule as proposed could have a material adverse impact on the coverage and reimbursement, use and sales of EPOGEN® and Sensipar®. Healthcare providers may narrow the circumstances in which they prescribe or administer our products if reimbursement rates are reduced or in anticipation of reimbursement being reduced, which could reduce the use and/or price of our products. A reduction in the use or price of our products could have a material adverse effect on us and our results of operations.

*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. A patent dispute or litigation may not discourage a potential violator from bringing the product that is alleged to infringe to market and we may be subject to competition during certain periods of litigation. 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. 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.

In recent years, policymakers have proposed reforming U.S. patent laws and regulations. For example, patent reform legislation was introduced in both houses of the U.S. Congress in 2009, and the Senate Judiciary Committee approved a patent reform bill on April 2, 2009. 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 ultimately may 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.

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*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
- 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, 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 business may be affected by litigation and government investigations.*

We and certain of our subsidiaries are involved in legal proceedings. Civil and criminal litigation is inherently unpredictable, and the outcome can result in excessive verdicts, fines, penalties 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

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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. 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. On October 30, 2009 fourteen states and the District of Columbia s state attorneys general filed an amended complaint in intervention against Amgen alleging violations of the federal Anti-Kickback Statute and various state false claims acts. Additionally, the U.S. government may seek to intervene in the lawsuit filed by the states at any time.

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.

*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 have experienced extreme volatility and disruption which has led 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.* ) 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 could have a material adverse affect on the sales of our products, our business and results of operations.

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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 that 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 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 which may result in other than temporary declines in the value of our investments. Any of these events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on the sale of investments.

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

We rely on single-source unaffiliated third-party suppliers for certain raw materials, medical devices and components necessary for the formulation, fill and finish of our products. Certain of these raw materials, medical devices and components are the proprietary products of these 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 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

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- unexpected demand for or shortage of raw materials, medical devices or components
- labor disputes or shortages, including the effects of a pandemic flu outbreak or otherwise
- failure to comply with our quality standards which results in quality and product failures, product contamination and/or recall

These events could adversely affect our ability to satisfy demand for our products, which could adversely affect our product 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. However, we may experience these or other shortages in the future resulting in delayed shipments, supply constraints, contract disputes and/or stock-outs of our products. Also, certain of the raw materials required in the commercial and clinical manufacturing and the formulation 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 includes bovine serum and 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 as 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, used in the manufacture of our products could adversely impact or disrupt our 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, Sensipar®/Mimpara® and Nplate® as well as our late-stage product candidate denosumab and plan to use contract manufacturers to produce a number of our other 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 and components 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
- facility contamination by microorganisms or viruses
- labor disputes or shortages, including the effects of a pandemic flu outbreak
- compliance with regulatory requirements
- changes in forecasts of future demand

timing and actual number of production runs

updating of manufacturing specifications

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- production success rates and bulk drug 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. 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.

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 and license a new manufacturing plant and it can take longer than three years to qualify and license a new contract manufacturer. In order to maintain supply, mitigate risks associated with the majority of our formulation, fill and finish operations being performed in a single facility and to satisfy anticipated demand for our late-stage product candidates, in particular denosumab, we must successfully implement certain manufacturing projects on schedule.

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 the rest of the world. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics centers and our third-party logistics providers.

*We manufacture and formulate, fill and finish substantially all our products at our Puerto Rico manufacturing facility; if significant natural disasters or production failures occur at this facility, we may not be able to supply these products.*

We currently perform all of the formulation, fill and finish for EPOGEN®, Aranesp®, Neulasta® and NEUPOGEN®, 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 if denosumab is approved by the FDA, it will be primarily produced at the Puerto Rico facility. Our global supply of these products is significantly dependent on the uninterrupted and efficient operation of this facility. 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

failures to comply with regulatory requirements, including those of the FDA

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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 voluntarily recalled in September 2009 were manufactured at our Puerto Rico facility and we have made commitments to the FDA to address the causes behind the recall. In future inspections, our failure to adequately address the FDA s expectations could lead to further inspections of the facility or regulatory actions. (See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales*. )

*Our 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 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, are easier to administer or that are otherwise competitive with 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 proposed bills to create a regulatory pathway for the abbreviated approval of biosimilars, and 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 European Commission 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 European Commission issued marketing authorizations for the first G-CSF biosimilar products and the product was launched in certain EU countries in 2008 and 2009. There are several G-CSF biosimilars available in the EU marketed by different companies and these G-CSF biosimilar

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products compete with NEUPOGEN® and Neulasta®. We cannot predict to what extent the entry of biosimilar products or other competing products will impact future NEUPOGEN® or Neulasta® sales in the EU. Our inability to compete effectively could reduce sales, which could have a material adverse effect on our results of operations.

In the United States, there is no regulatory pathway for the abbreviated approval of BLAs for biosimilars, but legislation on biosimilars has been proposed and may be enacted in the in the near future. Such biosimilars would reference biotechnology products already approved under the U.S. Public Health Service Act. Under current law, potential competitors may introduce biotechnology products in the United States only by filing a complete BLA. Before biosimilar products could enter the U.S. market through an abbreviated approval process, the U.S. Congress would need to pass legislation to create a new approval pathway and the FDA may also then promulgate associated regulations or guidance. The Obama Administration has expressed support for the creation of such an approval pathway for biosimilars, including as a part of its broader healthcare reform effort, which the Administration has identified as one of its top priorities. In late 2009, both the full House of Representatives and the Senate passed bills that would provide twelve years of data exclusivity for innovative biological products. Data exclusivity protects the data in the innovator s regulatory application by, for a limited period of time, prohibiting others from gaining FDA approval based, in part, on reliance or reference to the innovator s data in their application to the FDA. The debate on biosimilars continues, however, with a number of members of the U.S. Congress and the Obama administration supporting a shorter period of data exclusivity. We cannot predict what the specific provisions of any final legislation might be or the timing of implementation of the pathway by the FDA. To the extent that an abbreviated biosimilar pathway is created through legislation in the United States, we would likely face greater competition 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 if an abbreviated regulatory pathway for biosimilars is adopted. However, the absence of an abbreviated approval pathway for biosimilar products may not be a complete barrier to the introduction of biosimilar-type products in the United States.

*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. These entities purchasing leverage has increased due to this concentration and consolidation 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. One of our products, EPOGEN®, is primarily sold 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. 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.

*Our marketing of ENBREL is dependent in part upon Pfizer (formerly Wyeth).*

On October 15, 2009, Pfizer and Wyeth completed their merger and our relationship with Pfizer may be different than our prior relationship with Wyeth. Under a co-promotion agreement, we and Pfizer market and sell ENBREL in the United States and Canada. A management committee comprised of an equal number of representatives from us and Pfizer is responsible for overseeing the marketing and sales of ENBREL including strategic planning, the approval of an annual marketing plan and the establishment of a brand team. The brand

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team, with equal representation from us and Pfizer, prepares and implements the annual marketing plan, which includes a minimum level of financial and sales personnel commitment from each party, and is responsible for all sales activities. If Pfizer fails to effectively deliver on its marketing commitments to us or if we and Pfizer fail to coordinate our efforts effectively, our sales of ENBREL may be materially adversely affected.

*We may be forced to undertake cost savings and/or restructuring initiatives in the future.*

As a result of various regulatory and reimbursement developments that began in 2007, we completed a restructuring of our worldwide operations in order to improve our cost structure while continuing to make significant R&D investments and build the framework for our future growth. As part of these actions, we reduced staff, made changes to certain capital projects, closed certain production operations and abandoned leases primarily for certain R&D facilities that will not be used in our operations. Our business continues to face a variety of challenges. As a result, we may be forced to undertake further cost saving and/or restructuring initiatives in the future. The current economic climate has forced many U.S. companies to cut costs in order to maintain their competitive standing, including through restructurings and reorganizations. We have worked, and we continue to work, to increase cost efficiencies and to reduce discretionary expenditures. The anticipated benefits of our cost reduction initiatives are based on forecasts which could vary substantially from actual results, and we cannot provide assurance that any such cost saving initiatives will not have a material adverse effect on our business.

*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, 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 of government agencies or these other groups/organizations may relate to such matters as usage, dosage, route of administration and use of related therapies and reimbursement of our products by government and private payers. Recommendations or guidelines that are followed by patients and healthcare providers could result in decreased use and/or dosage of our products. Some examples of agency and organizational guidelines include:

- On July 31, 2009, the Kidney Disease: Improving Global Outcomes group ( KDIGO ) released its Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder ( CKD-MBD ). The guideline includes detailed recommendations for the diagnosis and evaluation of the three components of CKD-MBD followed by recommendations for treatment. These recommendations could affect how healthcare providers prescribe Sensipar® for ESRD patients. The impact of the KDIGO is guidelines on clinical practice or the use of Sensipar® is not yet known.

- 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 their 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 February 2007, following the reported results from our Anemia of Cancer ( AoC ) 103 Study, the United States Pharmacopoeia Dispensing Information Drug Reference Guides removed Aranesp® in the treatment of AoC.

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.

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*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 gain or maintain 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 you 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 these 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.*

In connection with our continuous process improvement activities, we evaluate our processes and procedures in order to identify opportunities to achieve greater efficiencies in how we conduct our business in order to reduce costs. In particular, we evaluate our manufacturing practices and related processes to increase production yields and/or success rates as well as capacity utilization to gain increased cost efficiencies. 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 charges and/or the recognition of other related charges. The recognition of such charges, if any, could have a material and adverse affect on our results of operations.

**Item 1B. UNRESOLVED STAFF COMMENTS**

None.

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**Item 2. PROPERTIES**

The following table summarizes our significant properties and their primary functions as of December 31, 2009. For additional information regarding manufacturing initiatives see *Item 1. Business Manufacturing, Distribution and Raw Materials*.

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

We believe 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 manufacture and formulate, fill and finish substantially all our products at our Puerto Rico manufacturing facility; if significant natural disasters or production failures occur at this facility, we may not be able to supply these products.* , *We rely on single-source 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 our legal proceedings in which we are involved are discussed in Note 20, *Contingencies and commitments* to our Consolidated Financial Statements in our 2009 Form 10-K and are hereby incorporated by reference.

**Item 4. RESERVED**

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## PART II

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

*Common stock*

Our common stock trades on The NASDAQ Stock Market under the symbol AMGN. As of February 12, 2010, there were approximately 10,685 holders of record of our common stock. No cash dividends have been paid on the common stock to date, and we currently do not intend to pay any dividends.

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 Stock Market:

| | High | Low |
|---|---|---|
| **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 |
| **Year ended December 31, 2008** | | |
| Fourth quarter | $ 61.55 | $ 47.76 |
| Third quarter | 65.89 | 48.64 |
| Second quarter | 47.16 | 41.49 |
| First quarter | 48.14 | 39.97 |

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*Performance graph*

The chart set forth below shows the value of an investment of $100 on December 31, 2004 in each of Amgen Common Stock, the Amex Biotech Index, the Amex Pharmaceutical Index and Standard & Poor s 500 Index (the S&P 500 ). All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices and are calculated as of December 31st of each year. The historical stock price performance of the Company s Common Stock shown in the performance graph below is not necessarily indicative of future stock price performance.

| | 12/31/2004 | 12/31/2005 | 12/31/2006 | 12/31/2007 | 12/31/2008 | 12/31/2009 |
|---|---|---|---|---|---|---|
| Amgen (AMGN) | $ 100.00 | $ 122.93 | $ 106.48 | $ 72.39 | $ 90.02 | $ 88.18 |
| Amex Biotech (BTK) | $ 100.00 | $ 125.11 | $ 138.59 | $ 144.51 | $ 118.91 | $ 173.11 |
| Amex Pharmaceutical (DRG) | $ 100.00 | $ 103.54 | $ 114.50 | $ 115.66 | $ 97.05 | $ 113.53 |
| S&P 500 (SPX) | $ 100.00 | $ 104.83 | $ 121.20 | $ 127.85 | $ 81.11 | $ 102.15 |

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.

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*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 that 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 the stock price, blackout periods in which we are restricted from repurchasing shares, and our credit rating and may include private block purchases as well as market transactions.

During the three months ended December 31, 2009, we had one outstanding stock repurchase program. A summary of our repurchase activity for the three months ended December 31, 2009 is as follows:

| | Total number of shares purchased | Average price paid per share | Total number of shares purchased as part of publicly announced programs | Maximum $ value that may yet be purchased under the programs[1] |
|---|---|---|---|---|
| October 1 October 31 | 3,845,000 | $ 54.93 | 3,845,000 | $ 1,963,027,922 |
| November 1 November 30 | 12,210,000 | 55.53 | 12,210,000 | 1,285,036,989 |
| December 1 December 31 | 5,677,300 | 56.65 | 5,677,300 | 5,963,425,662 |
| | 21,732,300 | 55.72 | 21,732,300 | |

(1) In December 2009, the Board of Directors authorized us to repurchase up to an additional $5.0 billion of our common stock adding to the $5.0 billion previously authorized in July 2007. As of December 31, 2009, we had $6.0 billion available for stock repurchases as authorized by our Board of Directors.

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**Item 6. SELECTED FINANCIAL DATA**

| Consolidated Statement of Income Data: | Years ended December 31, 2009 | 2008 | 2007 | 2006 | 2005 |
|---|---|---|---|---|---|
| | (In millions, except per share data) | | | | |
| Revenues: | | | | | |
| Product sales | $ 14,351 | $ 14,687 | $ 14,311 | $ 13,858 | $ 12,022 |
| Other revenues | 291 | 316 | 460 | 410 | 408 |
| Total revenues | 14,642 | 15,003 | 14,771 | 14,268 | 12,430 |
| Operating expenses[1][2]: | | | | | |
| Cost of sales (excludes amortization of certain acquired intangible assets presented below)[3] | 2,091 | 2,296 | 2,548 | 2,095 | 2,082 |
| Research and development[4] | 2,864 | 3,030 | 3,266 | 3,366 | 2,314 |
| Selling, general and administrative | 3,820 | 3,789 | 3,361 | 3,366 | 2,790 |
| Amortization of certain acquired intangible assets[5] | 294 | 294 | 298 | 370 | 347 |
| Write-off of acquired in-process research and development[6] | | | 590 | 1,231 | |
| Other charges[7] | 67 | 380 | 728 | | 49 |
| Net income[13] | 4,605 | 4,052 | 3,078 | 2,809 | 3,633 |
| Diluted earnings per share[13] | 4.51 | 3.77 | 2.74 | 2.36 | 2.90 |
| Cash dividends declared per share | | | | | |

| Consolidated Balance Sheet Data: | At December 31, 2009 | 2008 | 2007 | 2006 | 2005 |
|---|---|---|---|---|---|
| | | | (In millions) | | |
| Total assets[2][13] | $ 39,629 | $ 36,427 | $ 34,618 | $ 33,711 | $ 29,252 |
| Total debt[8][9][10][11][13] | 10,601 | 9,352 | 10,114 | 7,725 | 3,951 |
| Stockholders equity[10][11][12][13] | 22,667 | 20,885 | 18,512 | 19,841 | 20,427 |

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, primarily related 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. In August 2004, we acquired all of the outstanding common stock of Tularik Inc. ( Tularik ). Included in operating expenses are acquisition-related charges of $1 million, $58 million, $41 million and $12 million, in 2008, 2007, 2006 and 2005, respectively. Acquisition charges, net of tax, for the four years ended December 31, 2008 were $1 million, $35 million, $26 million and $7 million, respectively. Acquisition charges consist of, where applicable, the incremental compensation provided to certain employees under short-term retention plans, including non-cash compensation expense associated with stock options assumed in connection with the acquisition, non-cash expense related to valuing the inventory acquired at fair value, which is in excess of our manufacturing cost, and external, incremental consulting and systems integration costs directly associated with integrating the acquired company.

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(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.

(4) Included in R&D expenses for 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), $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, primarily related to ENBREL, acquired in the Immunex acquisition. Amortization charges, net of tax, for the five years ended December 31, 2009 were $186 million, $183 million, $185 million, $200 million and $215 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 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. These 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 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, principally related 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. In 2005, we settled certain legal matters, primarily related to a patent legal proceeding, and recorded an expense of $49 million, net of amounts previously accrued. The remaining amounts included in Other charges in 2009, 2008 and 2007, primarily relate to restructuring charges (see Note 9, *Restructuring* to the Consolidated Financial Statements).

(8) In January 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 November 2009, we repaid our $1.0 billion 4.00% notes.

(9) In May 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 June and November 2008, we repaid our $2.0 billion of floating rate notes.

(10) On March 2, 2007, as a result of holders of substantially all of our outstanding 2032 Modified Convertible Notes exercising their March 1, 2007 put option, we repurchased the majority of the then outstanding convertible notes, at their then-accreted value of $1.7 billion. In May 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 these notes were used to repurchase shares of our common stock under an accelerated share repurchase program ( ASR ) entered into in May 2007.

(11) In February 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 these notes, a total of $3.0 billion of our common stock was repurchased under our stock repurchase program. Also, concurrent with the issuance of these 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 these notes, we sold warrants to acquire shares of our common stock. Proceeds received from the issuance of the warrants totaled approximately $774 million.

(12) Throughout the five years ended December 31, 2009, we have had share repurchase programs authorized by the Board of Directors through which we have repurchased $3.2 billion, $2.3 billion, $5.1 billion, $5.0 billion and $4.4 billion, respectively, of Amgen common stock.

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(13) 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 new 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 2032 Modified 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 2009, 2008, 2007, 2006 and 2005 is non-cash interest expense of $250 million ($155 million, net of tax), $235 million ($144 million, net of tax), $168 million ($88 million, net of tax) , $197 million ($141 million, net of tax) and $67 million ($41 million, net of tax), respectively, related to the amortization of the discounts resulting from the adoption of the new accounting standard. See Note 1, *Summary of significant accounting policies,* Note 2, *Change in method of accounting for convertible debt instruments* and Note 16, *Financing arrangements* to the Consolidated Financial Statements for further information.

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

*Forward looking statements*

This report and other documents we file with the SEC contain forward looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business or others on our behalf, our beliefs and our management s assumptions. In addition, we, or others on our behalf, may make forward looking statements in press releases or written statements, or in our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Words such as expect, anticipate, outlook, could, target, project, intend, plan, believe, seek, estimate, should, may, 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 operate in a highly regulated industry and various U.S. and foreign regulatory bodies have substantial authority over how we conduct our business. Government authorities in the United States and in other countries regulate the manufacturing and marketing of our products and our ongoing R&D activities. The regulatory environment is evolving and there is increased scrutiny on drug safety and increased authority being granted to regulatory bodies, in particular the FDA, to assist in ensuring the safety of therapeutic products, which may lead to fewer products being approved by the FDA or other regulatory bodies, delays in receiving approvals or additional safety-related requirements or restrictions on the use of our products, including expanded safety labeling, required risk management activities, including a REMS, and/or additional or more extensive clinical trials as part of PMCs, PMRs or a pharmacovigilance program. This is increasingly true of new therapies with novel mechanisms of action. While these therapies may offer important benefits and/or better treatment alternatives, they may also involve a relatively new or higher level of scientific complexity and, therefore, generate increased safety concerns.

Most patients receiving our principal products for approved indications are covered by either government or private payer healthcare programs, which are placing greater emphasis on cost containment, including requiring that the economic value of products be clearly demonstrated. Governments may regulate access to, prices or reimbursement levels of our products to control costs or to affect levels of use of our products and private insurers may be influenced by government reimbursement methodologies. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to healthcare

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providers or patients in response to ongoing initiatives to reduce or reallocate healthcare expenditures. Therefore, sales of our principal products have and will continue to be affected by the availability and extent of reimbursement from third-party payers, including government and private insurance plans, and administration of those programs. Additionally, ongoing healthcare reform efforts may also have a significant impact on our business. For example healthcare reform, focused on expanding healthcare coverage to millions of uninsured Americans and reducing the rate of increase in the costs of healthcare, remains a priority for President Obama, U.S. Congress and a number of states. Developments in this area have been highly dynamic and difficult to predict. As recently as February 23, 2010, President Obama released a new proposal for healthcare reform which includes a combination of provisions from both the Senate and House of Representatives bills passed in late 2009. Certain healthcare reform proposals being considered, which may or may not be adopted into law, could:

- restrict the coverage and reimbursement of our products by Medicare, Medicaid and other government programs
- reduce the number of years of data exclusivity for innovative biological products potentially leading to earlier biosimilar competition and/or
- require additional healthcare reform costs be borne by pharmaceutical and biotechnology companies

At this time, we cannot predict which or whether any reform measures will be adopted into law.

We primarily earn revenues and income and generate cash 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 co-promotion 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 and Selected Product Candidates*. Our product sales are subject to certain influences throughout the year, including wholesaler and customer buying patterns, both of which fluctuate around holidays, and contract-driven customer buying. These factors can periodically result in higher U.S. wholesaler distributor inventory levels in the United States, and therefore higher product sales. We did not experience as large of an increase in wholesaler inventory levels in the fourth quarter of 2009 as in the prior year.

Worldwide product sales for the year ended December 31, 2009 were $14.4 billion, representing a decrease of 2% compared to 2008. U.S. product sales for the year ended December 31, 2009 were $11.1 billion compared to $11.5 billion in 2008, representing a decrease of 3%. The decrease in U.S. product sales was largely attributable to a 24% decline in Aranesp® sales primarily reflecting the negative impact of a product safety-related label change that occurred in August 2008. Combined sales of our other products in the United States in 2009 increased 1% compared to 2008 as increased EPOGEN® sales in 2009 largely offset the decline in ENBREL sales. This decrease in ENBREL sales primarily reflects the unfavorable change in wholesaler inventories resulting from an approximate $100 million wholesaler inventory build in 2008 related to the shift of ENBREL to a wholesaler distribution model.

International product sales were relatively unchanged at $3.2 billion for the year ended December 31, 2009. International product sales for 2009 were unfavorably impacted by foreign currency exchange rate changes of $213 million. Excluding the impact of foreign currency exchange rate changes, international product sales for the year ended December 31, 2009 increased 6%. This increase in international product sales is primarily due to the launches of Vectibix®, Mimpara® and Nplate® into our existing international markets and the expansion of Neulasta® and NEUPOGEN® into new international territories.

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 are partially offset 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 the Euro.

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Our operating expenses for the year ended December 31, 2009 declined approximately $650 million, or 7%, over 2008 of which approximately one-half of this reduction was attributable to lower legal settlements and restructuring and related costs. In addition, cost of sales declined in 2009 principally due to improved operating efficiencies and lower sales volume, partially offset by a less favorable product mix. Our R&D expenses in 2009 also declined primarily due to lower clinical trial costs due to the completion of certain late-stage registrational studies for denosumab and Vectibix®. These decreases in our operating expenses were partially offset by a slight increase in our SG&A expenses primarily due to increased promotional expenses, including spending for activities in advance of our anticipated launch of Prolia. This reduction in operating expenses also reflects, in part, our continuing efforts to maintain control over discretionary expenditures.

For the year ended December 31, 2009, our net income was $4.6 billion, or $4.51 per share on a diluted basis, reflecting increases of 14% and 20%, respectively, compared to 2008. The growth in our net income principally reflects our reduced operating expenses, discussed above, and a reduction in our provision for income taxes primarily due to favorable income tax settlements of approximately $220 million and increased manufacturing and profits in Puerto Rico, which are taxed under an incentive grant. Our 2009 EPS also benefited from a reduction in our weighted average shares used to compute diluted EPS resulting from our stock repurchase program, including 59 million shares repurchased in 2009 at a total cost of $3.2 billion.

Our financial condition remains strong. At December 31, 2009, our cash, cash equivalents and marketable securities aggregated $13.4 billion, our total debt outstanding was $10.6 billion and our stockholders equity aggregated $22.7 billion. In addition, our cash flow from operations for the year ended December 31, 2009 aggregated $6.3 billion, representing a 6% increase over the prior year. Capital expenditures for 2009 were approximately $530 million, which represents a decrease from $672 million in 2008 due to improved productivity and efficiency in our capital program. We believe that 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. Of our total cash, cash equivalents and marketable securities balance as of December 31, 2009, $12.1 billion was generated from operations in foreign tax jurisdictions and is intended for use in our foreign operations. 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.

Looking forward, we believe that our business will continue to face various regulatory, reimbursement and competitive challenges. In particular, our ESA products, Aranesp® and EPOGEN®, will continue to be impacted by regulatory developments, such as the REMS, which has been recently approved by the FDA, and recent or potential future product label changes, including any that may result from the advisory committee meeting proposed by the FDA to be held in 2010 to re-evaluate the use of ESAs in CKD. In the United States, we rely in large part on the reimbursement of our products through government programs such as Medicare and Medicaid. Reimbursement challenges may result from the MEDCAC meeting scheduled for March 24, 2010 to examine currently available evidence on the use of ESAs to manage anemia in patients who have CKD and the provisions of the CMS proposed rule to implement a bundling prospective payment system for ESRD. In addition, the outcome of the proposed healthcare reform in the United States is very much uncertain at this time. Further, certain of our products will continue to face increasing competitive pressure, including our marketed products in the United States, in particular ENBREL as well as from biosimilar and other products in Europe which compete with Aranesp®, Neulasta® and NEUPOGEN®.

We also have various opportunities to grow our business in the future, primarily due to our late-stage product candidate, denosumab. We continue to work with the FDA regarding our BLA for Prolia. On February 19, 2010, we announced that the FDA has evaluated the content of our Complete Response submission for Prolia in the treatment of PMO, which we submitted on January 25, 2010, and classified it as a Class 2 resubmission. With the Class 2 designation, the FDA set a corresponding PDUFA action date of July 25, 2010. Additionally, in December 2009, the CHMP announced a positive opinion for the marketing authorization for Prolia for the treatment of osteoporosis in postmenopausal women at increased risk of fracture and for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. Furthermore, we announced positive study results from three phase 3 denosumab trials in the treatment of bone metastases that will form the basis of the clinical evidence package for denosumab in advanced cancer, which will be submitted to regulatory authorities later

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in 2010. We also expect the results in 2010 of an additional phase 3 study to evaluate denosumab in patients with non-metastatic prostate cancer to prevent bone metastases. In addition, international expansion into emerging markets will also be an important opportunity for growth.

**Results of Operations**

*Product sales*

For the years ended December 31, 2009, 2008 and 2007, worldwide product sales and total product sales by geographic region were as follows (dollar amounts in millions):

| | 2009 | Change | 2008 | Change | 2007 |
|---|---|---|---|---|---|
| Aranesp® | $ 2,652 | (15)% | $ 3,137 | (13)% | $ 3,614 |
| EPOGEN® | 2,569 | 5% | 2,456 | (1)% | 2,489 |
| Neulasta®/NEUPOGEN® | 4,643 | 0% | 4,659 | 9% | 4,277 |
| ENBREL | 3,493 | (3)% | 3,598 | 11% | 3,230 |
| Sensipar® | 651 | 9% | 597 | 29% | 463 |
| Other | 343 | 43% | 240 | 1% | 238 |
| Total product sales | $ 14,351 | (2)% | $ 14,687 | 3% | $ 14,311 |
| Total U.S. | $ 11,135 | (3)% | $ 11,460 | 0% | $ 11,443 |
| Total International | 3,216 | 0% | 3,227 | 13% | 2,868 |
| Total product sales | $ 14,351 | (2)% | $ 14,687 | 3% | $ 14,311 |

Product sales are influenced by a number of factors, some of which may impact sales of certain of our existing products more significantly than others, including: demand, third-party reimbursement availability and policies, government programs, regulatory developments or guidelines, clinical trial outcomes, clinical practice, contracting and pricing strategies, wholesaler and end-user inventory management practices, patient population growth, fluctuations in foreign currency exchange rates, new product launches and indications, expansion into new countries, competitive products, product supply and acquisitions. In addition, general economic conditions may effect, or in some cases amplify, certain of these factors with a corresponding impact on our product sales. (See *Item 1. Business Marketed Products and Selected Product Candidates* for a discussion of our principal products and their approved indications.)

*Aranesp®*

For the years ended December 31, 2009, 2008 and 2007, total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

| | 2009 | Change | 2008 | Change | 2007 |
|---|---|---|---|---|---|
| Aranesp® U.S. | $ 1,251 | (24)% | $ 1,651 | (23)% | $ 2,154 |
| Aranesp® International | 1,401 | (6)% | 1,486 | 2% | 1,460 |
| Total Aranesp® | $ 2,652 | (15)% | $ 3,137 | (13)% | $ 3,614 |

U.S. Aranesp® sales for the year ended December 31, 2009 decreased 24%. U.S. sales of Aranesp® in 2008 benefited from certain changes in accounting estimates related to product sales return reserves. Excluding the positive impact of these changes in accounting estimates, U.S. sales of Aranesp® decreased approximately 21% compared to the year ended December 31, 2008. This decrease was principally driven by a decline in demand reflecting the negative impact, primarily in the supportive cancer care setting, of a product safety-related label change which occurred in August 2008 and a low single digit decrease in the average net sales price. In addition, the decline in sales also reflects both a decline in the segment and a slight loss of segment share.

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International Aranesp® sales for year ended December 31, 2009 decreased 6%, due to the unfavorable impact of changes in foreign currency exchange rates. For the year ended December 31, 2009, excluding the impact of foreign currency exchange rate changes of approximately $85 million, international Aranesp® sales remained unchanged.

The decrease in U.S. Aranesp® sales for the year ended December 31, 2008 reflects the negative impact on demand, primarily in the supportive cancer care setting, of physician conformance to regulatory and reimbursement developments which principally occurred in the second half of 2007, additional product label changes which occurred in 2008, and to a lesser extent, loss of segment share. The decline in demand was partially offset by an increase in the average net sales price. In addition, U.S. sales of Aranesp® for the year ended December 31, 2008 benefited from a slight change in an accounting estimate related to product sales return reserves. The regulatory and reimbursement developments negatively impacting sales, included (i) the loss of Aranesp® for use in the treatment AoC following the reported results of our AoC phase 3 study in February 2007, (ii) various ESA product safety-related label changes in the United States during 2008 and 2007 and (iii) the CMS NCD issued in July 2007, which significantly restricted Medicare reimbursement for use of Aranesp® in chemotherapy induced anemia ( CIA ) and which we believe has also negatively impacted Aranesp® use in CIA for patients covered by private insurance plans.

The increase in international Aranesp® sales for the year ended December 31, 2008 was due to changes in foreign currency exchange rates, which positively impacted sales growth by approximately $104 million. Excluding the impact of foreign currency exchange rate changes, international Aranesp® sales decreased 5%. This decrease reflects dosing conservatism in the oncology segment and pricing pressures across all ESAs in Europe, which resulted in an overall decrease in the ESA market.

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

regulatory developments, including:

- the REMS for our ESAs, which has been recently approved by the FDA, or other risk management activities undertaken by us or required by the FDA or other regulatory authorities;
- the ESA product label changes reflecting certain results of our TREAT study ( TREAT label changes );
- the proposed FDA advisory committee meeting in 2010 to re-evaluate the use of ESAs to treat anemia in patients with CKD;
- future product label changes, including those we are currently discussing with regulatory authorities;

reimbursement developments, including those resulting from:

- the CMS MEDCAC meeting in March 2010 to examine currently available evidence on the use of ESAs to manage anemia in patients who have CKD;
- government s and/or third-party payer s reaction to regulatory developments, including the REMS for our ESAs, the TREAT label changes and future product label changes;
- changes in reimbursement rates or changes in the basis for reimbursement by the federal and state governments , including Medicare and Medicaid;

- cost containment pressures by third-party payers, including governments and private insurance plans;

our ability to maintain worldwide segment share and differentiate Aranesp® from current and potential future competitive therapies or products, including J&J s Epoetin alfa product marketed in the United States and certain other locations outside of the United States and other competitors products outside of the United States, including biosimilar products that have been launched;

proposed healthcare reform in the United States;

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

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

our contracting and related pricing strategies;

severity and duration of the current global economic downturn;

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;

patient population growth; and

expansion into new international territories.

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

See *Item 1. Business Key Developments,* *Item 1. Business Marketed Products and Selected Product Candidates* 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, 2009, 2008 and 2007, total EPOGEN® sales were as follows (dollar amounts in millions):

| | 2009 | Change | 2008 | Change | 2007 |
|---|---|---|---|---|---|
| EPOGEN® U.S. | $ 2,569 | 5% | $ 2,456 | (1)% | $ 2,489 |

EPOGEN® sales for the year ended December 31, 2009 increased 5%, primarily due to an increase in demand. The increase in demand was principally due to patient population growth, increased dose utilization and an increase in the average net sales price.

The 1% decrease in EPOGEN® sales for the year ended December 31, 2008 was primarily due to a decrease in demand, reflecting a decline in the average net sales price. The increase in demand resulting from patient population growth was offset by a decline in dose/utilization in certain settings. The decline in dose/utilization was related to various ESA product safety-related label changes during 2008 and 2007 and the CMS revision to its EMP, which became effective January 1, 2008. We believe that the EMP implementation significantly impacted physician behavior resulting in declines in dosing trends, as particularly noted in the quarter of implementation. However, this dose decline subsequently moderated throughout 2008.

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

reimbursement developments, including those resulting from:

- changes in reimbursement rates or changes in the basis for reimbursement by the federal and state governments, including Medicare and Medicaid, such as the CMS proposed rule to implement the bundled prospective payment system, which becomes effective in 2011, for dialysis services, drugs and biologicals furnished for treatment of ESRD that are currently billed separately;

- the federal government s reaction to regulatory developments, including the REMS for our ESAs, which has been recently approved by the FDA, and future product label changes;

- the CMS MEDCAC meeting in March 2010 to examine currently available evidence on the use of ESAs to manage anemia in patients who have CKD;

- cost containment pressures from the federal and state governments on healthcare providers;

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regulatory developments, including those resulting from:

- the REMS for our ESAs or other risk management activities undertaken by us or required by the FDA or other regulatory authorities;

- the proposed FDA advisory committee meeting in 2010 to re-evaluate the use of ESAs in CKD;

- future product label changes;

changes in dose fluctuations as healthcare providers continue to refine their treatment practices to maintain patient Hb levels in the 10 to 12 g/dL range;

proposed healthcare reform in the United States;

severity and duration of the current global economic downturn;

governmental or private organization regulations or guidelines relating to the use of our products, including changes in medical guidelines and legislative actions;

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

our contracting and related pricing strategies;

changes in dose utilization;

development of new modalities or therapies to treat anemia associated with CRF; and

patient population growth.

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

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

*Neulasta®/NEUPOGEN®*

For the years ended December 31, 2009, 2008 and 2007, total Neulasta®/NEUPOGEN® sales by geographic region were as follows (dollar amounts in millions):

| | 2009 | Change | 2008 | Change | 2007 |
|---|---|---|---|---|---|
| Neulasta® U.S. | $ 2,527 | 1% | $ 2,505 | 7% | $ 2,351 |
| NEUPOGEN® U.S. | 901 | 1% | 896 | 4% | 861 |
| U.S. Neulasta®/NEUPOGEN® Total | 3,428 | 1% | 3,401 | 6% | 3,212 |
| Neulasta® International | 828 | 2% | 813 | 25% | 649 |
| NEUPOGEN® International | 387 | (13)% | 445 | 7% | 416 |
| International Neulasta®/NEUPOGEN® Total | 1,215 | (3)% | 1,258 | 18% | 1,065 |
| Total Neulasta®/NEUPOGEN® | $ 4,643 | (0)% | $ 4,659 | 9% | $ 4,277 |

U.S. sales of Neulasta®/NEUPOGEN® for the year ended December 31, 2009 increased 1%, primarily due to a low single digit increase in demand partially offset by unfavorable changes in wholesaler inventories. The increase in demand was principally due to an increase in the average net sales price. International Neulasta®/NEUPOGEN® sales for the year ended December 31, 2009 decreased 3%, due to the unfavorable impact of changes in foreign currency exchange rates, partially offset by an increase in demand. For the year ended December 31, 2009, excluding the impact of foreign currency exchange rate changes of approximately $94 million,

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international Neulasta®/NEUPOGEN® sales increased 4%. The increase in demand was primarily due to the continued conversion from NEUPOGEN® to Neulasta® and expansion into new international territories.

The increase in U.S. Neulasta®/NEUPOGEN® sales for the year ended December 31, 2008 primarily reflects an increase in demand for Neulasta® driven by an increase in the average net sales price partially offset by a slight decline in units sold. The increase in international Neulasta®/NEUPOGEN® sales for the year ended December 31, 2008 reflects increased demand principally driven by continued conversion from NEUPOGEN® to Neulasta® as well as changes in foreign currency exchange rates, which positively impacted the growth in combined international sales by $86 million. Excluding the favorable impact of foreign currency exchange rate changes, international Neulasta®/NEUPOGEN® sales increased 10% compared to 2007.

In addition to other factors mentioned in the *Product sales* section above, future Neulasta®/NEUPOGEN® sales will be dependent, in part, on such factors as:

- 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;
- competitive products, including biosimilar products that have been or may be approved and launched in the EU (see *Item 1. Business Marketed Products and Selected Product Candidates* for additional discussion);
- the availability, extent and access to reimbursement by government and third-party payers;
- proposed healthcare reform in the United States;
- governmental or private organization regulations or guidelines relating to the use of our products;
- cost containment pressures from governments and private insurers on healthcare providers;
- penetration of existing segments;
- 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;
- severity and duration of the current global economic downturn;
- our contracting and related pricing strategies;
- expansion into new international territories; and

patient population growth.

See *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, 2009, 2008 and 2007, total ENBREL sales by geographic region were as follows (dollar amounts in millions):

| | 2009 | Change | 2008 | Change | 2007 |
|---|---|---|---|---|---|
| ENBREL U.S. | $ 3,283 | (3)% | $ 3,389 | 11% | $ 3,052 |
| ENBREL Canada | 210 | 0 % | 209 | 17% | 178 |
| Total ENBREL | $ 3,493 | (3)% | $ 3,598 | 11% | $ 3,230 |

ENBREL sales for the year ended December 31, 2009 declined 3%, which primarily reflects an unfavorable change in wholesaler inventories resulting from an approximate $100 million wholesaler inventory build in 2008

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related to a shift of ENBREL to a wholesaler distribution model, partially offset by an increase in demand. The increase in demand was driven by a mid-single digit increase in the average net sales price partially offset by a decline in units sold due to share declines as a result of competitive activity. ENBREL continues to maintain a leading position in both the rheumatology and dermatology segments.

ENBREL sales growth for the year ended December 31, 2008 reflects higher demand principally due to increases in the average net sales price. ENBREL sales were also favorably impacted by approximately $100 million due to a change in our distribution model for ENBREL. Previously, ENBREL was shipped directly to pharmacies. However, beginning in the three months ended March 31, 2008, we commenced using a wholesaler distributor model, similar to our other marketed products. Also, ENBREL sales growth for the year ended December 31, 2008 was affected by share declines in the rheumatology and dermatology segments in the United States compared to the prior year due to increased competitive activity. However, sales growth continued in both rheumatology and dermatology.

In addition to other factors mentioned in the *Product sales* section above, future ENBREL sales will be dependent, in part, on such factors as:

- the effects of competing products or therapies, including new competitive products coming to market, such as Centocor Ortho Biotech s Simponi (golimumab) and Stelara (ustekinumab) and UCB/Nektar Therapeutics Cimzia® (PEGylated anti-TNF alpha) (see *Item 1. Business Marketed Products and Selected Product Candidates*) and, in part, our ability to differentiate ENBREL based on a combination of its safety profile and efficacy;

- proposed healthcare reform in the United States;

- severity and duration of the current global economic downturn;

- the availability, extent and access to reimbursement by government and third-party payers;

- future product label changes;

- risk management activities, including the proposed modification to our REMS, undertaken by us or required by the FDA or other regulatory authorities;

- growth in the rheumatology and dermatology segments;

- 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 product, regulatory or private healthcare organization medical guidelines and reimbursement practices;

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

- cost containment pressures from governments and private insurers on healthcare providers;

- our contracting and related pricing strategies; and

patient population growth.

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

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*Selected operating expenses*

The following table summarizes our operating expenses for the years ended December 31, 2009, 2008 and 2007 (dollar amounts in millions):

| | 2009 | Change | 2008 | Change | 2007 |
|---|---|---|---|---|---|
| Operating expenses: | | | | | |
| Cost of sales (excludes amortization of certain acquired intangible assets) | $ 2,091 | (9)% | $ 2,296 | (10)% | $ 2,548 |
| % of product sales | 15% | | 16% | | 18% |
| Research and development | $ 2,864 | (5)% | $ 3,030 | (7)% | $ 3,266 |
| % of product sales | 20% | | 21% | | 23% |
| Selling, general and administrative | $ 3,820 | 1% | $ 3,789 | 13% | $ 3,361 |
| % of product sales | 27% | | 26% | | 23% |
| Amortization of certain acquired intangible assets | $ 294 | 0% | $ 294 | (1)% | $ 298 |
| Write-off of acquired in-process research and development | $ | 0% | $ | (100)% | $ 590 |
| Other charges | $ 67 | (82)% | $ 380 | (48)% | $ 728 |

*Cost of sales*

Cost of sales, which excludes the amortization of certain acquired intangible assets, ( Cost of sales ) decreased 9% for the year ended December 31, 2009 compared to 2008. The decrease was primarily driven by lower excess capacity charges, lower royalty expenses and lower sales volume, partially offset by less favorable product mix and higher fill and finish costs resulting from lower utilization at our manufacturing facility in Puerto Rico. The decrease in Cost of sales was also driven by lower excess inventory write-offs, primarily due to the $84 million write-off of inventory in 2008 resulting from a strategic decision to change manufacturing processes.

Cost of sales decreased 10% for the year ended December 31, 2008 compared to 2007. The decrease was primarily driven by lower restructuring charges incurred in 2008, as discussed below. In addition, the decline in Cost of sales was due to lower inventory write-offs and lower cost ENBREL, partially offset by higher sales volume and excess capacity charges.

Cost of sales for the years ended December 31, 2009, 2008 and 2007 included $1 million, $6 million and $150 million, respectively, of restructuring and related charges. The restructuring charges incurred in the year ended December 31, 2007 primarily related to accelerated depreciation resulting from the decision to accelerate closure of one of our ENBREL commercial bulk manufacturing operations in connection with the rationalization of our worldwide network of manufacturing facilities. See Note 9, *Restructuring* to the Consolidated Financial Statements for further discussion.

*Research and development*

R&D costs are expensed as incurred and primarily include 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 that have no alternative future use. Net payment or reimbursement of R&D costs for R&D collaborations is recognized when the obligations are incurred or as we become entitled to the cost recovery.

R&D expenses decreased 5% for the year ended December 31, 2009 compared to 2008. This decline was primarily attributable to 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. Additionally, we incurred higher licensing fees, in 2009, related to the

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$60 million expense associated with the Array BioPharma Inc. agreement and the $50 million expense resulting from the payment to Cytokinetics, partially offset by the $100 million expense in 2008 resulting from the upfront payment associated with the Kyowa Hakko Kirin Co. Ltd. ( Kyowa Hakko ) collaboration.

R&D expenses decreased 7% for the year ended December 31, 2008 compared to 2007, which was principally due to $102 million of lower staff-related costs and discretionary expenses; $133 million of lower clinical trial costs; $100 million of cost recoveries derived from our licensing agreements, primarily with Daiichi Sankyo and Takeda and a $16 million decline in restructuring-related costs, as discussed below, partially offset by a $100 million expense in the year ended December 31, 2008 for the upfront payment under our licensing agreement with Kyowa Hakko. Our clinical trial costs were lower for the year ended December 31, 2008 primarily due to the completion of enrollment of our large denosumab clinical trials and the related significant costs associated with site initiation and patient enrollment no longer being incurred, partially offset by increased clinical costs for our emerging pipeline.

R&D expenses for the years ended December 31, 2009, 2008 and 2007 included $6 million, $3 million and $19 million, respectively, of restructuring and related charges. The restructuring charges incurred in the year ended December 31, 2007 primarily related to $38 million in charges related to asset impairments offset by a $19 million benefit associated with the reversal of previously accrued expenses for bonuses and stock-based compensation awards, which were forfeited as a result of the employees termination. See Note 9, *Restructuring* to the Consolidated Financial Statements for further discussion.

*Selling, general and administrative*

Selling, general and administrative ( SG&A ) expenses are primarily comprised 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 include costs and cost recoveries associated with certain collaborative 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 co-promotion 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.

SG&A expenses increased 1% for the year ended December 31, 2009 compared to 2008, primarily due to higher product promotional expenses of $207 million, including increased spending for activities in anticipation of the launch of Prolia. This increase was substantially offset by lower litigation expenses of $38 million, lower expenses associated with the Pfizer profit share of $32 million, expense recoveries associated with our GSK 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, 2009 and 2008, the expense associated with the Pfizer profit share was $1,163 million and $1,195 million, respectively.

SG&A expense increased 13% for the year ended December 31, 2008 compared to 2007, in part due to the impact of our restructuring plan which contributed $161 million to the increase in expenses, as discussed below. The increase was also due to higher expense associated with the Pfizer profit share of $211 million, product promotional spending of $39 million and staff-related costs of $94 million, partially offset by lower litigation expense of $50 million and lower severance costs of $21 million related to our acquisition of the remaining 51% ownership interest in Dompé. For the year ended December 31, 2007, the expense associated with the Pfizer profit share, excluding recoveries recorded as part of our restructuring, as discussed below, was $984 million.

For the year ended December 31, 2009, we recorded $29 million for certain cost saving initiatives. For the year ended December 31, 2008, we recorded $37 million for certain restructuring charges, which primarily included $17 million in asset impairments, $12 million in loss accruals for leases principally related to certain facilities that will not be used in our business and $9 million in implementation costs associated with certain restructuring initiatives. For the year ended December 31, 2007, we recorded $114 million in cost recoveries for

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certain restructuring charges, principally with respect to accelerated depreciation, in connection with our co-promotion agreement with Pfizer and $11 million of benefit associated with the reversal of previously accrued expenses for bonuses and stock-based compensation awards, which were forfeited as a result of the employees termination. See Note 9, *Restructuring* to the Consolidated Financial Statements for further discussion.

*Amortization of certain acquired intangible assets*

Amortization of certain acquired intangible assets relates to products technology rights acquired in connection with the Immunex acquisition. For the year ended December 31, 2007, amortization expense also included $3 million related to the impairment of a non-ENBREL related intangible asset previously acquired in the Immunex acquisition.

*Write-off of acquired in-process research and development*

In accordance with the accounting standards for business combinations, prior to January 1, 2009, the fair value of acquired IPR&D projects, which have no alternative future use and which have not reached technological feasibility at the date of acquisition, were immediately expensed. In 2007, we wrote-off $270 million and $320 million of acquired IPR&D related to the acquisitions of Alantos and Ilypsa, respectively. The Alantos IPR&D amount is related to an orally-administered treatment for type II diabetes that, at the date of acquisition, was in phase 2a clinical trials. The Ilypsa IPR&D amount is related to a phosphate binder that, at the date of acquisition, was in phase 2 clinical trials for the treatment of hyperphosphatemia in CKD patients on hemodialysis.

We used the income method to determine the estimated fair values of acquired IPR&D, which uses a discounted cash flow model and applies a probability weighting based on estimates of successful product development and commercialization to estimated future net cash flows resulting from projected revenues and related costs. These success rates take into account the stages of completion and the risks surrounding successful development and commercialization of the underlying product candidates. These cash flows were then discounted to present value using a discount rate of 10%. The estimated after-tax cash flows were probability weighted at success rates of 38% for the Alantos product candidate and 77% for the Ilypsa product candidate. The incremental R&D expenses assumed to be incurred to obtain necessary regulatory approval for the Alantos and Ilypsa product candidates are immaterial.

The above assumptions were used solely for the purposes of estimating fair values of these product candidates as of the date of their acquisition. However, we cannot provide assurance that the underlying assumptions used to forecast the cash flows or the timely and successful completion of development and commercialization will materialize, as estimated. The major risks and uncertainties associated with the timely and successful completion of development and commercialization of these product candidates are our ability to confirm their safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not able to market a human therapeutic without obtaining regulatory approvals, and such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D may vary from its estimated value at the date of acquisition.

We are continuing to develop the product candidate acquired in the Alantos acquisition. We have reviewed data from recently-completed phase 1 and 2 clinical trials for AMG 223, the product candidate acquired in the Ilypsa acquisition. The results were consistent with what is likely required for registration of a phosphate-binding therapy. However, in the context of our overall development portfolio, the Company will be reviewing other options for the commercialization of this investigational product.

In addition, in 2006, we wrote-off acquired IPR&D related to the acquisition of Abgenix. The IPR&D amount was primarily related to the rights which we did not own pursuant to our agreement with Abgenix to jointly develop and commercialize panitumumab and related to a royalty that we would have owed to Abgenix with respect to future sales of denosumab as a result of using certain of Abgenix s patented technologies in the development of this product candidate (see *Item 1. Business Marketed Products and Selected Product Candidates* ). The elimination of the royalty on potential future sales of denosumab did not result in us incurring

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any incremental R&D expenses. Panitumumab was Abgenix s fully human monoclonal antibody which, at acquisition, was in phase 2/3 clinical trials for the treatment of certain types of cancer. The incremental R&D expenses assumed to be incurred to obtain necessary regulatory approvals for the various indications of panitumumab were estimated at the time of acquisition at approximately $300 million and would be incurred through 2011 and there have been no significant changes in these estimates.

At the date of acquisition, we intended to develop panitumumab for treatment of various types of cancer. In 2006, panitumumab received FDA approval for the treatment of mCRC after disease progression on, or following, fluoropyrimidine-, oxaliplatin- and irinotecan- containing chemotherapy regimens and is marketed under the trademark Vectibix®. In December 2007, the European Commission granted a conditional marketing authorization for Vectibix® as monotherapy for the treatment of patients with EGFr expressing mCRC with non-mutated (wild-type) *KRAS* genes after failure of standard chemotherapy regimens. This conditional approval is reviewed annually by the CHMP, and in December 2008 we agreed as a condition of the renewal of approval to conduct an additional clinical trial in the existing approved indication. The conditional approval was granted again in December 2009. We are continuing to develop or are evaluating plans to develop Vectibix® in all of the remaining indications we had intended at the date of acquisition. However, since the acquisition, there have been several events that have affected the development plans for Vectibix® and because of these developments, our expected time to obtain regulatory approvals for the remaining indications has been delayed and the expected cost to obtain necessary approvals has increased compared to our original expectations. See *Item 1. Business Marketed Products and Selected Product Candidates* and *Item 1. Business Research and Development and Selected Product Candidates* for developments related to Vectibix® and denosumab.

*Other charges*

As discussed in Note 9, *Restructuring* to the Consolidated Financial Statements, on August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure while continuing to make significant R&D investments and build the framework for our future growth. Subsequently, we identified certain additional initiatives designed to further assist in improving our cost structure. As a result of these restructuring and related charges, we recorded in Other charges in 2009, 2008 and 2007 expenses for staff separation costs of $30 million, $7 million and $209 million, respectively, asset impairments of $36 million and $366 million in 2008 and 2007, respectively, and charges of $4 million, $49 million and $119 million, respectively, primarily related to the loss accruals for leases for certain facilities that will not be used in our business.

Also, in 2009, the Company recorded in Other charges loss accruals for settlements of certain legal proceedings aggregating $33 million. Also, in 2008, the Company recorded in Other charges loss accruals for settlements of certain commercial legal proceedings aggregating $288 million, principally related to the settlement of the Ortho Biotech antitrust suit. In addition, in 2007, the Company recorded a $34 million loss accrual for an ongoing commercial legal proceeding.

*Interest expense, net*

For the years ended December 31, 2009, 2008 and 2007, interest expense, net was $578 million, $551 million and $496 million, respectively. Included in interest expense, net for the years ended December 31, 2009, 2008 and 2007, is the impact of non-cash interest expense of $250 million, $235 million and $168 million, respectively, resulting from the adoption of the new accounting standard that changed the method of accounting for our convertible debt. (See Note 2, *Change in method of accounting for convertible debt instruments* to the Consolidated Financial Statements for further discussion.)

*Interest and other income, net*

Interest and other income, net decreased 22% for the year ended December 31, 2009 compared to 2008. This decline is primarily due to lower interest income of $45 million, principally due 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; partially offset by higher foreign currency exchange

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net gains of $27 million. Interest and other income, net increased 14% for the year ended December 31, 2008 compared to 2007. This increase is primarily due to higher net gains on sales of investments of $79 million; higher interest income of $20 million, principally due to higher portfolio investment returns; partially offset by higher foreign currency exchange net losses of $34 million.

*Income taxes*

Our effective tax rate was 11.5%, 19.2% and 18.9% for 2009, 2008 and 2007, respectively. Our effective tax rate for 2009 decreased over 2008 primarily due to: (i) the favorable resolution of certain prior years matters with tax authorities, (ii) higher profits and manufacturing in Puerto Rico, which are taxed under an incentive grant, and (iii) a tax benefit from adjustments to previously established 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 the year ended December 31, 2009 reduced the effective tax rate by 4.2%.

Our effective tax rate for 2008 remained relatively unchanged from 2007. Although the 2007 effective tax rate benefited from the favorable resolution of certain income tax examinations, this benefit was substantially offset by the write-off of nondeductible acquired IPR&D costs, resulting in a comparable effective tax rate between the two years.

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 5, *Income taxes* to the Consolidated Financial Statements for further discussion.)

*Recent accounting pronouncements*

In June 2009, the Financial Accounting Standards Board ( FASB ) issued a new accounting standard which amends guidance regarding consolidation of variable interest entities to address the elimination of the concept of a qualifying special purpose entity. This standard also replaces the quantitative-based risks and rewards calculation for determining which enterprise has a controlling financial interest in a variable interest entity with an approach focused on identifying which enterprise has the power to direct the activities of the variable interest entity and the obligation to absorb losses of the entity or the right to receive benefits from the entity. Additionally, this standard requires any enterprise that holds a variable interest in a variable interest entity to make ongoing assessments of whether it has a controlling financial interest in the variable interest entity and to provide enhanced disclosures that will provide users of financial statements with more transparent information about an enterprise s involvement in the variable interest entity. This standard is effective for us beginning January 1, 2010. The adoption of this standard is not expected to have a material impact on our consolidated results of operations, financial position or cash flows.

In October 2009, the FASB issued a new accounting standard which amends guidance on accounting for revenue arrangements involving the delivery of more than one element of goods and/or services. This standard addresses the unit of accounting for arrangements involving multiple deliverables and removes the previous separation criteria that objective and reliable evidence of fair value of any undelivered item must exist for the delivered item to be considered a separate unit of accounting. This standard also addresses how the arrangement consideration should be allocated to each deliverable. Finally, this standard expands disclosures related to multiple element revenue arrangements. This standard is effective for us beginning January 1, 2011. The adoption of this standard is not expected to have a material impact on our consolidated results of operations, financial position or cash flows.

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**Financial Condition, Liquidity and Capital Resources**

The following table summarizes selected financial data. The amounts reflect the adoption of a new accounting standard which changed the method of accounting for our convertible debt (see Note 2, *Change in method of accounting for convertible debt instruments* to the Consolidated Financial Statements for further discussion of our adoption of this new accounting standard, effective January 1, 2009) (in millions):

| | December 31, | |
|---|---|---|
| | **2009** | **2008** |
| Cash, cash equivalents and marketable securities | $ 13,442 | $ 9,552 |
| Total assets | 39,629 | 36,427 |
| Current debt | | 1,000 |
| Non-current debt | 10,601 | 8,352 |
| Stockholders equity | 22,667 | 20,885 |

We believe that 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. (See *Item 1A. Risk Factors Current economic conditions may magnify certain risks that affect our business.* )

*Cash, cash equivalents and marketable securities*

Of the total cash, cash equivalents and marketable securities at December 31, 2009, approximately $12.1 billion was generated from operations in foreign tax jurisdictions and is intended for use in our foreign operations. 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 objectives for our marketable security investment portfolio are liquidity and safety of principal. Investments are made with the objective of achieving the highest rate of return, consistent with these two objectives. Our investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

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*Financing arrangements*

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements and the amounts reflect, where applicable, the adoption of the new accounting standard that changed the method of accounting for our convertible debt (dollar amounts in millions):

| | December 31, | |
|---|---|---|
| | 2009 | 2008 |
| 0.125% convertible notes due 2011 (2011 Convertible Notes) | $ 2,342 | $ 2,206 |
| 0.375% convertible notes due 2013 (2013 Convertible Notes) | 2,088 | 1,970 |
| 5.85% notes due 2017 (2017 Notes) | 1,099 | 1,099 |
| 4.00% notes due 2009 (2009 Notes) | | 1,000 |
| 4.85% notes due 2014 (2014 Notes) | 1,000 | 1,000 |
| 5.70% notes due 2019 (2019 Notes) | 998 | |
| 6.40% notes due 2039 (2039 Notes) | 995 | |
| 6.375% notes due 2037 (2037 Notes) | 899 | 899 |
| 6.15% notes due 2018 (2018 Notes) | 499 | 499 |
| 6.90% notes due 2038 (2038 Notes) | 499 | 498 |
| Zero-coupon modified convertible notes due in 2032 (2032 Modified Convertible Notes) | 82 | 81 |
| 8.125% notes due 2097 (Other) | 100 | 100 |
| Total borrowings | 10,601 | 9,352 |
| Less current portion | | 1,000 |
| Total non-current debt | $ 10,601 | $ 8,352 |

In November 2009, $1.0 billion aggregate principal amount of notes with a fixed interest rate of 4.00% (the 2009 Notes ) became due and were repaid.

In January 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 a registered offering. The 2019 Notes and the 2039 Notes pay interest at fixed annual rates of 5.70% and 6.40%, respectively. The 2019 Notes and the 2039 Notes may be redeemed at any time at our option, in whole or in part, at 100% of the principal amount of the notes being redeemed plus accrued and unpaid interest, if any, and a make-whole amount, as defined. Upon the occurrence of a change in control triggering event, as defined, we may be required to purchase for cash all or a portion of the 2019 Notes and the 2039 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. Debt issuance costs totaled approximately $13 million and are being amortized over the lives of the notes.

In May 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 a registered offering. The 2018 Notes and 2038 Notes pay interest at fixed annual rates of 6.15% and 6.90%, respectively. The 2018 Notes and 2038 Notes may be redeemed at any time at our option, in whole or in part, at 100% of 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 the 2018 Notes and 2038 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. Debt issuance costs totaled approximately $6 million and are being amortized over the life of the notes. Upon the receipt of the proceeds from the issuance of the 2018 Notes and 2038 Notes discussed above, in June 2008 we exercised our right to call and repaid $1.0 billion of the 2008 Floating Rate Notes which were scheduled to mature in November 2008. In November 2008, the remaining $1.0 billion aggregate principal amount of the 2008 Floating Rate Notes became due and were repaid.

As of December 31, 2009, we had $7.6 billion of additional notes outstanding. The notes consisted of (i) $2.3 billion of convertible notes that bear interest at a fixed rate of 0.125% and mature in February 2011 ( 2011 Convertible Notes ), (ii) $2.1 billion of convertible notes that bear interest at a fixed rate of 0.375% and mature in February 2013 ( 2013 Convertible Notes ), (iii) $1.1 billion of notes that bear interest at a fixed rate of

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5.85% and mature in 2017 ( 2017 Notes ), (iv) $1.0 billion of notes that bear interest at a fixed rate of 4.85% and mature in 2014 ( 2014 Notes ), (v) $899 million of notes that bear interest at a fixed rate of 6.375% and mature in 2037 ( 2037 Notes ), (vi) $100 million of other long-term debt securities that bear interest at a fixed rate of 8.125% and mature in 2097 and (vii) zero-coupon convertible notes due in 2032 with an accreted value of $82 million and having an aggregate face amount of $105 million and yield to maturity of 1.125%. See Note 16, *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 LIBOR-based floating rate 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, 2009, we had interest rate swap agreements for our 2014 Notes and 2018 Notes, with an aggregate face value of $1.5 billion. As of December 31, 2008, we had interest rate swap agreements for our 2009 Notes, 2014 Notes, 2018 Notes and other notes, with an aggregate face value of $2.6 billion.

As of December 31, 2009, 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, 2009, no amounts were outstanding under our commercial paper program.

As of December 31, 2009, 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 0.045% based on our current credit rating. As of December 31, 2009, 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.

As of December 31, 2009, 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. All of the $400 million of debt securities available for issuance may be offered from time to time under our medium-term note program with terms to be determined at the time of issuance. As of December 31, 2009, no securities were outstanding under the $400 million 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, 2009. None of our financing arrangements contain any financial covenants. Our outstanding convertible notes and other outstanding long-term debt are rated A+ with a stable outlook by Standard & Poor s, A3 with a stable outlook by Moody s Investors Service, Inc. and A with a stable outlook by Fitch, Inc.

*Cash flows*

The following table summarizes our cash flow activity (in millions):

| | 2009 | 2008 | 2007 |
|---|---|---|---|
| Net cash provided by operating activities | $ 6,336 | $ 5,988 | $ 5,401 |
| Net cash used in investing activities | (3,202) | (3,165) | (1,992) |
| Net cash used in financing activities | (2,024) | (3,073) | (2,668) |

*Operating*

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities increased in 2009 primarily due to higher net income of $553 million and a higher dividend payment from KA of $102 million partially offset by the prior year receipt of

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$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. Cash provided by operating activities increased in 2008 primarily as a result of improvement in operating income.

*Investing*

Net purchases of marketable securities were $2.7 billion for the year ended December 31, 2009 compared to net purchases of $2.6 billion for the year ended December 31, 2008 and net purchases of $52 million for the year ended December 31, 2007.

Capital expenditures totaled $530 million in 2009, $672 million in 2008 and $1.3 billion in 2007. Capital expenditures in 2009 were primarily associated with manufacturing capacity expansions in Puerto Rico and other site developments. Capital expenditures in 2008 were primarily associated with manufacturing capacity expansions in Puerto Rico, Fremont and other site developments and investment in our global ERP system and other information systems projects. Capital expenditures in 2007 were primarily associated with manufacturing capacity and site expansions in Puerto Rico and other locations and investment in our global ERP system. We currently estimate 2010 spending on capital projects and equipment to be approximately $600 million.

On January 4, 2008, we completed our acquisition of Dompé and pursuant to the merger agreement, we paid $56 million in cash, net of cash acquired and transaction costs of $2 million.

On July 18, 2007, we completed our acquisition of Ilypsa and pursuant to the merger agreement, we paid $398 million in cash, net of cash acquired and transaction costs of $2 million. On July 16, 2007, we completed our acquisition of Alantos and pursuant to the merger agreement, we paid $299 million in cash, net of cash acquired and transaction costs of $1 million.

*Financing*

In December 2009, the Board of Directors authorized us to repurchase up to an additional $5.0 billion of common stock adding to the $5.0 billion previously authorized in July 2007. As of December 31, 2009, we had $6.0 billion available for stock repurchases as authorized by our Board of Directors. 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 our credit rating and may include private block purchases as well as market transactions. A summary of our repurchase activity under our stock repurchase programs is as follows (in millions):

| | 2009 | | 2008 | | 2007 | |
|---|---|---|---|---|---|---|
| | Shares | Dollars | Shares | Dollars | Shares | Dollars |
| First quarter | 37.5 | $ 1,997 | | $ | 8.8 | $ 537 |
| Second quarter | | | 32.7 | 1,549[1] | 73.9[2] | 4,463 |
| Third quarter | | | | 19[1] | 2.5[2] | |
| Fourth quarter | 21.7 | 1,211 | 12.6 | 700 | 1.8 | 100 |
| Total | 59.2 | $ 3,208 | 45.3 | $ 2,268 | 87.0 | $ 5,100 |

(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 ASR program entered into in May 2008.

(2) The total number of shares repurchased during the three months ended June 30, 2007 excludes 2.5 million shares received in July 2007 in connection with the final settlement of an ASR entered into in May 2007.

As discussed above, in January 2009, we issued $1.0 billion aggregate principal amount of notes due in 2019 and $1.0 billion aggregate principal amount of notes due in 2039 resulting in net proceeds received of $2.0 billion. In November 2009, we repaid $1.0 billion of 4.00% notes that matured.

As discussed above, in May 2008, we issued $500 million aggregate principal amount of notes due in 2018 and $500 million aggregate principal amount of notes due in 2038 resulting in net proceeds received of $991

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million. In June 2008, upon receipt of the proceeds from the issuance of these notes, we exercised our right to call and repaid $1.0 billion of floating rate notes scheduled to mature in November 2008 and in November 2008, we repaid the remaining $1.0 billion of floating rate notes that matured.

In May 2007, we issued $2.0 billion aggregate principal amount of 2008 Floating Rate Notes, $1.1 billion aggregate principal amount of 5.85% notes due in 2017 and $900 million aggregate principal amount of 6.375% notes due in 2037, resulting in net proceeds of $4.0 billion. A total of $3.2 billion of the net proceeds raised from the issuance of these notes were used to repurchase shares of our common stock under an ASR entered into in May 2007.

On March 2, 2007, as a result of holders of substantially all of our outstanding 2032 Modified Convertible Notes exercising their March 1, 2007 put option, we repurchased $2.3 billion aggregate principal amount or the majority of the then outstanding convertible notes at their then-accreted value for $1.7 billion in cash. In addition $135 million of other debt securities matured and were repaid in 2007.

We receive cash from the exercise of employee stock options. Employee stock option exercises provided $171 million, $155 million and $277 million of cash during the years ended December 31, 2009, 2008 and 2007, 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 be material to our consolidated financial position or consolidated results of operations.

**Contractual Obligations**

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

The following table represents our contractual obligations as of December 31, 2009, aggregated by type (in millions):

| | | Payments due by period | | | |
|---|---|---|---|---|---|
| **Contractual obligations** | **Total** | **Less than 1 year** | **2-3 years** | **4-5 years** | **More than 5 years** |
| Long-term debt obligations[1] | $ 17,736 | $ 323 | $ 3,276 | $ 4,225 | $ 9,912 |
| Operating lease obligations | 1,017 | 136 | 231 | 184 | 466 |
| Purchase obligations[2] | 3,715 | 939 | 793 | 278 | 1,705 |
| Total contractual obligations | $ 22,468 | $ 1,398 | $ 4,300 | $ 4,687 | $ 12,083 |

(1) The long-term debt obligation amounts include future interest payments. Future interest payments are included on the 2011 Convertible Notes at a fixed rate of 0.125%, the 2013 Convertible Notes at a fixed rate of 0.375%, the 2017 Notes at a fixed rate of 5.85%, the 2014 Notes at a fixed rate of 4.85%, the 2019 Notes at a fixed rate of 5.70%, the 2039 Notes at a fixed rate of 6.40%, the 2037 Notes at a fixed rate of 6.375%, the 2018 Notes at a fixed rate of 6.15%, the 2038 Notes at a fixed rate of 6.90% and the other notes at a fixed rate of 8.125%. To achieve a desired mix of fixed and floating interest rate debt, we enter into interest rate swap agreements. These interest rate swap agreements effectively convert a fixed rate interest coupon to a LIBOR-based floating rate coupon over the life of the respective note. We used an interest rate forward curve at December 31, 2009 to compute the net amounts to be included in the table above for future interest payments on our variable rate interest rate swaps.

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(2) Purchase obligations primarily relate 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; (iv) open purchase orders for the acquisition of goods and services in the ordinary course of business and (v) our agreement with International Business Machines Corporation ( IBM ), which we entered into on October 22, 2008, for certain information systems infrastructure services. The term of the agreement is five years with three one-year renewals, at our option, for a total of up to eight years. The cost to us for the initial five-year term, is estimated to be $505 million, included in the table above is $363 million for the remaining obligation. The estimated aggregate additional cost of the three one-year renewal options not included in the table above is approximately $219 million. Our obligation to pay certain of these amounts may be reduced based on certain future events.

Long-term liabilities for unrecognized tax benefits ( UTBs ) (net of federal tax benefits on state taxes) and related accrued interest and penalty totaling approximately $1.1 billion at December 31, 2009 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. As of December 31, 2009, we do not have any liabilities for UTBs classified as current liabilities.

In addition to the above table, we are contractually obligated to make potential future success-based development, regulatory and commercial milestone payments in conjunction with collaborative agreements we have entered into with third-parties. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, we may be required to pay such amounts. As payment of these amounts is not considered probable, these contingent payments have not been included in the table above or recorded on our Consolidated Balance Sheets. Further, the timing of any future payment is not reasonable estimable. Individually, future payment of any amounts under these arrangements is not expected to be material in any one reporting period. As of December 31, 2009, the maximum amount that may be payable in the future under all such arrangement is approximately $1.8 billion.

**Summary of Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with 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.

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We analyze the adequacy of our sales deductions accruals each quarter. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate. Accruals are also adjusted to reflect actual results. The following table summarizes amounts recorded in Accrued liabilities in the Consolidated Balance Sheets regarding sales deductions (in millions):

| | Rebates | Chargebacks | Cash discounts | Other deductions | Total |
|---|---|---|---|---|---|
| Balance as of January 1, 2007 | $ 788 | $ 73 | $ 36 | $ 182 | $ 1,079 |
| Amounts charged against product sales | 2,156 | 1,649 | 337 | 357 | 4,499 |
| Payments | (2,189) | (1,652) | (331) | (342) | (4,514) |
| Balance as of December 31, 2007 | 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 |

For the years ended December 31, 2009, 2008 and 2007, total sales deductions were 24%, 22% and 24% of gross product sales. Included in these amounts are immaterial adjustments related to prior year sales based on changes in estimates. Such amounts represent less than 2% of the aggregate sales deductions charged against product sales for each of the three years ended December 31, 2009. 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 principally distributed to hospitals and/or wholesalers depending upon the distribution practice in each country for which the product is sold. We monitor the inventory levels of our products at our wholesale distributors using data from our wholesalers and other third-parties and we believe that 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 primarily based 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 earned by healthcare providers in the United States may include performance-based offers, such as attaining contractually-specified segment share or other performance-based measures. As a result, the calculation of the accrual for these rebates is complicated by the need to estimate customer buying patterns and the resulting applicable contractual rebate rate(s) to be earned over a contractual period. These rebates totaled $1.5 billion, $1.8 billion and $2.2 billion for the years ended December 31, 2009, 2008 and 2007, respectively. We believe that 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 3.5% of the estimated rebate amounts charged against product sales for such periods. These changes in annual estimates substantially relate to sales made in the immediately preceding annual period. A 3.5% change in our rebate estimate attributable to rebates recognized in 2009 would have had an impact of approximately $52 million on our 2009 product sales and a corresponding impact on our financial condition and liquidity.

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Wholesaler chargebacks relate to our contractual agreements to sell products to healthcare providers in the United States at fixed prices that are lower than the prices we charge wholesalers. When the healthcare providers purchase our products through wholesalers at these reduced prices, the wholesaler charges us for the difference between the prices they pay us and the prices they sold the products to the healthcare providers. The provision for chargebacks is based on the expected sales by our wholesaler customers to healthcare providers. These chargebacks from wholesalers totaled $2.4 billion, $1.6 billion and $1.6 billion for the years ended December 31, 2009, 2008 and 2007, 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 settle these deductions generally within a few weeks of incurring the liability.

*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% 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 considering 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 late-stage product candidate, Prolia. In the United States, Prolia is currently being reviewed by the FDA for use in the treatment of PMO in women. On February 19, 2010, we announced that the FDA has evaluated the content of our Complete Response submission for Prolia in the treatment of PMO, which we submitted on January 25, 2010, and classified it as a Class 2 resubmission. With the Class 2 designation, the FDA set a corresponding PDUFA action date of July 25, 2010. In addition in December 2009, the CHMP announced a positive opinion for the marketing authorization of 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. If approved by the European Commission, we would receive marketing authorization for Prolia in all EU Member States. The timing of actual launch dates would vary by country based on reimbursement authority approval of pricing which could follow the EMA approval by many months.

*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 has greater than a 50% likelihood of being 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

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resolution of an examination. We believe that our estimates for uncertain tax positions are appropriate and sufficient to pay assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties, where appropriate, related to UTBs in income tax expense.

Certain items are included in the Company s tax return at different times than they are reflected in the financial statements. Such timing differences create deferred tax assets and liabilities. Deferred tax assets are generally items that can be used as a tax deduction or credit in the tax return in future years but for which the Company has already recorded the tax benefit in the financial statements. The Company establishes valuation allowances against its deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities are either: (i) a tax expense recognized in the financial statements for which payment has been deferred; or (ii) an expense for which the Company has already taken a deduction on the tax return, but has not yet recognized the expense in the financial statements.

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, an additional tax provision and related liability would be required at the applicable U.S. and state marginal income tax rates which could materially impact our future effective tax rate.

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 20, *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 a global biotechnology company with operations in various countries. 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 as part of our risk management program. We do not use derivatives for speculative trading purposes and are not a party to leveraged derivatives.

The capital and credit markets have experienced extreme volatility and disruption which has led to uncertainty and liquidity issues for both borrowers and investors. Short-term interest rates on U.S. treasury instruments have declined considerably while other short-term rates have fluctuated in excess of historical norms. 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, 2009 and 2008. Similarly, over this same period there has been extraordinary

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volatility in the currency markets, and we have consequentially assumed a hypothetical 20% change in foreign exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2009 and 2008.

*Interest rate sensitive financial instruments*

Our investment portfolio of available-for-sale debt securities at December 31, 2009 and 2008 was comprised primarily of U.S. treasury securities; obligations of U.S. government agencies and FDIC guaranteed bank debt; corporate debt securities; mortgage and asset backed securities; money market mutual funds; and other short-term interest bearing securities, principally comprised of commercial paper. The fair value of our investment portfolio of debt securities was $13.3 billion and $9.4 billion at December 31, 2009 and 2008, 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, 2009 and 2008 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, 2009 and 2008 would not result in a material effect on the related income or cash flows in the respective ensuing year.

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. As of December 31, 2008, we had outstanding debt with a carrying value of $9.4 billion and a fair value of $9.8 billion. Our outstanding debt at December 31, 2009 and 2008 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, 2009, would have resulted in an increase of approximately $760 million 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, 2008, would have resulted in an increase of approximately $560 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 $1.5 billion and $2.6 billion at December 31, 2009 and 2008, respectively. These derivative contracts effectively convert a fixed rate interest coupon to a LIBOR-based floating rate coupon over the life of the respective note. A hypothetical 100 basis point increase in interest rates relative to interest rates at December 31, 2009 and 2008 would not have resulted in a material effect on 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 results of operations 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 partially offset 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 forward and options contracts that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2009, we had open forward and options contracts, primarily Euro based, with notional amounts of $3.4 billion and $376 million, respectively. As of December 31, 2008, we had open forward and options contracts, primarily Euro based, with notional amounts of $2.5 billion and $386 million, respectively. As of December 31, 2009, the net unrealized losses and at December 31, 2008 the net unrealized gains on these contracts were not material. With regard to forward and option 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 approximately $720 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, 2008, a hypothetical 20% adverse

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movement in foreign exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2008, would have resulted in a reduction in fair value of approximately $550 million on this date and, in the ensuing year, a reduction in income and cash flows of approximately $260 million.

Also at December 31, 2009 and 2008, we had open forward contracts with notional amounts totaling $414 million and $472 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, 2009 and 2008. With regard to forward contracts that were open at December 31, 2009 and 2008 a hypothetical 20% adverse movement in foreign exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2009 and 2008 would not have had a material impact on fair value on these dates or 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, 2009 and 2008, 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, 2009 and 2008 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 this 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, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2009.

Management determined that, as of December 31, 2009, 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.

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**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, 2009. 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, 2009, based on those 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, 2009.

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**Report of Independent Registered Public Accounting Firm**

**The Board of Directors and Stockholders of Amgen Inc.**

We have audited Amgen Inc. s (the Company ) internal control over financial reporting as of December 31, 2009, 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, 2009, 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, 2009 and 2008, and the related Consolidated Statements of Income, Stockholders Equity, and Cash Flows for each of the three years in the period ended December 31, 2009 and our report dated March 1, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California

March 1, 2010

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**Item 9B. OTHER INFORMATION**

Not applicable.

**PART III**

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

Information about our Directors is incorporated by reference from the section entitled ITEM 1 ELECTION OF DIRECTORS in our Proxy Statement for the 2010 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2009 (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 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.

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

**Securities Authorized for Issuance Under Existing Equity Compensation Plans**

The following table sets forth certain information as of December 31, 2009 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, 2009 (including upon the exercise of options, pursuant to purchases of stock or upon vesting of awards of restricted stock units or performance units).

| Plan Category | (a) Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights | (b) Weighted Average Exercise Price Outstanding Options and Rights | (c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) |
|---|---|---|---|
| Equity compensation plans approved by Amgen security holders: | | | |
| 2009 Equity Incentive Plan[1] | 10,797,273 | $ 50.65 | 85,264,250 |
| Amended and Restated 1991 Equity Incentive Plan[2] | 22,987,958 | $ 58.31 | |
| Amended and Restated Employee Stock Purchase Plan[3] | | $ | 6,691,213 |
| Total Approved Plans | 33,785,231 | $ 56.16 | 91,955,463 |
| Equity compensation plans not approved by Amgen security holders: | | | |
| Amended and Restated 1993 Equity Incentive Plan[4] | 342,071 | $ 44.88 | |
| Amended and Restated 1999 Equity Incentive Plan[4] | 12,371,992 | $ 61.41 | |
| Amended and Restated 1997 Equity Incentive Plan[5] | 1,394,661 | $ 52.76 | |
| Amended and Restated 1997 Special Non-Officer Equity Incentive Plan[6] | 12,144,790 | $ 64.35 | |
| Amended and Restated 1996 Incentive Stock Plan[7] | 320,365 | $ 68.82 | |
| Amended and Restated 1999 Incentive Stock Plan[7] | 2,051,331 | $ 64.33 | |
| Amended and Restated Assumed Avidia Equity Plan[8] | 17,990 | $ 2.00 | |
| Total Unapproved Plans | 28,643,200 | $ 62.24 | |
| Total All Plans | 62,428,431 | $ 59.50 | 91,955,463 |

(1) The number under column (a) with respect to this plan includes approximately 6.44 million shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $50.65, approximately 3.43 million shares issuable upon the vesting of outstanding restricted stock units and approximately 0.93 million shares issuable upon the vesting of outstanding performance units. The performance units awarded in 2009 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. 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 such forfeiture,

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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 16.44 million shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $58.31, approximately 4.60 million shares issuable upon the vesting of outstanding restricted stock units and approximately 1.95 million shares issuable upon the vesting of outstanding performance units based on a target performance, including approximately 0.87 million performance units granted in 2008 which continue to be subject to performance goals and approximately 1.08 million performance units granted in 2007 for which the performance period ended on December 31, 2009. The maximum that could be earned would be 200% of the units granted in 2008 and 225% of the units granted in 2007.

(3) The purchases occurred on June 30, 2009 and December 31, 2009 (the Purchase Dates ) with a purchase of 198,769 shares of Common Stock at a purchase price of $50.29 per shares on June 30, 2009 and 146,984 shares of Common Stock at a purchase price of $53.74 per share on December 31, 2009. 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 12.327 million shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $61.41 and approximately 45,000 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 11.86 million shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $64.35 and approximately 282,000 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 318,000 shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $68.82 and approximately 2,000 shares issuable upon the vesting of outstanding restricted stock units. The number under column (a) with respect to the Amended and Restated 1999 Incentive Stock Plan includes approximately 1.625 million shares issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $64.33 and approximately 426,000 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.

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**Security Ownership of Directors and Executive Officers and Certain Beneficial Owners**

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

**Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

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

**Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

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

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**PART IV**

**Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

*(a)1. Index to Financial Statements*

The following Consolidated Financial Statements are included herein:


| | 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, 2009 | F-2 |
| Consolidated Balance Sheets at December 31, 2009 and 2008 | F-3 |
| Consolidated Statements of Stockholders Equity for each of the three years in the period ended December 31, 2009 | F-4 |
| Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2009 | F-5 |
| Notes to Consolidated Financial Statements | F-6 - F-57 |


*(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-58 |


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 Effective January 9, 2006). (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 Effective 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 Effective 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 Effective 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 Effective May 12, 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 Effective May 12, 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 | 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.) |

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| Exhibit No. | Description |
|---|---|
| 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 | 8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.) |
| 4.7 | Officer s Certificate, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of February 26, 1997, establishing a series of securities entitled 8/8% 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 4.00% Senior Note due 2009. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.) |
| 4.13 | 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.) |
| 4.14 | 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.) |
| 4.15 | 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.) |
| 4.16 | Indenture, dated as of May 6, 2005. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.) |
| 4.17 | 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.) |

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| Exhibit No. | Description |
|---|---|
| 4.18 | 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.) |
| 4.19 | 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.) |
| 4.20 | 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.) |
| 4.21 | Registration Rights Agreement, dated as of May 30, 2007, among Amgen Inc. and Morgan Stanley & Co. Incorporated, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Barclays Capital Inc., Credit Suisse Securities (USA) LLC, Goldman, Sachs & Co., Citigroup Global Markets Inc., J.P. Morgan Securities Inc. and Lehman Brothers Inc. (Filed as an exhibit to Form 8-K on May 30, 2007 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 and Restricted Stock Unit Agreement for the Amgen Inc. 2009 Equity Incentive Plan. |
| 10.3+* | Amgen Inc. 2009 Performance Award Program (As Amended and Restated on December 4, 2009). |
| 10.4+ | 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 September 30, 2009 on November 6, 2009 and incorporated herein by reference.) |
| 10.5+ | Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.) |
| 10.6+ | 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.) |
| 10.7+ | Amgen Supplemental Retirement Plan (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.) |
| 10.8+ | Amendment and Restatement of the Amgen Change of Control Severance Plan (As Amended December 9, 2008). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.) |
| 10.9+ | 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.) |
| 10.10+ | 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.) |
| 10.11+ | 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.) |

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| Exhibit No. | Description |
|---|---|
| 10.12+ | 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.) |
| 10.13 | 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.) |
| 10.14 | 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.) |
| 10.15 | 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.) |
| 10.16 | 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.) |
| 10.17 | Amendment No. 12 to the Shareholders Agreement, dated January 31, 2001. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2005 on August 8, 2005 and incorporated herein by reference.) |
| 10.18 | 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.) |
| 10.19 | 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.) |
| 10.20 | 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.) |
| 10.21 | Amendment Agreement, dated June 30, 1988, to Research, Development, Technology Disclosure and License Agreement: GM-CSF dated March 31, 1987, between Kirin Brewery Company, Limited and Amgen Inc. (Filed as an exhibit to Form 8 amending the Quarterly Report on Form 10-Q for the quarter ended June 30, 1988 on August 25, 1988 and incorporated herein by reference.) |
| 10.22 | 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.) |
| 10.23 | 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.) |

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| Exhibit No. | Description |
|---|---|
| 10.24 | 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.) |
| 10.25 | 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.) |
| 10.26 | 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.) |
| 10.27 | 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.) |
| 10.28 | 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.) |
| 10.29 | Amendment No. 3 to Amended and Restated Promotion Agreement, effective as of January 1, 2005, by and among Wyeth, Amgen Inc. and Immunex Corporation (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2005 on May 4, 2005 and incorporated herein by reference.) |
| 10.30 | Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International related to the 0.125% Convertible Senior Notes Due 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.) |
| 10.31 | 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.) |
| 10.32 | Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated February 14, 2006, to Amgen Inc. from Morgan Stanley & Co. International Limited related to the 0.125% Convertible Senior Notes Due 2011 Notes. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.) |
| 10.33 | 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.) |
| 10.34 | Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International for warrants expiring in 2013. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.) |

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| Exhibit No. | Description |
|---|---|
| 10.35 | 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.) |
| 10.36 | Purchase Agreement, dated May 24, 2007, among Amgen Inc., Morgan Stanley & Co. Incorporated, Merrill Lynch, Pierce, Fenner & Smith Incorporated and the Initial Purchasers Names in Schedule A thereof. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.) |
| 10.37 | Purchase Agreement, dated May 29, 2007, between Amgen Inc. and Merrill Lynch International. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.) |
| 10.38 | 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.) |
| 10.39 | 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.) |
| 10.40 | 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.) |
| 10.41 | 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.) |
| 10.42 | 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.) |
| 10.43 | 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.) |
| 10.44 | 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.) |
| 10.45 | Variable Term Accelerated Share Repurchase Transaction dated May 28, 2008, between Amgen Inc. and Lehman Brothers, Inc. acting as Agent Lehman Brothers OTC Derivatives Inc., acting as Principal. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 on August 8, 2008 and incorporated herein by reference.) |

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| Exhibit No. | Description |
|---|---|
| 10.46 | Underwriting Agreement, dated May 20, 2008, among Amgen Inc. with Goldman, Sachs & Co. and Merrill Lynch, Pierce, Fenner & Smith Incorporated, as the representatives of the underwriters. (Filed as an exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.) |
| 10.47 | Underwriting Agreement, dated January 13, 2009, by and among the Company and Goldman, Sachs & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. Incorporated, as representatives of the several underwriters named therein. (Filed as an exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.) |
| 10.48 | 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.) |
| 10.49* | Amendment Number 5, 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). |
| 10.50 | 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.) |
| 10.51 | 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.) |
| 10.52 | 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.) |
| 21* | Subsidiaries of the Company. |
| 23 | Consent of the Independent Registered Public Accounting Firm. The consent is set forth on pages 106 and 107 of this Annual Report on Form 10-K. |
| 24 | Power of Attorney. The Power of Attorney is set forth on pages 104 and 105 of this Annual Report on Form 10-K. |
| 31* | Rule 13a-14(a) Certifications. |
| 32** | Section 1350 Certifications. |
| 101.INS** | XBLR Instance Document. |
| 101.SCH** | XBLR Taxonomy Extension Schema Document. |
| 101.CAL** | XBLR Taxonomy Calculation Linkbase Document. |
| 101.DEF** | XBLR Taxonomy Definition Linkbase Document |
| 101.LAB** | XBLR Taxonomy Label Linkbase Document. |
| 101.PRE** | XBLR Taxonomy Presentation Linkbase Document. |

(* = filed herewith)

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

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

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**SIGNATURES**

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

AMGEN INC.
(Registrant)

Date: 03/01/2010

By: /s/ Robert A. Bradway
**Robert A. Bradway**
**Executive Vice President**
**and Chief Financial Officer**

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**EXHIBIT 24**

**POWER OF ATTORNEY**

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Robert A. Bradway and Michael A. Kelly, 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<br>**Kevin W. Sharer** | Chairman of the Board, Chief Executive Officer and President, and Director (Principal Executive Officer) | 03/01/2010 |
| /s/ Robert A. Bradway<br>**Robert A. Bradway** | Executive Vice President and Chief Financial Officer (Principal Financial Officer) | 03/01/2010 |
| /s/ Michael A. Kelly<br>**Michael A. Kelly** | Vice President Finance and Chief Accounting Officer (Principal Accounting Officer) | 03/01/2010 |
| /s/ David Baltimore<br>**David Baltimore** | Director | 03/01/2010 |
| /s/ Frank J. Biondi, Jr.<br>**Frank J. Biondi, Jr.** | Director | 03/01/2010 |
| /s/ Jerry D. Choate<br>**Jerry D. Choate** | Director | 02/20/2010 |
| /s/ Vance D. Coffman<br>**Vance D. Coffman** | Director | 03/01/2010 |
| /s/ François De Carbonnel<br>**François de Carbonnel** | Director | 02/23/2010 |
| /s/ Frederick W. Gluck<br>**Frederick W. Gluck** | Director | 03/01/2010 |
| /s/ Rebecca M. Henderson | Director | 03/01/2010 |

| | | | |
|---|---|---|---|
| **Rebecca M. Henderson** | | | |
| /s/ Frank C. Herringer | | Director | 03/01/2010 |
| **Frank C. Herringer** | | | |

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| Signature | Title | Date |
|---|---|---|
| /s/ GILBERT S. OMENN<br>**Gilbert S. Omenn** | Director | 03/01/2010 |
| /s/ JUDITH C. PELHAM<br>**Judith C. Pelham** | Director | 03/01/2010 |
| /s/ J. PAUL REASON<br>**J. Paul Reason** | Director | 03/01/2010 |
| /s/ LEONARD D. SCHAEFFER<br>**Leonard D. Schaeffer** | Director | 02/17/2010 |

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**EXHIBIT 23**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in this Annual Report (Form 10-K) of Amgen Inc. of our report dated March 1, 2010, with respect to the consolidated financial statements of Amgen Inc, included in the 2009 Annual Report to Shareholders of Amgen Inc.

Our audits also included the financial statement schedule of Amgen Inc. listed in Item 15(a). This schedule is the responsibility of Amgen Inc. s management. Our responsibility is to express an opinion based on our audits. In our opinion, as to which the date is March 1, 2010, the financial statement schedule referred to above, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

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

Registration Statement (Form S-8 No. 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);

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

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

Registration Statement (Form S-3 No. 333-132286) relating to the potential resale of securities acquired from Amgen Inc. by selling security holders in unregistered private offerings;

Registration Statement (Form S-8 No. 333-132932) pertaining to the Amgen Inc. Amended and Restated 1996 Incentive Stock Plan (formerly known as Abgenix, Inc. 1996 Incentive Stock Plan, as amended and restated), the Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (formerly known as Abgenix, Inc. 1999 Nonstatutory Stock Option Plan, as amended and restated);

Registration Statement (Form S-8 No. 333-133002) pertaining to the Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (formerly known as Abgenix, Inc. 1999 Nonstatutory Stock Option Plan, as amended and restated);

Registration Statement (Form S-8 No. 333-138325) pertaining to the Amgen Inc. Amended and Restated Assumed Avidia Equity Incentive Plan (formerly known as the Avidia, Inc. Amended and Restated 2003 Equity Incentive Plan);

Registration Statement (Form S-4 No. 333-147482) relating to the possible exchange of unregistered Senior Floating Notes for registered Senior Floating Notes relating to the Prospectus of Amgen Inc. for the registration of Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017, 6.375% Senior Notes Due 2037; 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 report dated March 1, 2010, with respect to the consolidated financial statements of Amgen Inc. incorporated herein by reference and our report included in the preceding paragraph with respect to the financial statement schedule of Amgen Inc. included in this Annual Report (Form 10-K) of Amgen Inc. for the year ended December 31, 2009.

/s/ Ernst & Young LLP

Los Angeles, California

March 1, 2010

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**Report of Independent Registered Public Accounting Firm**

**The Board of Directors and Stockholders of Amgen Inc.**

We have audited the accompanying Consolidated Balance Sheets of Amgen Inc. (the Company ) as of December 31, 2009 and 2008, and the related Consolidated Statements of Income, Stockholders Equity, and Cash Flows for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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, 2009, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2010 expressed an unqualified opinion thereon.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for convertible debt instruments with the adoption of the guidance originally issued in Financial Accounting Standards Board s Staff Position No. APB 14-1 (codified in FASB ASC Topic 470, *Debt/Capitalization of Interest*) effective January 1, 2009.

/s/ Ernst & Young LLP

Los Angeles, California

March 1, 2010

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**AMGEN INC.**

**CONSOLIDATED STATEMENTS OF INCOME**

**Years ended December 31, 2009, 2008 and 2007**

**(In millions, except per share data)**

| | 2009 | 2008 | 2007 |
|---|---|---|---|
| Revenues: | | | |
| Product sales | $ 14,351 | $ 14,687 | $ 14,311 |
| Other revenues | 291 | 316 | 460 |
| Total revenues | 14,642 | 15,003 | 14,771 |
| Operating expenses: | | | |
| Cost of sales (excludes amortization of certain acquired intangible assets presented below) | 2,091 | 2,296 | 2,548 |
| Research and development | 2,864 | 3,030 | 3,266 |
| Selling, general and administrative | 3,820 | 3,789 | 3,361 |
| Amortization of certain acquired intangible assets | 294 | 294 | 298 |
| Write-off of acquired in-process research and development | | | 590 |
| Other charges | 67 | 380 | 728 |
| Total operating expenses | 9,136 | 9,789 | 10,791 |
| Operating income | 5,506 | 5,214 | 3,980 |
| Interest expense, net | 578 | 551 | 496 |
| Interest and other income, net | 276 | 352 | 309 |
| Income before income taxes | 5,204 | 5,015 | 3,793 |
| Provision for income taxes | 599 | 963 | 715 |
| Net income | $ 4,605 | $ 4,052 | $ 3,078 |
| Earnings per share: | | | |
| Basic | $ 4.53 | $ 3.79 | $ 2.76 |
| Diluted | $ 4.51 | $ 3.77 | $ 2.74 |
| Shares used in calculation of earnings per share: | | | |
| Basic | 1,016 | 1,070 | 1,117 |
| Diluted | 1,021 | 1,075 | 1,123 |

See accompanying notes, including Note 1 for discussion of required retrospective adoption of a new accounting standard effective January 1, 2009, applicable to our convertible debt.

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**AMGEN INC.**

**CONSOLIDATED BALANCE SHEETS**

**December 31, 2009 and 2008**

**(In millions, except per share data)**

| | 2009 | 2008 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 2,884 | $ 1,774 |
| Marketable securities | 10,558 | 7,778 |
| Trade receivables, net | 2,109 | 2,073 |
| Inventories | 2,220 | 2,075 |
| Other current assets | 1,161 | 1,521 |
| Total current assets | 18,932 | 15,221 |
| Property, plant and equipment, net | 5,738 | 5,879 |
| Intangible assets, net | 2,567 | 2,988 |
| Goodwill | 11,335 | 11,339 |
| Other assets | 1,057 | 1,000 |
| Total assets | $ 39,629 | $ 36,427 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 574 | $ 504 |
| Accrued liabilities | 3,299 | 3,382 |
| Current portion of other long-term debt | | 1,000 |
| Total current liabilities | 3,873 | 4,886 |
| Convertible notes | 4,512 | 4,257 |
| Other long-term debt | 6,089 | 4,095 |
| Other non-current liabilities | 2,488 | 2,304 |
| Contingencies and commitments | | |
| Stockholders equity: | | |
| Common stock and additional paid-in capital; | | |
| $0.0001 par value; 2,750 shares authorized; | | |
| outstanding 995 shares in 2009 and 1,047 shares in 2008 | 26,944 | 26,441 |
| Accumulated deficit | (4,322) | (5,673) |
| Accumulated other comprehensive income | 45 | 117 |
| Total stockholders equity | 22,667 | 20,885 |
| Total liabilities and stockholders equity | $ 39,629 | $ 36,427 |

See accompanying notes, including Note 1 for discussion of required retrospective adoption of a new accounting standard effective January 1, 2009, applicable to our convertible debt.

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**AMGEN INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

**Years ended December 31, 2009, 2008 and 2007**

**(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, 2006 | 1,166 | $ 25,215 | $ (5,386) | $ 12 | $ 19,841 |
| Comprehensive income: | | | | | |
| Net income | | | 3,078 | | 3,078 |
| Other comprehensive income, net of tax | | | | 41 | 41 |
| Comprehensive income | | | | | 3,119 |
| Issuance of common stock in connection with the Company s equity award programs | 8 | 333 | | | 333 |
| Stock-based compensation | | 316 | | | 316 |
| Tax impact related to employee stock options | | 26 | | | 26 |
| Repurchases of common stock | (87) | | (5,123) | | (5,123) |
| 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 |

See accompanying notes, including Note 1 for discussion of required retrospective adoption of a new accounting standard effective January 1, 2009, applicable to our convertible debt.

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**AMGEN INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**Years ended December 31, 2009, 2008 and 2007**

**(In millions)**

| | 2009 | 2008 | 2007 |
|---|---|---|---|
| Cash flows from operating activities: | | | |
| Net income | $ 4,605 | $ 4,052 | $ 3,078 |
| Depreciation and amortization | 1,049 | 1,073 | 1,202 |
| Write-off of acquired in-process research and development | | | 590 |
| Stock-based compensation expense | 284 | 262 | 263 |
| Deferred income taxes | 47 | (137) | 56 |
| Property, plant and equipment impairments | 21 | 59 | 404 |
| Dividend received from equity investee | 110 | 8 | 76 |
| Other items, net | 111 | 244 | 173 |
| Changes in operating assets and liabilities, net of acquisitions: | | | |
| Trade receivables, net | (36) | 65 | 38 |
| Inventories | (134) | (59) | (109) |
| Other current assets | (3) | 15 | (119) |
| Accounts payable | 71 | 95 | (181) |
| Accrued income taxes | (142) | 14 | (810) |
| Other accrued liabilities | 320 | (30) | 688 |
| Deferred revenue | 33 | 327 | 52 |
| Net cash provided by operating activities | 6,336 | 5,988 | 5,401 |
| Cash flows from investing activities: | | | |
| Purchases of property, plant and equipment | (530) | (672) | (1,267) |
| Cash paid for acquisitions, net of cash acquired | | (56) | (697) |
| Purchases of marketable securities | (12,418) | (10,345) | (5,579) |
| Proceeds from sales of marketable securities | 8,252 | 6,762 | 5,073 |
| Proceeds from maturities of marketable securities | 1,443 | 1,018 | 454 |
| Other | 51 | 128 | 24 |
| Net cash used in investing activities | (3,202) | (3,165) | (1,992) |
| Cash flows from financing activities: | | | |
| Repurchases of common stock | (3,208) | (2,268) | (5,100) |
| Repayment of debt | (1,000) | (2,000) | (1,840) |
| Net proceeds from issuance of debt | 1,980 | 991 | 3,982 |
| Net proceeds from issuance of common stock in connection with the Company s equity award programs | 171 | 155 | 277 |
| Other | 33 | 49 | 13 |
| Net cash used in financing activities | (2,024) | (3,073) | (2,668) |
| Increase (decrease) in cash and cash equivalents | 1,110 | (250) | 741 |
| Cash and cash equivalents at beginning of period | 1,774 | 2,024 | 1,283 |
| Cash and cash equivalents at end of period | $ 2,884 | $ 1,774 | $ 2,024 |

See accompanying notes, including Note 1 for discussion of required retrospective adoption of a new accounting standard effective January 1, 2009, applicable to our convertible debt.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2009**

**1. Summary of significant accounting policies**

*Business*

Amgen Inc. (including its subsidiaries, referred to as Amgen, the Company, we, our and us ) is a global biotechnology medicines company th 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 financial statements in conformity with accounting principles generally accepted in the United States ( GAAP ) 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.

*Financial Accounting Standards Board Accounting Standards Codification*

Effective July 1, 2009, the Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC or Codification ) became the authoritative source of GAAP. All existing FASB accounting standards and guidance were superseded by the ASC. Instead of issuing new accounting standards in the form of statements, staff positions and Emerging Issues Task Force abstracts, the FASB now issues Accounting Standards Updates that update the Codification. Rules and interpretive releases of the Securities and Exchange Commission ( SEC ) under authority of federal securities laws continue to be additional sources of authoritative GAAP for SEC registrants.

*Change in method of accounting for convertible debt instruments*

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 new 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 2032 Modified 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. See Note 2, *Change in method of accounting for convertible debt instruments* and Note 16, *Financing arrangements*.

*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.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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. ( Centocor Ortho Biotech Products )), 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 collectibility 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 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, 2009, 2008 and 2007, we recognized royalty income from J&J of $128 million, $126 million and $182 million, respectively. Corporate partner revenues are primarily 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. See Note 8, *Related party transactions.* In addition, corporate partner revenues include license fees and milestone payments associated with 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. Our collaboration agreements with third parties are performed on a best efforts basis with no guarantee of either technological or commercial success.

*Research and development costs*

R&D costs are expensed as incurred and primarily include 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 collaborations is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 7, *Collaborative arrangements*.

*Selling, general and administrative costs*

Selling, general and administrative ( SG&A ) expenses are primarily comprised 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.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

SG&A expenses also include costs and cost recoveries associated with certain collaborative arrangements including the co-promotion agreement with Pfizer Inc. ( Pfizer ) (formerly Wyeth). 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 7, *Collaborative arrangements*.

Advertising costs are expensed as incurred. For the years ended December 31, 2009, 2008 and 2007, advertising costs were $95 million, $81 million and $93 million, respectively.

*Acquired in-process research and development*

For business combinations that occurred prior to January 1, 2009, under the then existing accounting rules the estimated fair value of acquired in-process R&D ( IPR&D ) projects, which had not reached technological feasibility at the date of acquisition and which did not have an alternative future use, were immediately expensed. In 2007, we wrote-off $270 million and $320 million of acquired IPR&D related to the Ilypsa, Inc. ( Ilypsa ) and Alantos Pharmaceuticals Holding, Inc. ( Alantos ) acquisitions, respectively. Acquired IPR&D for acquisitions prior to January 1, 2009 is considered part of total R&D expense. See Note 3, *Acquisitions.*

For business combinations that occur on or after January 1, 2009, under current GAAP the estimated fair values of acquired IPR&D projects which have not reached technological feasibility at the date of acquisition are capitalized and subsequently tested for impairment through completion of the development process, at which point the capitalized amounts are amortized over their estimated useful life. If a project is abandoned rather than completed, all capitalized amounts are written-off immediately.

*Share based payments*

We have employee compensation plans under which various types of stock-based instruments are granted. All share-based payments to employees, including grants of employee stock options, are recognized in the Consolidated Statements of Income as compensation expense (based on their estimated fair values) generally over the vesting period of the awards. See Note 4, *Employee stock-based payments.*

*Income taxes*

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

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the financial statements on a particular tax position are measured based on the largest benefit that has a greater than a 50% likelihood of being 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 5, *Income taxes.*

*Collaborative arrangements*

Effective January 1, 2009, we adopted a new accounting standard that provides financial statement presentation and disclosure guidance for collaborative arrangements, as defined, which include certain arrangements we have entered into regarding the R&D, manufacture and/or commercialization of products and product candidates.

Under this standard, 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.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

We evaluate whether an arrangement is a collaborative arrangement at its inception based on the facts and circumstances specific to the arrangement. We re-evaluate whether an arrangement qualifies or continues to qualify as a collaborative arrangement whenever there is a change in either the roles of the participants or the participants exposure to significant risks and rewards dependent on the ultimate commercial success of the endeavor. For collaborative arrangements where it is determined that we are the principal participant, in accordance with existing accounting rules, revenue generated and costs incurred with third parties are recorded on a gross basis in our financial statements.

The adoption of this standard did not have a material impact on our consolidated results of operations, financial position or cash flows. See Note 7, *Collaborative arrangements*.

*Fair value measurement*

We adopted a new accounting standard that defines fair value and establishes a framework for fair value measurements effective January 1, 2008 for financial assets and liabilities and effective January 1, 2009 for non-financial assets and liabilities that are not remeasured on a recurring basis. Under this standard, fair value is generally defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the exit price ) in an orderly transaction between market participants at the measurement date. The adoption of this accounting standard did not have a material impact on our consolidated results of operations, financial position or cash flows.

Effective April 1, 2009, we adopted a new accounting standard that modifies the guidance used in determining whether the impairment of a debt security is other-than-temporary. Under this accounting standard, the impairment of a debt security is considered other-than-temporary if an entity concludes that it intends to sell the impaired security, that it is more likely than not it will be required to sell the security before the recovery of its cost basis or that it does not otherwise expect to recover the cost basis of the security. This accounting standard also amends the presentation requirements of other-than-temporarily impaired debt securities and expands disclosure requirements in the financial statements for investments in both debt and equity securities. The adoption of this accounting standard did not have a material impact on our consolidated results of operations, financial position or cash flows.

Effective April 1, 2009, we adopted a new accounting standard that provides additional guidance in estimating fair value when the market volume and level of activity for an asset or liability have significantly decreased and in identifying circumstances that indicate a transaction may not be orderly. The adoption of this accounting standard did not have a material impact on our consolidated results of operations, financial position or cash flows.

Effective October 1, 2009, we adopted a new accounting standard which clarifies guidance for determining the fair value of a liability when a quoted price in an active market for an identical liability is not available. This standard provides for the use of one or more valuation techniques, including quoted prices of identical or similar liabilities when traded as assets, quoted prices of similar liabilities and other techniques consistent with the fair value measurement framework, such as the amount an entity would pay to transfer the identical liability or would receive to enter into the identical liability. The adoption of this standard did not have a material impact on our consolidated results of operations, financial position or cash flows.

See Note 18, *Fair value measurement*.

*Cash equivalents*

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

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Available-for-sale securities*

We consider our marketable security investment portfolio and marketable equity investments 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 11, *Available-for-sale securities*.

*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 ( FIFO ) 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 12, *Inventories*.

*Property, plant and equipment, net*

Property, plant and equipment is recorded at cost, net of accumulated depreciation and amortization. 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 13, *Property, plant and equipment.*

*Intangible assets and goodwill*

Intangible assets other than goodwill are recorded at cost, net of accumulated amortization. Amortization of intangible assets is provided over their estimated useful lives on a straight-line basis. We review our intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note 14, *Intangible assets*.

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.

*Derivative instruments*

Effective January 1, 2009, we adopted a new accounting standard that requires additional disclosures about our derivative instruments and hedging activities. This standard requires that the objectives for using derivative instruments be disclosed to better convey the purpose of their use in terms of the risks that we are intending to manage. This standard also requires disclosure of how derivatives and related hedged items

affect our financial statements. The adoption of this standard did not have a material impact on our consolidated results of operations, financial position or cash flows. See Note 19, *Derivative instruments*.

*Subsequent events*

We have evaluated subsequent events through the date of issuance of our financial statements in this Form 10-K.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Recent accounting pronouncements*

In June 2009, the FASB issued a new accounting standard which amends guidance regarding consolidation of variable interest entities to address the elimination of the concept of a qualifying special purpose entity. This standard also replaces the quantitative-based risks and rewards calculation for determining which enterprise has a controlling financial interest in a variable interest entity with an approach focused on identifying which enterprise has the power to direct the activities of the variable interest entity and the obligation to absorb losses of the entity or the right to receive benefits from the entity. Additionally, this standard requires any enterprise that holds a variable interest in a variable interest entity to make ongoing assessments of whether it has a controlling financial interest in the variable interest entity and to provide enhanced disclosures that will provide users of financial statements with more transparent information about an enterprise s involvement in the variable interest entity. This standard is effective for us beginning January 1, 2010. The adoption of this standard is not expected to have a material impact on our consolidated results of operations, financial position or cash flows.

In October 2009, the FASB issued a new accounting standard which amends guidance on accounting for revenue arrangements involving the delivery of more than one element of goods and/or services. This standard addresses the unit of accounting for arrangements involving multiple deliverables and removes the previous separation criteria that objective and reliable evidence of fair value of any undelivered item must exist for the delivered item to be considered a separate unit of accounting. This standard also addresses how the arrangement consideration should be allocated to each deliverable. Finally, this standard expands disclosures related to multiple element revenue arrangements. This standard is effective for us beginning January 1, 2011. The adoption of this standard is not expected to have a material impact on our consolidated results of operations, financial position or cash flows.

**2. Change in method of accounting for convertible debt instruments**

As discussed in Note 1, *Summary of significant accounting policies Change in method of accounting for convertible debt instruments,* effective January 1, 2009, we adopted a new accounting standard which changed the method of accounting for certain types of convertible debt, including our 2011 Convertible Notes, 2013 Convertible Notes and our 2032 Modified Convertible Notes, and, as required by this standard, we retrospectively applied this change in accounting to all prior periods for which we had applicable outstanding convertible debt.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following tables illustrate the impact of adopting this accounting standard on our Consolidated Statements of Income (in millions, except per share information):

| | Year ended December 31, 2009 | | |
|---|---|---|---|
| | Excluding the effect of the accounting standard | Effect of the accounting standard | Including the effect of the accounting standard |
| Operating income | $ 5,506 | $ | $ 5,506 |
| Interest expense, net | 328 | 250 | 578 |
| Interest and other income, net | 276 | | 276 |
| Income before income taxes | 5,454 | (250) | 5,204 |
| Provision for income taxes | 694 | (95) | 599 |
| Net income | $ 4,760 | $ (155) | $ 4,605 |
| Earnings per share: | | | |
| Basic | $ 4.69 | $ (0.16) | $ 4.53 |
| Diluted | $ 4.66 | $ (0.15) | $ 4.51 |

| | Year ended December 31, 2008 | | |
|---|---|---|---|
| | As originally reported | Effect of the accounting standard | Revised |
| Operating income | $ 5,214 | $ | $ 5,214 |
| Interest expense, net | 316 | 235 | 551 |
| Interest and other income, net | 352 | | 352 |
| Income before income taxes | 5,250 | (235) | 5,015 |
| Provision for income taxes | 1,054 | (91) | 963 |
| Net income | $ 4,196 | $ (144) | $ 4,052 |
| Earnings per share: | | | |
| Basic | $ 3.92 | $ (0.13) | $ 3.79 |
| Diluted | $ 3.90 | $ (0.13) | $ 3.77 |

| | Year ended December 31, 2007 | | |
|---|---|---|---|
| | As originally reported | Effect of the accounting standard | Revised |
| Operating income | $ 3,980 | $ | $ 3,980 |
| Interest expense, net | 328 | 168 | 496 |
| Interest and other income, net | 309 | | 309 |

| | | | |
|---|---|---|---|
| Income before income taxes | 3,961 | (168) | 3,793 |
| Provision for income taxes | 795 | (80) | 715 |
| Net income | $ 3,166 | $ (88) | $ 3,078 |
| Earnings per share: | | | |
| Basic | $ 2.83 | $ (0.07) | $ 2.76 |
| Diluted | $ 2.82 | $ (0.08) | $ 2.74 |

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following tables illustrate the impact of adopting this accounting standard on our Consolidated Balance Sheets (in millions):

| | December 31, 2009 | | |
|---|---|---|---|
| | Excluding the effect of the accounting standard | Effect of the accounting standard | Including the effect of the accounting standard |
| **Non-current assets:** | | | |
| Other assets | $ 1,069 | $ (12) | $ 1,057 |
| **Non-current liabilities:** | | | |
| Convertible notes | 5,082 | (570) | 4,512 |
| Other non-current liabilities | 2,274 | 214 | 2,488 |
| **Stockholders equity:** | | | |
| Common stock and additional paid-in capital | 26,030 | 914 | 26,944 |
| Accumulated deficit | (3,752) | (570) | (4,322) |

| | December 31, 2008 | | |
|---|---|---|---|
| | As originally reported | Effect of the accounting standard | Revised |
| **Non-current assets:** | | | |
| Other assets | $ 1,016 | $ (16) | $ 1,000 |
| **Non-current liabilities:** | | | |
| Convertible notes | 5,081 | (824) | 4,257 |
| Other non-current liabilities | 1,995 | 309 | 2,304 |
| **Stockholders equity:** | | | |
| Common stock and additional paid-in capital | 25,527 | 914 | 26,441 |
| Accumulated deficit | (5,258) | (415) | (5,673) |

The effect of this accounting standard on Other non-current liabilities in the Consolidated Balance Sheets reflects the impact of deferred taxes. In addition, the effect of this accounting standard on Common stock and additional paid-in capital in the Consolidated Balance Sheets reflects, principally, the impact of the equity component of our convertible debt partially offset by deferred taxes.

As a result of the accounting change, our common stock and additional paid-in capital as of January 1, 2007, increased from $24.2 billion, as originally reported, to $25.2 billion and our accumulated deficit as of January 1, 2007, increased from $5.2 billion, as originally reported, to $5.4 billion after applying this accounting standard. There was no impact resulting from this accounting change on our cash flows from operating activities, investing activities or financing activities as reflected in the Consolidated Statements of Cash Flows.

**3. 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

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

*Ilypsa, Inc.*

On July 18, 2007, we completed the acquisition of Ilypsa, which was accounted for as a business combination. Ilypsa was a privately held company that specialized in the development of non-absorbed drugs for renal disorders. Pursuant to the merger agreement, we paid cash of approximately $400 million to acquire all of the outstanding shares of Ilypsa. The purchase price paid, including transaction costs, was allocated to acquired IPR&D of $320 million and other net assets acquired of $42 million, based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair values of assets and liabilities acquired of approximately $41 million was assigned to goodwill. The estimated fair value of the acquired IPR&D was determined based upon discounted after-tax cash flows adjusted for the probabilities of successful development and commercialization. The amount allocated to acquired IPR&D was immediately expensed in the Consolidated Statement of Income (see Note 1, *Summary of significant accounting policies Acquired in-process research and development* ). The results of Ilypsa s operations have been included in the consolidated financial statements commencing July 18, 2007. Pro forma results of operations for the year ended December 31, 2007 assuming the acquisition of Ilypsa had taken place at the beginning of 2007 would not differ significantly from the actual reported results.

*Alantos Pharmaceuticals Holding, Inc.*

On July 16, 2007, we completed the acquisition of Alantos, which was accounted for as a business combination. Alantos was a privately held company that specialized in the development of drugs for the treatment of diabetes and inflammatory diseases. Pursuant to the merger agreement, we paid cash of approximately $300 million to acquire all of the outstanding shares of Alantos. The purchase price paid, including transaction costs, was allocated to acquired IPR&D of $270 million and other net assets acquired of approximately $10 million, based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair values of assets and liabilities acquired of $23 million was assigned to goodwill. The estimated fair value of the acquired IPR&D was determined based upon discounted after-tax cash flows adjusted for the probabilities of successful development and commercialization. The amount allocated to acquired IPR&D was immediately expensed in the Consolidated Statement of Income (see Note 1, *Summary of significant accounting policies Acquired in-process research and development* ). The results of Alantos operations have been included in the consolidated financial statements commencing July 16, 2007. Pro forma results of operations for the year ended December 31, 2007 assuming the acquisition of Alantos had taken place at the beginning of 2007 would not differ significantly from the actual reported results.

In addition, proforma results of operations for the year ended December 31, 2007, assuming both the acquisitions of Ilypsa and Alantos had taken place at the beginning of 2007, would not differ significantly from the actual reported results.

**4. Employee stock-based payments**

On May 6, 2009, our stockholders approved the Amgen Inc. 2009 Equity Incentive Plan (the 2009 Plan ) for non-employee members of our Board of Directors, the employees and consultants of Amgen, its subsidiaries and affiliates. The 2009 Plan replaced our existing equity plans (the Prior Plans ). After May 6, 2009, 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, will be reduced by one share for each stock option granted and by 1.9 shares for other types of awards granted, including

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

restricted stock or performance units. If any shares subject to an award granted under our Prior Plans after December 31, 2008 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 will be added back to the pool of available shares under the 2009 Plan on the same basis that they were removed. As of December 31, 2009, the 2009 Plan provides for future grants and/or issuances of up to approximately 85 million shares of our common stock. Our stock-based instruments, more fully described below, principally include stock options, restricted stock units and performance units. 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, 2009, 2008 and 2007 (in millions):

| | 2009 | 2008 | 2007 |
|---|---|---|---|
| Stock options | $ 115 | $ 103 | $ 181 |
| Restricted stock units | 134 | 105 | 76 |
| Performance units | 35 | 54 | 6 |
| Total stock-based compensation expense, pre-tax | 284 | 262 | 263 |
| Tax benefit from stock-based compensation expense | (97) | (89) | (81) |
| Total stock-based compensation expense, net of tax | $ 187 | $ 173 | $ 182 |

*Employee stock option and restricted stock unit grants*

Our equity-based compensation plan provides for grants of stock options to employees. The option exercise price 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. This plan also provide for grants of restricted stock units. Grants of these equity instruments generally vest over a four year period. In addition, stock option awards expire seven years from the date of grant. Eligible employees generally receive a grant of stock options and/or restricted stock units annually with the number of shares and type of instrument 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-based plans provide for accelerated or continued vesting of restrictions 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. For stock option and restricted stock unit awards subject to graded vesting, we recognize compensation cost on a straight-line basis over the service period for the entire award.

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, 2009, 2008 and 2007:

| | 2009 | 2008 | 2007 |
|---|---|---|---|
| Fair value of our common stock | $ 50.65 | $ 43.60 | $ 62.92 |
| Fair value of stock options granted | $ 18.35 | $ 14.50 | $ 19.06 |
| Expected volatility | 39.6% | 31.6% | 24.9% |
| Expected life (in years) | 4.6 | 4.6 | 4.7 |
| Risk-free interest rate | 2.1% | 2.9% | 4.5% |
| 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

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

common stock. We estimated the expected life of stock options using the simplified method during the year ended December 31, 2007. Under this method, the expected life was equal to the arithmetic average of the vesting term and the original contractual term of the option. Commencing in 2008, 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.

Stock option information with respect to our stock-based compensation plans during the three years ended December 31, 2009 is as follows:

| | Options (in millions) | Weighted-average exercise price | Weighted-average remaining contractual life (years) | Aggregate intrinsic value (in millions) |
|---|---|---|---|---|
| Balance unexercised at December 31, 2006 | 68.2 | $ 60.11 | | |
| Granted | 7.6 | $ 62.89 | | |
| Exercised | (4.2) | $ 42.92 | | |
| Forfeited/expired | (9.5) | $ 65.99 | | |
| Balance unexercised at December 31, 2007 | 62.1 | $ 60.70 | | |
| Granted | 6.9 | $ 43.60 | | |
| Exercised | (3.8) | $ 37.82 | | |
| Forfeited/expired | (14.4) | $ 63.39 | | |
| Balance unexercised at December 31, 2008 | 50.8 | $ 59.31 | | |
| Granted | 6.6 | $ 50.65 | | |
| Exercised | (3.9) | $ 39.96 | | |
| Forfeited/expired | (2.7) | $ 61.94 | | |
| Balance unexercised at December 31, 2009 | 50.8 | $ 59.50 | 3.1 | $ 150 |
| Vested or expected to vest at December 31, 2009 | 50.1 | $ 59.64 | 3.1 | $ 145 |
| Exercisable at December 31, 2009 | 35.4 | $ 62.20 | 2.2 | $ 53 |

The total intrinsic value of options exercised during the year ended December 31, 2009 was $57 million.

The fair value of a restricted stock unit is equal to the closing price of Amgen common stock on the grant dates. Information regarding our restricted stock units during the three years ended December 31, 2009 is as follows:

| Nonvested units | Units (in millions) | Weighted-average grant date fair value |
|---|---|---|
| Nonvested at December 31, 2006 | 4.1 | $ 65.77 |
| Granted | 3.6 | $ 60.59 |
| Vested | (1.2) | $ 64.74 |
| Forfeited | (0.9) | $ 64.85 |

| | | | |
|---|---|---|---|
| Nonvested at December 31, 2007 | 5.6 | $ | 62.94 |
| Granted | 5.2 | $ | 42.63 |
| Vested | (1.7) | $ | 62.94 |
| Forfeited | (0.6) | $ | 55.58 |
| | | | |
| Nonvested at December 31, 2008 | 8.5 | $ | 50.73 |
| Granted | 3.6 | $ | 51.24 |
| Vested | (2.8) | $ | 53.94 |
| Forfeited | (0.5) | $ | 49.14 |
| | | | |
| Nonvested at December 31, 2009 | 8.8 | $ | 50.00 |

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The total fair value of shares of restricted stock units that vested during the year ended December 31, 2009 was $139 million.

As of December 31, 2009, there was $470 million of total unrecognized compensation cost related to nonvested awards of both stock options and restricted stock units, 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 2009, 2008 and 2007 are based upon one or more of the 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. The number of shares of Amgen s common stock payable to the recipient for performance units granted in 2009, 2008 and 2007 will equal the number of performance units 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 2009, 2008 and 2007 include total stockholder return performance goals, which are considered market conditions. The performance units granted in 2009 and 2007 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 2009 and 2007 was based on the grant date fair value of a unit multiplied by the estimated 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. The impact of the Company s stockholder returns for the awards granted in 2009, 2008 and 2007 is reflected in the grant date fair values of the units.

Information regarding our performance units is as follows (in millions):

| | | | As of December 31, 2009 | | | |
|---|---|---|---|---|---|---|
| Year granted | Plan year end date | Units granted | Units outstanding | Number of units earned | Number of shares of common stock issued, net of tax | Date issued |
| 2004 | 12/31/2006 | 1.3 | | 1.7 | 1.0 | May 2007 |
| 2005 | 12/31/2007 | 1.1 | | 1.7 | 1.0 | May 2008 |
| 2006 | 12/31/2008 | 1.1 | | 0.6 | 0.4 | May 2009 |
| 2007 | 12/31/2009 | 1.3 | 1.1[1] | 1.1[2] | N/A[3] | N/A[3] |
| 2008 | 12/31/2010 | 0.9 | 0.9[1] | N/A[3] | N/A[3] | N/A[3] |
| 2009 | 12/31/2011 | 1.0 | 0.9[1] | N/A[3] | N/A[3] | N/A[3] |

(1) The performance period for the performance units which were granted in 2007 is complete and these units are no longer subject to any performance goals. The performance units which were granted in 2009 and 2008 continue to be subject to performance goals with respect to the Company s total stockholder return.

(2) Shares of common stock related to the units earned for the 2007 plan year are anticipated to be issued in 2010.

(3) N/A = Not applicable

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

We used a Monte Carlo simulation model to estimate the grant date fair value of performance units granted in 2009. We used a lattice model to estimate the grant date fair value of performance units granted in 2008 and 2007. 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, 2009, 2008 and 2007.

| | 2009 | 2008 | 2007 |
|---|---|---|---|
| Fair value of our common stock | $ 47.63 | $ 44.62 | $ 56.56 |
| Fair value of unit | $ 48.22 | $ 36.91 | $ 71.41 |
| Expected volatility | 34.3% | 32.4% | 28.1% |
| Risk-free interest rate | 1.2% | 2.0% | 4.0% |
| Expected dividend yield | 0% | 0% | 0% |

For the year ended December 31, 2009, the Monte Carlo simulation model also assumed correlations of returns of the stock prices of our common stock and the common stock of a comparator group of companies and stock price volatilities of the comparator group of companies. 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 provisions of the award.

As of December 31, 2009, there was approximately $38 million of total estimated unrecognized compensation cost related to the 2009 and 2008 performance unit grants that is expected to be recognized over a weighted-average period of approximately 1 year.

**5. Income taxes**

The provision for income taxes includes the following (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| Current provision: | | | |
| Federal | $ 325 | $ 866 | $ 467 |
| State | 85 | 82 | 40 |
| Foreign | 155 | 152 | 176 |
| Total current provision | 565 | 1,100 | 683 |
| Deferred provision (benefit): | | | |
| Federal | 92 | (86) | 61 |
| State | (59) | (43) | (30) |
| Foreign | 1 | (8) | 1 |
| Total deferred provision (benefit) | 34 | (137) | 32 |
| Total provision | $ 599 | $ 963 | $ 715 |

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 are as follows (in millions):

| | December 31, | |
|---|---|---|
| | 2009 | 2008 |
| Deferred tax assets: | | |
| Intercompany inventory related items | $ 351 | $ 359 |
| Expense accruals | 519 | 576 |
| Acquired net operating loss and credit carryforwards | 178 | 243 |
| Expenses capitalized for tax | 177 | 175 |
| Stock-based compensation | 229 | 220 |
| Deferred revenue | 128 | 153 |
| Other | 108 | 111 |
| Total deferred tax assets | 1,690 | 1,837 |
| Valuation allowance | (92) | (106) |
| Net deferred tax assets | 1,598 | 1,731 |
| Deferred tax liabilities: | | |
| Acquired intangibles | (882) | (1,025) |
| Fixed assets | (201) | (184) |
| Other | (138) | (154) |
| Total deferred tax liabilities | (1,221) | (1,363) |
| Total deferred taxes | $ 377 | $ 368 |

At December 31, 2009 and 2008, we had net current deferred tax assets of $634 million and $859 million, respectively, primarily composed of temporary differences related to inventory and accrued liabilities. In addition, at December 31, 2009 and December 31, 2008 we had net non-current deferred tax liabilities of $257 million and $491 million, respectively, primarily composed of temporary differences related to acquired intangibles and fixed assets partially offset by stock-based compensation and deferred revenue.

The valuation allowance for deferred tax assets decreased by $14 million in 2009. The decrease was primarily due to the utilization and expiration of certain acquired net operating loss carryforwards. Valuation allowances are provided when we believe that 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, 2009, we had net operating loss carryforwards of $487 million available to reduce future taxable income in various state taxing jurisdictions. We have provided a valuation allowance against $241 million of the state operating loss carryforwards. The state operating loss carryforwards will begin expiring in 2010.

At December 31, 2009, we had $125 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.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The reconciliation of the total gross amounts of UTBs (excluding interest and the federal tax benefit of state taxes related to UTBs) for the years ended December 31, 2009, 2008 and 2007 is as follows (in millions):

| | 2009 | 2008 | 2007 |
|---|---|---|---|
| Balance at beginning of year | $ 1,113 | $ 922 | $ 945 |
| Additions based on tax positions related to the current year | 302 | 382 | 458 |
| Reductions for tax positions of prior years | (215) | | (284) |
| Settlements | (60) | (191) | (197) |
| Balance at end of year | $ 1,140 | $ 1,113 | $ 922 |

Substantially all of the UTBs as of December 31, 2009, if recognized, would affect our effective tax rate.

During 2007, we settled our examination with the Internal Revenue Service ( IRS ) for the years ended December 31, 2002, 2003 and 2004. We agreed to certain adjustments proposed by the IRS arising out of the examination primarily related to transfer pricing tax positions and remeasured our UTBs accordingly. Our closing agreement with the IRS also covered certain transfer pricing issues for the years ended December 31, 2005 and 2006.

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

During 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 and have remeasured our UTBs accordingly. Also during 2009, we settled the examination of our California state income tax returns for certain matters for the years ended December 31, 2004 and 2005 and have remeasured our UTBs accordingly.

The Company does not expect any significant changes to the above UTBs during the next twelve months.

Interest and penalties related to UTBs are included in our provision for income taxes. During 2009, 2008 and 2007, we recognized approximately $57 million, $71 million and $41 million, respectively, of interest and penalty expense through the income tax provision in the Consolidated Statements of Income. At December 31, 2009 and 2008, we had accrued approximately $125 million and $119 million, respectively, of interest and penalties associated with UTBs.

The reconciliation between the federal statutory rate and our effective tax rate is as follows:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| Federal statutory rate applied to income before income taxes | 35.0 % | 35.0 % | 35.0 % |
| Foreign earnings, including earnings invested indefinitely | (19.6)% | (16.7)% | (16.9)% |
| State taxes | 1.1 % | 1.4 % | 1.2 % |
| Acquired IPR&D | 0.0 % | 0.0 % | 5.5 % |
| Audit settlements | (4.2)% | 0.0 % | (3.7)% |
| Utilization of tax credits, primarily research and experimentation | (0.8)% | (1.1)% | (1.7)% |
| Other, net | 0.0 % | 0.6 % | (0.5)% |

| | | | |
|---|---|---|---|
| Effective tax rate | 11.5 % | 19.2 % | 18.9 % |

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, 2009, these earnings amounted to approximately $14.3 billion. If these earnings were repatriated to the United States, we would be required to accrue and pay approximately $5.1 billion of additional income taxes based on the current tax rates in effect. For

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

the years ended December 31, 2009, 2008 and 2007, our total foreign income before income taxes was approximately $3.1 billion, $2.6 billion and $2.4 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, 2004 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, 2009, 2008 and 2007, totaled $497 million, $673 million and $895 million, respectively.

**6. Earnings per share**

Basic earnings per share ( EPS ) is based upon the weighted-average number of our common shares outstanding. Diluted EPS is based upon the weighted-average number of our common shares and dilutive potential common shares outstanding. Potential common shares outstanding principally include stock options, restricted stock units and other equity awards under our employee compensation plans and potential issuance of stock upon the assumed conversion of our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified Convertible Notes, as discussed below, and upon the assumed exercise of our warrants using the treasury stock method (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 16, *Financing arrangements.*

Upon conversion of our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified Convertible Notes, the principal amount or accreted value would be settled in cash and the excess of the conversion value, as defined, over the principal amount or accreted value 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 or accreted value, if any, are considered as dilutive potential common shares for purposes of calculating diluted EPS. For the years ended December 31, 2009, 2008 and 2007, the conversion values for our convertible notes were less than the related principal amounts or accreted value and, accordingly, no shares were assumed to be issued for purposes of computing diluted EPS. For further information regarding our convertible notes, see Note 16, *Financing arrangements*.

The following table sets forth the computation for basic and diluted EPS (in millions, except per share information):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| Income (Numerator): | | | |
| Net income for basic and diluted EPS | $ 4,605 | $ 4,052 | $ 3,078 |
| Shares (Denominator): | | | |
| Weighted-average shares for basic EPS | 1,016 | 1,070 | 1,117 |
| Effect of dilutive securities | 5 | 5 | 6 |
| Weighted-average shares for diluted EPS | 1,021 | 1,075 | 1,123 |
| Basic EPS | $ 4.53 | $ 3.79 | $ 2.76 |
| Diluted EPS | $ 4.51 | $ 3.77 | $ 2.74 |

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

For the years ended December 31, 2009, 2008 and 2007, there were employee stock options, calculated on a weighted average basis, to purchase 42 million, 45 million and 48 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 conversion of our convertible debt or upon exercise of our warrants, are not included in any of the periods presented above as their impact on diluted EPS would also have been anti-dilutive.

**7. 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 8, *Related party transactions.*

*Pfizer Inc. (formerly Wyeth)*

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. Pfizer and Amgen share in the agreed upon selling and marketing expenses approved by the joint management committee. In addition, we 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.

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, 2009, 2008 and 2007, ENBREL sales aggregated $3.5 billion, $3.6 billion and $3.2 billion, respectively. During the years ended December 31, 2009, 2008 and 2007, the Pfizer profit share expense was $1,163 million, $1,195 million and $984 million, respectively, and is included in Selling, general and administrative expense in the Consolidated Statements of Income. The Pfizer profit share expense for 2007 excludes recoveries of certain expenses recorded as part of our restructuring, as discussed in Note 9, *Restructuring.* In addition, cost recoveries from Pfizer for their share of the selling and marketing co-promotion expense were $75 million, $77 million and $74 million for the years ended December 31, 2009, 2008 and 2007, respectively, and are included in Selling, general and administrative expense in the Consolidated Statements of Income.

*GlaxoSmithKline plc*

In July 2009, we entered into a collaboration agreement with GlaxoSmithKline plc ( GSK ) for the commercialization of our late-stage product candidate, denosumab, in Europe, Australia, New Zealand and Mexico (the Primary Territories ) for osteoporosis indications. We will commercialize denosumab for all indications in the United States and Canada and for oncology indications in the Primary Territories. We have determined that we are the principal participant in the Primary Territories. Accordingly, we will record product sales to third parties net of estimated returns, rebates and other deductions. GSK will commercialize denosumab for all indications in countries where we do not currently have a commercial presence, including China, Brazil, India, Taiwan and South Korea (the Expansion Territories ). In the Expansion Territories, GSK will be responsible for all

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

development and commercialization costs and will purchase denosumab from us to meet demand. We will record product sales to GSK for their purchase of denosumab in the Expansion Territories. We have the option of expanding our role in the commercialization of denosumab in the Primary Territories and certain of the Expansion Territories in the future.

In the Primary Territories, we will share equally in 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 that will decline as certain sales thresholds are met. GSK will also be responsible for bearing a portion of the cost of certain specified development activities. During the year ended December 31, 2009, we had no product sales of denosumab. During the year ended December 31, 2009, cost recoveries from GSK were $29 million and are included in Selling, general and administrative expense in the Consolidated Statement of Income. Under this agreement, we also received an initial payment of $45 million and may receive additional amounts upon the achievement of certain commercial milestones. The initial payment of $45 million is being amortized over our estimated period of continuing involvement of approximately 13 years and is recognized as revenue in Other revenue in our Consolidated Statement of Income. As of December 31, 2009, no amounts have been recognized with respect to the commercial milestones.

*Takeda Pharmaceutical Company Limited*

In February 2008, we entered into a collaboration agreement with Takeda Pharmaceutical Company Limited ( Takeda ), which provides them the exclusive rights to develop and commercialize for the Japanese market up to 12 clinical stage molecules, including Vectibix® (collectively the products ), from our pipeline across a range of therapeutic areas, including oncology and inflammation. Under this agreement, Amgen received an upfront payment of $200 million and may receive additional amounts upon the achievement of various success-based development and regulatory approval milestones. In addition, Takeda is obligated to pay Amgen up to an additional $190 million of future worldwide development costs for the 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 we will receive 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 and may receive 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 100% of 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.

During the years ended December 31, 2009 and 2008, cost recoveries from Takeda were $112 million and $120 million, respectively, and are included in Research and development expense in the Consolidated Statements 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, of which $15 million and $14 million were recognized for the years ended December 31, 2009 and 2008, respectively.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Daiichi Sankyo Company, Limited*

In July 2007, we entered into a collaboration and license agreement with Daiichi Sankyo Company, Limited ( Daiichi Sankyo ), which provides them the exclusive rights to develop and commercialize our late-stage product candidate, 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 has substantially satisfied its obligations to reimburse Amgen for these costs. If approved for sale, Amgen will receive royalties on future sales of denosumab in Japan. Pursuant to the terms of the agreement, Daiichi Sankyo may receive milestone payments from Amgen aggregating $60 million dependent on various regulatory approvals of denosumab. During the years ended December 31, 2009, 2008 and 2007, cost recoveries from Daiichi Sankyo were $64 million, $60 million and $40 million, respectively, and are included in Research and development expense in the Consolidated Statements of Income.

*Other*

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

We entered into our collaboration agreement with Kyowa Hakko in March 2008, which granted us an exclusive license to develop and commercialize Kyowa Hakko s humanized monoclonal antibody KW-0761 worldwide, except in Japan, Korea, China and Taiwan. KW-0761 is being studied in inflammation and oncology settings and at the time the agreement was entered into was in a phase 1 clinical trial. In connection with entering the agreement, we paid Kyowa Hakko $100 million which we expensed when paid.

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, CK-1827452, which at the time the agreement was entered into was in phase 1 clinical trials. The collaboration is worldwide, excluding Japan. In connection with entering into the agreement, we paid Cytokinetics $42 million. In 2009, we exercised an 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.

Pursuant to the terms of these agreements, we may also be required to pay additional amounts upon the achievement of various success-based 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. Given their nature, these payments are not considered probable as the occurrence of the related events has a high degree of uncertainty and many of the events may never occur. Further, the timing of any future payments is not reasonably estimable. Individually, future payment of any amounts under these arrangements is not expected to be material in any one reporting period.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. 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, 2009, 2008 and 2007, our share of KA s profits were $72 million, $72 million and $51 million, respectively. At December 31, 2009 and 2008, the carrying value of our equity method investment in KA, net of dividends received, was $318 million and $356 million, respectively, and is included in non-current Other assets in the Consolidated Balance Sheets. The amount of dividends received were $110 million and $8 million for the years ended December 31, 2009 and 2008, respectively. 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, pegfilgrastim, granulocyte colony-stimulating factor ( G-CSF ), recombinant human erythropoietin and romiplostim are pursuant to exclusive licenses from KA, which we currently market under the brand names Aranesp®, Neulasta®, NEUPOGEN®, EPOGEN® 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, 2009, 2008 and 2007, KA earned royalties from us of $327 million, $321 million and $336 million, respectively. These amounts are included in Cost of sales (excludes amortization of certain acquired intangible assets) in the Consolidated Statements of Income. At December 31, 2009 and 2008, we owed KA $104 million and $89 million, respectively, which are included in Accrued liabilities in the Consolidated Balance Sheets.

KA s expenses primarily consist 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, 2009, 2008 and 2007, we earned revenues from KA of $102 million, $124 million and $180 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. In addition, included in Other revenues in the Consolidated Statements of Income for the year ended December 31, 2007 is $45 million received from KA with respect to achieving certain regulatory filing milestones. During the years ended December 31, 2009, 2008 and 2007, we recorded cost recoveries from KA of $96 million, $82 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.

**9. Restructuring**

On August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure. This restructuring plan was primarily the result of regulatory and reimbursement developments that began in 2007 involving erythropoiesis-stimulating 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 have completed all of the actions and incurred all related costs included in our restructuring plan and subsequently identified initiatives.

Through December 31, 2009, we incurred $957 million of costs related to the above-noted actions. The charges included $213 million of separation costs associated with approximately 3,100 staff members, $476 million of asset impairments, $148 million of accelerated depreciation and $120 million of other net charges, which include $165 million of loss accruals for leases, $41 million for implementation costs associated with certain cost

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

saving initiatives, $19 million of other charges and $10 million loss on the disposal of certain less significant marketed products, offset by $115 million of cost recoveries from Pfizer.

The following tables summarize the charges (credits) related to the above-noted actions by type of activity (in millions):

| Year ended December 31, 2009 | Separation costs | Asset impairments | Accelerated depreciation | Other | Total |
|---|---|---|---|---|---|
| Cost of sales (excludes amortization of certain acquired intangible assets) | $ | $ 1 | $ | $ | $ 1 |
| R&D | (3) | 8 | | 1 | 6 |
| SG&A | (2) | | | 31 | 29 |
| Other charges | 30 | | | 4 | 34 |
| | $ 25 | $ 9 | $ | $ 36 | $ 70 |
| **Year ended December 31, 2008** | | | | | |
| Cost of sales (excludes amortization of certain acquired intangible assets) | $ | $ 6 | $ | $ | $ 6 |
| R&D | 3 | | | | 3 |
| SG&A | | 17 | | 20 | 37 |
| Other charges | 7 | 36 | | 49 | 92 |
| Interest and other income, net | | | | 10 | 10 |
| | $ 10 | $ 59 | $ | $ 79 | $ 148 |
| **Year ended December 31, 2007** | | | | | |
| Cost of sales (excludes amortization of certain acquired intangible assets) | $ (1) | $ 4 | $ 147 | $ | $ 150 |
| R&D | (19) | 38 | | | 19 |
| SG&A | (11) | | 1 | (114) | (124) |
| Other charges | 209 | 366 | | 119 | 694 |
| | $ 178 | $ 408 | $ 148 | $ 5 | $ 739 |

During the years ended December 31, 2009, 2008 and 2007, we recorded staff separation costs of $30 million, $10 million and $209 million, respectively, principally consisting of severance. Partially offsetting these amounts in Cost of sales (excluding amortization of certain acquired intangible assets), Research and development expense and Selling, general and administrative expense for the years ended December 31, 2009 and 2007 are the reversal of previously accrued expenses for bonuses and stock-based compensation awards totaling $5 million and $31 million, respectively, which were forfeited as a result of the employees termination.

We also recorded asset impairment charges of $9 million, $59 million and $408 million during the years ended December 31, 2009, 2008 and 2007, respectively. These charges principally represent the write-off of the total cost of the related assets as they were abandoned with no alternative future uses or residual value. The charges for 2008 included impairments primarily for certain manufacturing-related assets. The charges in 2007 were primarily incurred in connection with our decisions to make changes to certain manufacturing and, to a lesser degree, certain R&D capital projects and to close certain production operations. In particular, these decisions in 2007 included the subsequent indefinite postponement of our planned Ireland manufacturing operations, certain revisions to our planned manufacturing expansion in Puerto Rico and the

closure of a clinical manufacturing facility in Thousand Oaks, California.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In addition, in connection with the rationalization of our worldwide network of manufacturing facilities in 2007, we decided to accelerate the closure of one of our ENBREL commercial bulk manufacturing operations in West Greenwich, Rhode Island. The decision to accelerate the closure of this manufacturing operation was principally based on a thorough review of the supply plans for bulk ENBREL inventory across its worldwide manufacturing network, including consideration of expected increases in manufacturing yields, and the determination that the related assets were not expected to have any alternative future uses in our operations. Because the related estimated future cash flows for this manufacturing operation were sufficient to recover the respective book values, we were required to accelerate depreciation of the related assets rather than immediately impairing their carrying values. The amount included in Cost of sales (excluding amortization of certain acquired intangible assets) in the table above, $147 million, represents the excess of the accelerated depreciation expense recognized during the year ended December 31, 2007 over the depreciation that would otherwise have been recorded, $6 million, if there were no plans to accelerate the closure of this manufacturing operation.

Other restructuring charges incurred in 2009 primarily relate to integration costs associated with our cost savings initiatives and loss accruals for certain leases that will not be used in our business. Integration costs totaled $32 million and are included in Research and development and Selling, general and administrative expenses in the Consolidated Statement of Income. Loss accruals for leases were $4 million and are included in Other charges in the Consolidated Statement of Income. In 2008, other restructuring charges of $70 million also primarily included integration costs and loss accruals for certain leases that will not be used in our business of $9 million and $59 million, respectively. All of the integration costs and $12 million of the lease loss accruals are included in SG&A. The remaining loss accruals for leases of $47 million are included in Other charges in the Consolidated Statement of Income. In addition, in 2008, we recorded a $10 million loss on the disposal of certain less significant marketed products that is included in Interest and other income, net in the Consolidated Statement of Income. Other restructuring charges for 2007 of $5 million are primarily comprised of cost recoveries for certain restructuring charges, principally accelerated depreciation, and loss accruals for leases for certain R&D facilities that will not be used in our business. The cost recoveries totaled $114 million and were recognized in connection with our co-promotion agreement with Pfizer. As such, they were recorded as a reduction of the Pfizer profit share expense included in Selling, general and administrative expense in the Consolidated Statement of Income. The loss accruals for certain leases primarily related to R&D facilities under construction that were not occupied totaled $102 million and are included in Other charges in the Consolidated Statement of Income.

The following table summarizes the charges and spending relating to the above-noted actions (in millions):

| | Separation costs | Other | Total |
|---|---|---|---|
| Restructuring reserves as of January 1, 2007 | $ | $ | $ |
| Expense | 209 | 119 | 328 |
| Payments | (112) | (17) | (129) |
| Restructuring reserves as of December 31, 2007 | 97 | 102 | 199 |
| Expense | 10 | 76 | 86 |
| Payments | (103) | (16) | (119) |
| Restructuring reserves as of December 31, 2008 | 4 | 162 | 166 |
| Expense | 30 | 36 | 66 |
| Payments | (31) | (68) | (99) |
| Restructuring reserves as of December 31, 2009 | $ 3 | $ 130 | $ 133 |

Substantially all other remaining liabilities represent payments for leases over a period of 14 years.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. Other charges**

For the years ended December 31, 2009, 2008 and 2007, we recorded loss accruals for settlements of certain legal proceedings aggregating $33 million, $288 million and $34 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.

For the years ended December 31, 2009, 2008 and 2007, we recorded charges associated with restructuring and/or cost savings initiatives totaling $34 million, $92 million and $694 million, respectively. Such expenses are included in Other charges in the Consolidated Statements of Income. (See Note 9, *Restructuring* for further discussion.)

**11. Available-for-sale securities**

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

| December 31, 2009 | Amortized cost | Gross unrealized gains | Gross unrealized losses | Estimated fair value |
|---|---|---|---|---|
| Type of security: | | | | |
| 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 |

| December 31, 2008 | Amortized cost | Gross unrealized gains | Gross unrealized losses | Estimated fair value |
|---|---|---|---|---|
| Type of security: | | | | |
| U.S. Treasury securities | $ 1,896 | $ 58 | $ (2) | $ 1,952 |
| Obligations of U.S. government agencies and FDIC guaranteed bank debt | 3,396 | 100 | (3) | 3,493 |
| Corporate debt securities | 1,432 | 10 | (72) | 1,370 |
| Mortgage and asset backed securities | 508 | 2 | (6) | 504 |
| Money market mutual funds | 1,565 | | | 1,565 |
| Other short-term interest bearing securities | 561 | | | 561 |
| Total debt securities | 9,358 | 170 | (83) | 9,445 |
| Equity securities | 65 | | (8) | 57 |

| | | | |
|---|---|---|---|
| $ 9,423 | $ 170 | $ (91) | $ 9,502 |

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

| Contractual maturity | December 31, 2009 | 2008 |
|---|---|---|
| In one year or less | $ 3,444 | $ 3,179 |
| After one year through three years | 6,369 | 3,724 |
| After three years through five years | 3,207 | 2,199 |
| After five years | 322 | 343 |
| Total debt securities | 13,342 | 9,445 |
| Equity securities | 55 | 57 |
| | $ 13,397 | $ 9,502 |

| Classification in the Consolidated Balance Sheets | December 31, 2009 | 2008 |
|---|---|---|
| Cash and cash equivalents | $ 2,884 | $ 1,774 |
| Marketable securities | 10,558 | 7,778 |
| Other assets noncurrent | 55 | 30 |
| | 13,497 | 9,582 |
| Less cash | (100) | (80) |
| | $ 13,397 | $ 9,502 |

For the years ended December 31, 2009, 2008 and 2007, realized gains totaled $104 million, $124 million and $17 million, respectively, and realized losses totaled $62 million, $49 million and $20 million, respectively. The cost of securities sold is based on the specific identification method.

The primary objectives of our investment portfolio are liquidity and safety of principal. Investments are made with the objective of achieving the highest rate of return consistent with these two objectives. Our investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

We review our available-for-sale securities for other-than-temporary declines in fair value below their 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 less than our cost basis and adverse conditions specifically related to the security including any changes to the rating of the security by a rating agency. As of December 31, 2009 and 2008, we believe that the cost bases for our available-for-sale securities were recoverable in all material respects.

**12. Inventories**

Inventories consisted of the following (in millions):

| | December 31, 2009 | 2008 |
|---|---|---|
| Raw materials | $ 97 | $ 112 |
| Work in process | 1,683 | 1,519 |

| | | |
|---|---|---|
| Finished goods | 440 | 444 |
| | $ 2,220 | $ 2,075 |

As of December 31, 2009, we had $258 million of Prolia inventory capitalized in preparation for its anticipated product launch. We are currently in discussions with regulatory authorities in the United States, European Union and various other countries regarding the approval of Prolia. The amount capitalized for Prolia inventory is included in work in process.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

**13. Property, plant and equipment**

Property, plant and equipment consisted of the following (in millions):

| | December 31, | |
|---|---|---|
| | 2009 | 2008 |
| Land | $ 450 | $ 456 |
| Buildings and improvements | 3,293 | 3,205 |
| Manufacturing equipment | 1,462 | 1,431 |
| Laboratory equipment | 892 | 923 |
| Furniture, fixtures and other assets | 3,369 | 3,154 |
| Construction in progress | 910 | 826 |
| | 10,376 | 9,995 |
| Less accumulated depreciation and amortization | (4,638) | (4,116) |
| | $ 5,738 | $ 5,879 |

During the years ended December 31, 2009, 2008 and 2007, we recognized depreciation and amortization charges associated with our property, plant and equipment of $624 million, $648 million and $786 million, respectively.

**14. Intangible assets**

Amortization of intangible assets other than goodwill is provided over their estimated useful lives ranging from 5 to 15 years on a straight-line basis (weighted average remaining amortization period of 7 years at December 31, 2009). Intangible assets other than goodwill consisted of the following (in millions):

| Intangible assets subject to amortization | Weighted average amortization period | December 31, 2009 | December 31, 2008 |
|---|---|---|---|
| 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 | 541 | 537 |
| | | 5,301 | 5,297 |
| Less accumulated amortization | | (2,734) | (2,309) |
| | | $ 2,567 | $ 2,988 |

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. Acquired R&D technology rights principally include certain technology acquired in the Abgenix, Inc. ( Abgenix ) acquisition in 2006. The amortization of other intangible assets is principally included in Cost of sales and Selling, general and administrative expense in the Consolidated Statements of Income. During the years ended December 31, 2009, 2008 and 2007, we

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

recognized amortization charges associated with our intangible assets of $425 million, $425 million and $416 million, respectively. The total estimated amortization for each of the next five years for our intangible assets is $418 million, $366 million, $338 million, $338 million and $321 million in 2010, 2011, 2012, 2013 and 2014, respectively.

**15. Accrued liabilities**

Accrued liabilities consisted of the following (in millions):

| | December 31, 2009 | 2008 |
|---|---|---|
| Sales deductions | $ 970 | $ 876 |
| Employee compensation and benefits | 751 | 799 |
| Clinical development costs | 361 | 429 |
| Sales returns reserve | 211 | 233 |
| Other | 1,006 | 1,045 |
| | $ 3,299 | $ 3,382 |

**16. Financing arrangements**

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements (dollar amounts in millions):

| | December 31, 2009 | 2008 |
|---|---|---|
| 0.125% convertible notes due 2011 (2011 Convertible Notes) | $ 2,342 | $ 2,206 |
| 0.375% convertible notes due 2013 (2013 Convertible Notes) | 2,088 | 1,970 |
| 5.85% notes due 2017 (2017 Notes) | 1,099 | 1,099 |
| 4.00% notes due 2009 (2009 Notes) | | 1,000 |
| 4.85% notes due 2014 (2014 Notes) | 1,000 | 1,000 |
| 5.70% notes due 2019 (2019 Notes) | 998 | |
| 6.40% notes due 2039 (2039 Notes) | 995 | |
| 6.375% notes due 2037 (2037 Notes) | 899 | 899 |
| 6.15% notes due 2018 (2018 Notes) | 499 | 499 |
| 6.90% notes due 2038 (2038 Notes) | 499 | 498 |
| Zero-coupon modified convertible notes due in 2032 (2032 Modified Convertible Notes) | 82 | 81 |
| 8.125% notes due 2097 (Other) | 100 | 100 |
| Total borrowings | 10,601 | 9,352 |
| Less current portion | | 1,000 |
| Total non-current debt | $ 10,601 | $ 8,352 |

*2011 and 2013 Convertible Notes*

In February 2006, we issued $2.5 billion principal amount of convertible notes due in February 2011 (the 2011 Convertible Notes ) and $2.5 billion principal amount of convertible notes due in February 2013 (the 2013 Convertible Notes ). The 2011 Convertible Notes and the 2013 Convertible Notes were issued at par and pay interest at a rate of 0.125% and 0.375%, respectively. The 2011 Convertible Notes and 2013 Convertible Notes may be converted into shares of our common stock based on an initial conversion rate of 12.5247 shares and 12.5814 shares, respectively, per $1,000 principal amount of notes (which represents an initial conversion

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

price of approximately $79.84 and $79.48 per share, respectively). These conversion rates will be adjusted if we make specified types of distributions or enter into certain other transactions with respect to our common stock. The 2011 Convertible Notes and 2013 Convertible Notes may only be converted: (i) during any calendar quarter if the closing price of our common stock exceeds 130% of the respective 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 respective 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) to the extent the conversion value exceeds the principal amount of the note, shares of our common stock, cash or a combination of common stock and cash, at our option (the excess conversion value ). As of December 31, 2009, these notes were not convertible. 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 100% of the principal amount of the notes plus accrued interest.

Concurrent with the issuance of the 2011 Convertible Notes and 2013 Convertible Notes, we purchased convertible note hedges. The convertible note hedges allow us to receive shares of our common stock and/or cash from the counterparties to the transactions 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 2011 Convertible Notes and 2013 Convertible Notes upon conversion. These transactions will terminate at the earlier of the maturity dates of the related notes or the first day none of the related notes remain outstanding due to conversion or otherwise. The cost of the convertible note hedges aggregated approximately $1.5 billion.

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. Proceeds received from the issuance of the warrants totaled approximately $774 million.

Because we have the choice of settling the convertible note hedges and warrants 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.

Effective January 1, 2009, we adopted a new accounting standard that changed the method of accounting for certain types of convertible debt and, as required by this new standard, we retrospectively applied this change in accounting to all prior periods for which we had applicable outstanding convertible debt (see Note 2, *Change in method of accounting for convertible debt instruments* ). 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 2032 Modified Convertible Notes (discussed below), 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.

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The discounts associated with the 2011 Convertible Notes and the 2013 Convertible Notes resulting from the adoption of this new accounting standard are being amortized over periods that end on the scheduled maturity dates of these notes and result in effective interest rates of approximately 6.24% for the 2011 Convertible Notes and approximately 6.35% for the 2013 Convertible Notes.

For the years ended December 31, 2009, 2008 and 2007, total interest expense for the 2011 Convertible Notes was $140 million, $132 million and $124 million, respectively, including non-cash interest expense of $136 million, $128 million and $121 million, respectively, related to the amortization of the discount resulting from the adoption of the new accounting standard. The remaining balance of the interest expense relates to the contractual coupon rates.

For the years ended December 31, 2009, 2008 and 2007, total interest expense for the 2013 Convertible Notes was $127 million, $120 million and $113 million, respectively, including non-cash interest expense of $118 million, $110 million and $104 million, respectively, related to the amortization of the discount resulting from the adoption of the new accounting standard. The remaining balance of the interest expense relates 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 are as follows (in millions):

| | | Liability component | | Equity component |
|---|---|---|---|---|
| **Balance as of December 31, 2009** | **Principal balance** | **Unamortized discount** | **Net carrying amount** | **Net carrying amount** |
| 2011 Convertible Notes | $ 2,500 | $ 158 | $ 2,342 | $ 643 |
| 2013 Convertible Notes | 2,500 | 412 | 2,088 | 829 |
| **Balance as of December 31, 2008** | | | | |
| 2011 Convertible Notes | $ 2,500 | $ 294 | $ 2,206 | $ 643 |
| 2013 Convertible Notes | 2,500 | 530 | 1,970 | 829 |

*2017 Notes and 2037 Notes*

In May 2007, we issued $2.0 billion aggregate principal amount of floating rate notes due in November 2008 (the 2008 Floating Rate Notes ), $1.1 billion aggregate principal amount of notes due in 2017 (the 2017 Notes ) and $900 million aggregate principal amount of notes due in 2037 (the 2037 Notes ). The annual interest rate on our 2008 Floating Rate Notes was equal to LIBOR plus 0.08%, which was reset quarterly. The 2017 Notes and 2037 Notes pay interest at fixed annual rates of 5.85% and 6.375%, respectively. The 2017 Notes and 2037 Notes may be redeemed at any time at our option, in whole or in part, at 100% of 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 the 2017 Notes and 2037 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. A total of $3.2 billion of the net proceeds raised from the issuance of these notes were used to repurchase shares of our common stock under an accelerated share repurchase program ( ASR ) entered into in May 2007. Upon the receipt of the proceeds from the issuance of the 2018 Notes and 2038 Notes discussed below, in June 2008 we exercised our right to call and repaid $1.0 billion of the 2008 Floating Rate Notes which were scheduled to mature in November 2008. The remaining $1.0 billion of the 2008 Floating Rate Notes matured and were repaid in November 2008.

*2009 Notes*

In November 2009, $1.0 billion aggregate principal amount of notes with a fixed interest rate of 4.00% (the 2009 Notes ) became due and were repaid.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*2014 Notes*

At December 31, 2009 and 2008, we had outstanding $1.0 billion aggregate principal amount of notes with a fixed interest rate of 4.85% due 2014 (the 2014 Notes ).

*2019 Notes and 2039 Notes*

In January 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 a registered offering. The 2019 Notes and the 2039 Notes pay interest at fixed annual rates of 5.70% and 6.40%, respectively. The 2019 Notes and the 2039 Notes may be redeemed at any time at our option, in whole or in part, at 100% of the principal amount of the notes being redeemed plus accrued and unpaid interest, if any, and a make-whole amount, as defined. Upon the occurrence of a change in control triggering event, as defined, we may be required to purchase for cash all or a portion of the 2019 Notes and the 2039 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. Debt issuance costs totaled approximately $13 million and are being amortized over the lives of the notes.

*2018 Notes and 2038 Notes*

In May 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 a registered offering. The 2018 Notes and 2038 Notes pay interest at fixed annual rates of 6.15% and 6.90%, respectively. The 2018 Notes and 2038 Notes may be redeemed at any time at our option, in whole or in part, at 100% of 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 the 2018 Notes and 2038 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. Debt issuance costs totaled approximately $6 million and are being amortized over the life of the notes.

*2032 Modified Convertible Notes*

In 2002, we issued zero-coupon 30 year convertible notes ( 2032 Convertible Notes ) with an aggregate face amount of $4.0 billion and yield to maturity of 1.125% which resulted in an original issue discount of $1.1 billion. The holders of the 2032 Convertible Notes had the right to require us to repurchase all or a portion of their notes at various put dates, including March 1, 2005 when we were required to repurchase $1.6 billion aggregate principal amount of 2032 Convertible Notes for their then-accreted value of $1.2 billion in cash.

In 2005, we exchanged new zero-coupon convertible notes (the 2032 Modified Convertible Notes ) and a cash payment of approximately $6 million for the remaining 2032 Convertible Notes then outstanding. Because the 2032 Modified Convertible Notes may be partially or wholly settled in cash, they are subject to the new convertible debt accounting standard discussed above. The additional discount on the 2032 Modified Convertible Notes recognized pursuant to the retrospective application of this new accounting standard (in excess of the discount recognized under the contractual terms of these securities) was amortized as non-cash interest expense from the date the 2032 Modified Convertible Notes were issued to March 1, 2006, the date when the notes were expected to be put back to us. We repurchased substantially all of the outstanding 2032 Modified Convertible Notes on March 2, 2007 at their then accreted value of $1.7 billion.

We continue to recognize interest expense for the amortization of the discount based on the contractual rate for the 2032 Modified Convertible Notes that remain outstanding. For years ended December 31, 2009, 2008 and 2007, amortization of the discount for the 2032 Modified Convertible Notes was approximately $1 million, $1 million and $4 million, respectively. As of December 31, 2009 and 2008, the equity component of the 2032 Modified Convertible Notes was approximately $29 million.

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Holders of the remaining outstanding 2032 Modified Convertible Notes may, subject to certain conditions, convert each of their notes based on a conversion rate of 8.8601 shares of our common stock. The conversion price per share of the convertible notes as of any day will equal the accreted value on that day, divided by the conversion rate, or $88.01, as of December 31, 2009. If converted, the 2032 Modified Convertible Notes will be settled in cash for an amount equal to the lesser of the accreted value of the 2032 Modified Convertible Notes at the conversion date or the conversion value, as defined, and shares of our common stock, if any, to the extent the conversion value exceeds the amount paid in cash. As of December 31, 2009, these notes were not convertible and the accreted value exceeded the amount that would have been received upon conversion.

*Other*

We had $100 million of debt securities outstanding at December 31, 2009 and 2008 with a fixed interest rate of 8.125% due in 2097.

*Shelf registration statements and other facilities*

As of December 31, 2009, 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, 2009, no amounts were outstanding under our commercial paper program.

As of December 31, 2009, 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 0.045% based on our current credit rating. As of December 31, 2009, 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.

As of December 31, 2009, 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. All of the $400 million of debt securities available for issuance may be offered from time to time under our medium-term note program with terms to be determined at the time of issuance. As of December 31, 2009, no securities were outstanding under the $400 million medium-term note program.

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 LIBOR-based floating rate 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, 2009 and 2008, we had interest rate swap agreements with an aggregate face value of $1.5 billion and $2.6 billion, respectively.

Certain of our financing arrangements contain non-financial covenants and we were in compliance with all applicable covenants as of December 31, 2009. None of our financing arrangements contain any financial covenants.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Contractual maturities of long-term debt obligations*

The aggregate contractual maturities of all long-term debt obligations due subsequent to December 31, 2009 are as follows (in millions):

| Maturity date | Amount |
|---|---|
| 2010 | $ |
| 2011[1] | 2,500 |
| 2012[2] | 84 |
| 2013[1] | 2,500 |
| 2014 | 1,000 |
| Thereafter | 5,100 |
| Total | $ 11,184 |

(1) This amount represents the principal amount due under the note after full accretion of the debt discount.

(2) This amount represents the 2032 Modified Convertible Notes accreted value on March 1, 2012, the next date on which holders may put the debt to us for repayment.

*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, 2009, 2008 and 2007 was $578 million, $551 million and $496 million, respectively. Interest costs capitalized for the years ended December 31, 2009, 2008 and 2007 were $32 million, $22 million and $28 million, respectively. Interest paid, net of interest rate swaps, during the years ended December 31, 2009, 2008 and 2007, totaled $293 million, $303 million and $258 million, respectively. Included in interest expense, net for the years ended December 31, 2009, 2008 and 2007, is the impact of non-cash interest expense of $250 million, $235 million and $168 million, respectively, resulting from the adoption of the new accounting standard that changed the method of accounting for our convertible debt. (See above and Note 2, *Change in method of accounting for convertible debt instruments.* )

**17. Stockholders equity**

*Stock repurchase program*

A summary of the activity under our stock repurchase program is as follows (in millions):

| | 2009 | | 2008 | | 2007 | |
|---|---|---|---|---|---|---|
| | Shares | Dollars | Shares | Dollars | Shares | Dollars |
| First quarter | 37.5 | $ 1,997 | | $ | 8.8 | $ 537 |
| Second quarter | | | 32.7 | 1,549[1] | 73.9[2] | 4,463 |
| Third quarter | | | | 19[1] | 2.5[2] | |
| Fourth quarter | 21.7 | 1,211 | 12.6 | 700 | 1.8 | 100 |
| Total | 59.2 | $ 3,208 | 45.3 | $ 2,268 | 87.0 | $ 5,100 |

(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 ASR entered into in May 2008.

(2) The total number of shares repurchased during the three months ended June 30, 2007 excludes 2.5 million shares received in July 2007 in connection with the final settlement of an ASR entered into in May 2007.

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**AMGEN INC.**

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In both July 2007 and December 2009, the Board of Directors authorized us to repurchase up to $5.0 billion of common stock of which a total of $6.0 billion remains available for stock repurchases as of December 31, 2009. 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 our credit rating and may include private block purchases as well as market transactions.

*Accumulated other comprehensive income*

The components of accumulated other comprehensive income ( OCI ) are as follows (in millions):

| | Foreign currency translation | Cash flow hedges | Available-for-sale securities | Other | Accumulated other comprehensive income |
|---|---|---|---|---|---|
| Balance as of January 1, 2007 | $ 45 | $ (25) | $ (8) | $ | $ 12 |
| Other comprehensive income: | | | | | |
| Foreign currency translation adjustments | 30 | | | | 30 |
| Unrealized (losses)/gains | | (32) | 73 | | 41 |
| Reclassification adjustments to income | | | 3 | | 3 |
| Income taxes | (16) | 12 | (29) | | (33) |
| 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 loss: | | | | | |
| 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*

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. At December 31, 2009 and 2008, no shares of preferred stock were issued or outstanding.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**18. 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 |
| 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.

U.S. Treasury securities, money market mutual funds and equity securities are valued using quoted market prices in active markets with no valuation adjustment. Accordingly, these securities are categorized in Level 1. Obligations of U.S. government agencies and FDIC guaranteed bank debt, corporate debt securities, mortgage and asset backed securities and other short-term interest bearing securities are valued using methodologies based on market observable inputs, principally, quoted prices of transactions of similar securities in active markets, quoted prices of recent transactions of identical or similar assets in markets that are not active, benchmark yields and issuer credit spreads. Accordingly, these securities are categorized in Level 2.

Our derivative assets and liabilities include interest rate swaps and foreign currency forward and option contracts. The fair values of these derivatives are determined using methodologies based on market observable inputs, including interest rate and volatility curves, credit spreads and foreign currency spot prices. All of these derivative contracts are categorized in Level 2.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following fair value hierarchy tables present information about each major category of the Company s financial assets and liabilities measured at fair value on a recurring basis (in millions):

| | 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 securities: | | | | |
| 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 |
| | 4,774 | 8,623 | | 13,397 |
| Derivatives | | 153 | | 153 |
| Total | $ 4,774 | $ 8,776 | $ | $ 13,550 |
| **Liabilities:** | | | | |
| Derivatives | $ | $ 152 | $ | $ 152 |
| Total | $ | $ 152 | $ | $ 152 |

| | Fair value measurement at December 31, 2008 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 securities | $ 3,575 | $ 5,927 | $ | $ 9,502 |
| Derivatives | | 415 | | 415 |
| Total | $ 3,575 | $ 6,342 | $ | $ 9,917 |
| **Liabilities:** | | | | |
| Derivatives | $ | $ 66 | $ | $ 66 |
| Total | $ | $ 66 | $ | $ 66 |

There were no material remeasurements to fair value during the years ended December 31, 2009 and 2008 of assets and liabilities that are not measured at fair value on a recurring basis.

*Summary of the fair value of other financial instruments*

*Short-term assets and liabilities*

The fair values of trade receivables and accounts payable approximate their carrying values due to the short-term nature of these financial instruments.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Notes payable*

The following tables present the carrying value and fair value of our convertible notes, modified convertible notes and other long-term notes. The fair values of our convertible and modified convertible notes were estimated using discounted cash flow models based upon market observable inputs, including benchmark yields adjusted for our credit risk, which were corroborated by prices on recent transactions (Level 2). The fair values of our other long-term notes were estimated using quoted prices, which were corroborated by market prices of recent transactions (Level 2). The fair values of our convertible notes and modified convertible notes exclude the equity components of our convertible notes and represent only the liability component of these instruments, and their equity components are included in Common stock and additional paid-in capital in the Consolidated Balance Sheets (in millions):

| | December 31, 2009 | |
|---|---|---|
| | Carrying value | Fair value |
| 2011 Convertible Notes | $ 2,342 | $ 2,487 |
| 2013 Convertible Notes | 2,088 | 2,374 |
| 2017 Notes | 1,099 | 1,207 |
| 2014 Notes | 1,000 | 1,075 |
| 2019 Notes | 998 | 1,077 |
| 2039 Notes | 995 | 1,102 |
| 2037 Notes | 899 | 988 |
| 2018 Notes | 499 | 551 |
| 2038 Notes | 499 | 582 |
| 2032 Modified Convertible Notes | 82 | 81 |
| Other | 100 | 125 |
| Total | $ 10,601 | $ 11,649 |

| | December 31, 2008 | |
|---|---|---|
| | Carrying value | Fair value |
| 2011 Convertible Notes | $ 2,206 | $ 2,300 |
| 2013 Convertible Notes | 1,970 | 2,080 |
| 2017 Notes | 1,099 | 1,140 |
| 2009 Notes | 1,000 | 1,017 |
| 2014 Notes | 1,000 | 994 |
| 2037 Notes | 899 | 948 |
| 2018 Notes | 499 | 536 |
| 2038 Notes | 498 | 567 |
| 2032 Modified Convertible Notes | 81 | 58 |
| Other | 100 | 111 |
| Total | $ 9,352 | $ 9,751 |

**19. Derivative instruments**

The Company is exposed to certain risks related to its business operations. The primary 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 and interest rate swap contracts, to reduce our risk to these exposures. We do not use derivatives for speculative trading purposes and are not a party

to any leveraged derivatives.

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Consolidated Balance Sheets (see Note 18, *Fair value measurement* ). The accounting for changes in the fair value of a

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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.

We are exposed to possible changes in values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated 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 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, 2009, we had open foreign currency forward and option contracts, primarily Euro-based, with notional amounts of $3.4 billion and $376 million, respectively.

In connection with the anticipated issuance of long-term fixed-rate debt, we may 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 entered into these contracts and the time the related debt is issued. In connection with the issuance of our 2019 Notes and 2039 Notes in January 2009, we entered into forward interest rate contracts related to a portion of these borrowings.

These foreign currency forward and option contracts and forward interest rate contracts have been designated as cash flow hedges, and accordingly, the effective portion of the unrealized gains and losses on these contracts are reported in Accumulated other comprehensive income in the Consolidated Balance Sheet and reclassified to earnings in the same periods during which the hedged transactions affect earnings. The following table reflects the effective portion of the unrealized loss recognized in OCI for our cash flow hedge contracts (in millions):

| Derivatives in cash flow hedging relationships | Year ended December 31, 2009 |
|---|---|
| Foreign exchange contracts | $ (202) |
| Interest rate contracts | (11) |
| Total | $ (213) |

The following table reflects the location in the Consolidated Statement of Income and the effective portion of the loss reclassified from Accumulated OCI into income for our cash flow hedge contracts (in millions):

| Derivatives in cash flow hedging relationships | Statement of Income location | Year ended December 31, 2009 |
|---|---|---|
| Foreign exchange contracts | Product sales | $ (7) |
| Interest rate contracts | Interest expense, net | (1) |
| Total | | $ (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 resulted in less than $1 million of expense recorded in Interest expense, net and Interest and other income, net in the Consolidated Statement of Income for the year ended December 31, 2009. As of December 31, 2009, the amounts expected to be reclassified from Accumulated

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OCI into income over the next 12 months are approximately $49 million of losses on foreign currency forward and option contracts and $1 million of losses on forward interest rate contracts.

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 LIBOR-based floating rate coupon over the lives of the respective notes. As of December 31, 2009, we had interest rate swap agreements with an aggregate notional amount of $1.5 billion on 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 as well as the offsetting unrealized loss or gain on the hedged item attributable to the hedged risk are recognized in current earnings. For the year ended December 31, 2009, we included the unrealized gain on the hedged debt of $116 million in the same line item, Interest expense, net in the Consolidated Statement of Income, as the offsetting unrealized loss of $116 million on the related interest rate swap agreements.

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, 2009, the total notional amount of these foreign currency forward contracts was $414 million.

The following table reflects the location in the Consolidated Statement of Income and the amount of loss recognized in income for the derivative instruments not designated as hedging instruments (in millions):

| Derivatives not designated as hedging instruments | Statement of Income location | Year ended December 31, 2009 |
|---|---|---|
| Foreign exchange contracts | Interest and other income, net | $ (24) |

The following table reflects the fair values of both derivatives designated as hedging instruments and not designated as hedging instruments included in the Consolidated Balance Sheet as of December 31, 2009 (in millions):

| | Derivative assets | | Derivative liabilities | |
|---|---|---|---|---|
| | Balance Sheet location | Fair value | Balance Sheet location | Fair value |
| **Derivatives designated as hedging instruments:** | | | | |
| Interest rate contracts | Other current assets/Other non-current assets | $ 90 | Accrued liabilities/ Other non-current liabilities | $ |
| Foreign exchange 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 exchange contracts | Other current assets | | Accrued liabilities | |
| Total derivatives not designated as hedging instruments | | | | |
| Total derivatives | | $ 153 | | $ 152 |

Our foreign exchange contracts that were in a liability position as of December 31, 2009 contain certain credit risk related contingent provisions that are triggered if (i) we were to undergo a change in control and (ii) our or

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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.

**20. Contingencies and commitments**

*Contingencies*

In the ordinary course of business, we are involved in various legal proceedings and other matters that 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.

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

*Roche Matters*

*Amgen Inc. v. F. Hoffmann-La Roche Ltd., et al.*

On November 8, 2005, Amgen filed a lawsuit in 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 court that the importation, use, sale or offer to sell pegylated erythropoietin (alternatively referred to as peg-EPO or MIRCERA®) infringes Amgen s EPO patents. Amgen alleged infringement of six of its U.S. Patents that claim erythropoietin products, pharmaceutical compositions and processes for making erythropoietin, specifically U.S. Patent No. 5,547,933 ( the 933 Patent ), U.S. Patent No. 5,621,080 ( the 080 Patent ), U.S. Patent No. 5,955,422 ( the 422 Patent U.S. Patent No. 5,756,349 ( the 349 Patent ), U.S. Patent No. 5,618,698 ( the 698 Patent ) and U.S. Patent No. 5,441,868 ( the 868 Patent ). Amge sought a permanent injunction preventing the Roche Defendants from making, importing, using, offering for sale or selling recombinant human erythropoietin, including pegylated EPO, in the United States. The Roche Defendants amended answer asserted that all six of the patents-in-suit were not infringed, were invalid and were unenforceable due to inequitable conduct and counterclaimed asserting violations of federal and state antitrust laws. On June 5, 2007, the Massachusetts District Court entered an order dismissing the 080 Patent from the case.

The Massachusetts District Court conducted a jury trial on infringement and validity, a bench trial on other issues of validity and enforceability, and heard pre- and post-trial motions. On October 17, 2008, the Massachusetts District Court entered judgment that claim 1 of the 422 Patent, claims 3, 7, 8, 9, 11, 12 and 14 of the 933 Patent, claims 1 and 2 of the 868 Patent, claims 6 through 9 of the 698 Patent and claim 7 of the 349 Patent are valid and enforceable, and that claim 1 of the 422 Patent, claims 3, 7 and 8 of the 933 Patent, claims 1 and 2 of the 868 Patent, and claims 6 through 9 of the 698 Patent are infringed and permanently enjoined Roche from infringing the 422 Patent, the 933 Patent, the 868 Patent and the 698 Patent for the remaining life of these patents.

The Roche Defendants filed an appeal with the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court ) and Amgen filed a cross-appeal. On September 15, 2009, the Federal Circuit Court affirmed the Massachusetts District Court s judgment with respect to infringement of the 933, 422, 698 and 868 Patents and vacated the holding of non-infringement of the 349 Patent. The Federal Circuit Court also affirmed the validity of Amgen s patents except for a single issue of obviousness-type double patenting with respect to the 933, 422 and 349 Patents. The Federal Circuit Court remanded this validity issue and the issue of infringement of the 349 patent to the Massachusetts District Court for further proceedings.

Amgen and the Roche Defendants reached a settlement of the litigation in December 2009 and on December 22, 2009, the Massachusetts District Court entered final judgment and a permanent injunction against the Roche Defendants prohibiting Roche from infringing Amgen s patents, thus bringing the five-year patent

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

infringement dispute to an end. The judgment was accompanied by the Roche Defendant s admission that the five Amgen 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 do not include any financial payments between the parties.

*U.S. International Trade Commission*

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 Roche s importation of peg-EPO 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 of Roche s importation of peg-EPO into the United States. 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 to date are subject to a clinical trial exemption to patent infringement. On August 31, 2006, the ITC adopted the ALJ s summary determination terminating the investigation based on the clinical trial exemption to patent infringement liability under 35 U.S.C. 271(e)(1).

On October 11, 2006, Amgen filed a petition for review of the ITC s decision with 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 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. After the settlement of the dispute between the parties in December 2009, 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 it was not opposing Amgen s motion. No decision has been issued on Amgen s motion.

*Human Genome Sciences Litigations*

On November 30, 2007, Human Genome Sciences ( HGS ) filed an action under 35 U.S.C. §146 against Amgen in the Delaware District Court to review a Decision on Motions entered on July 26, 2007 and the Final Judgment entered November 20, 2007 by the Board of Patent Appeals and Interferences in Interference No. 105,240. On May 9, 2008, the Delaware District Court granted Amgen s Motion to Dismiss and HGS filed an appeal to the Federal Circuit Court. Thereafter, HGS withdrew its appeal and on October 14, 2009, the Federal Circuit Court entered an order on HGS motion to dismiss HGS appeal.

On October 21, 2009, the Delaware District Court entered orders on stipulated motions dismissing with prejudice HGS actions under 35 U.S.C. § 146 which had been filed by HGS after it had received unfavorable final judgments from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences on each of Interference No. 105,380 and Interference No. 105,381.

*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 Delaware District Court for infringement of four patents U.S. Patent Nos. 6,001,068; 6,031,003; 6,313,146 and 6,211,244. 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, unless there is an earlier decision by the Delaware District Court adverse to Amgen.

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The Delaware District Court has entered a scheduling order indicating that the case will be placed in the trial pool on September 1, 2010.

*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 alleging infringement of 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.

*Teva v. Amgen, the G-CSF Patent Litigation*

On November 30, 2009, Teva USA filed a lawsuit in the U.S. District Court for the Eastern District of Pennsylvania requesting that Amgen s U.S. Patent Nos. 5,580,755 and 5,582,823 relating to human G-CSF and methods for its use, be declared invalid and/or not infringed by Teva s Filgrastim molecule. Also on November 30, 2009, Teva 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 counterclaims seeking a declaration that Amgen s patents are valid and will be infringed by Teva s G-CSF product.

*Kennedy Institute v. Amgen Inc. and Wyeth*

On October 27, 2009, The Mathilda and Terence Kennedy Institute of Rheumatology Trust filed suit in the Delaware District Court alleging that Amgen and Wyeth have infringed U.S. Patent Number 6,270,766 by the distribution and sale of ENBREL for the treatment of arthritis by co-administration with methotrexate.

*Average Wholesale Price ( AWP ) Litigation*

Amgen and Immunex 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.

These cases have been consolidated into the MDL Proceeding, are being brought by consumer classes and certain state and local governmental entities. These cases consist of the following:

*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.; County of Suffolk v. Abbott Laboratories, Inc., et al.; County of Westchester v. Abbott Laboratories, Inc., et al.; County of Rockland v. Abbott Laboratories, Inc., et al.; City of New York v. Abbott Laboratories, Inc., et al.; County of Nassau v. Abbott Laboratories, Inc., et al; County of Onondaga*

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*v. Abbott Laboratories, Inc., et al.; County of Erie v. Abbott Laboratories, Inc., et al.; County of Chenango v. Abbott Laboratories, Inc., et al.; County of Chautauqua v. Abbott Laboratories, Inc., et al.; County of Tompkins v. Abbott Laboratories, Inc., et al.; County of Wayne v. Abbott Laboratories, Inc., et al.; County of Monroe v. Abbott Laboratories, Inc., et al.; County of Washington v. Abbott Laboratories, Inc., et al.; County of Herkimer v. Abbott Laboratories, Inc., et al.; County of Cayuga v. Abbott Laboratories, Inc., et al.; County of Allegany v. Abbott Laboratories, Inc., et al.; County of Rensselaer v. Abbott Laboratories, Inc., et al.; County of Albany v. Abbott Laboratories, Inc., et al.; County of Cattaraugus v. Abbott Laboratories, Inc., et al.; County of Yates v. Abbott Laboratories, Inc., et al.; County of Broome v. Abbott Laboratories, Inc., et al.; County of Warren v. Abbott Laboratories, Inc., et al.; County of Greene v. Abbott Laboratories, Inc., et al.; County of Saratoga v. Abbott Laboratories, Inc., et al.; County of St. Lawrence v. Abbott Laboratories, Inc., et al.; County of Oneida v. Abbott Laboratories, Inc., et al.; County of Genesee v. Abbott Laboratories, Inc., et al.; County of Fulton v. Abbott Laboratories, Inc., et al.; County of Steuben v. Abbott Laboratories, Inc., et al.; County of Putnam v. Abbott Laboratories, Inc., et al.; County of Niagara v. Abbott Laboratories, Inc., et al.; County of Jefferson v. Abbott Laboratories, Inc., et al.; County of Madison v. Abbott Laboratories, Inc., et al.; County of Lewis v. Abbott Laboratories, Inc., et al.; County of Columbia v. Abbott Laboratories, Inc., et al.; County of Essex v. Abbott Laboratories, Inc., et al.; County of Cortland v. Abbott Laboratories, Inc., et al.; County of Seneca v. Abbott Laboratories, Inc., et al.; County of Orleans v. Abbott Laboratories, Inc., et al.; County of Duchess v. Abbott Laboratories, Inc., et al.; County of Ontario v. Abbott Laboratories, Inc., et al.; County of Schuyler v. Abbott Laboratories, Inc., et al.; County of Wyoming v. Abbott Laboratories, Inc., et al.; State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., State of Iowa 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. A hearing before the Massachusetts District Court was held on April 9, 2008 and on July 2, 2008, the Massachusetts District Court issued an order of preliminary approval of the Track II defendants class settlement and scheduled a fairness hearing for December 16, 2008. At that hearing, the Massachusetts District Court was not satisfied with several notice requirements the plaintiffs were to have completed prior to the hearing and rescheduled the fairness hearing for April 27, 2009.

At the April 27, 2009, fairness hearing, the Massachusetts District Court was still not satisfied with several notice requirements and refused to grant final approval of the settlement agreement until those deficiencies were satisfied. The Massachusetts District Court held a May 28, 2009 status conference where mediation with respect to all non-settling MDL Proceeding cases was discussed. Final approval hearing of the Track II settlement before the Massachusetts District Court was scheduled for October 21, 2009. However, plaintiffs filed for an extension of the final approval hearing due to continued deficiencies in executing notices.

For the state and local governmental entities in the MDL Proceeding, on July 30, 2008, the Massachusetts District Court issued an order granting in part and denying in part Amgen s renewed Motion to Dismiss the First

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Amended Consolidated Complaint filed by New York City and 44 New York counties in the MDL Proceeding. The judge dismissed claims relating to all of Amgen s products named in the New York counties first amended complaint with the exception of claims relating to NEUPOGEN®. Subsequent to the filing of Amgen s motion, the New York counties filed a Revised First Amended Consolidated Complaint. It is unclear what bearing the Massachusetts District Court s decision will have on the revised complaint.

Certain AWP litigation cases remain part of the MDL Proceeding but are likely to be remanded. These cases are:

*State of Iowa v. Abbott Laboratories, Inc., et al.* This case was filed against Amgen and Immunex, along with several other pharmaceutical manufacturers, on October 9, 2007 in the U.S. District Court for the Southern District of Iowa. On October 9, 2007, Immunex was served with the complaint and on October 25, 2007, Amgen was served with the complaint. On November 20, 2007, this case was removed to the District of Massachusetts and was transferred to the MDL Proceeding. On January 18, 2008, a status conference was held. A Joint Motion to Dismiss was filed on February 20, 2008, and the motion was granted in part, denied in part on August 29, 2008. On January 22, 2009, Amgen s motion to dismiss in part regarding EPOGEN® was granted. On October 15, 2009, Amgen and Immunex reached a settlement with the state, and on November 9, 2009, both companies were dismissed with prejudice from the matter.

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

*Commonwealth of Pennsylvania v. TAP Pharmaceutical Products, Inc., et al.* This case was filed against Amgen in the Commonwealth Court for Pennsylvania in Harrisburg, Pennsylvania on March 10, 2004. On March 10, 2005, the Commonwealth of Pennsylvania filed an amended complaint, adding Immunex, and defendants filed Preliminary Objections. A hearing on the Preliminary Objections was held on June 8, 2005. On July 13, 2005, defendants filed a notice of removal from the Commonwealth Court for Pennsylvania to the U.S. District Court for the Eastern District of Pennsylvania (the Pennsylvania District Court ). This case was remanded to state court by order dated September 9, 2005. On October 11, 2006, the case was removed to the Pennsylvania District Court. Plaintiffs filed a motion to remand and on January 22, 2007, the Pennsylvania District Court stayed the case pending transfer to the MDL Proceeding. A hearing on plaintiff s motion to remand was held on February 1, 2007. On September 1, 2007, the case was remanded to the Commonwealth Court for Pennsylvania. Currently, the parties have briefed and are awaiting the court s ruling on the protective order to be entered in the case. Amgen and Immunex reached a settlement with the Commonwealth of Pennsylvania on November 17, 2009. On December 23, 2009, the judge granted plaintiff s motion to discontinue with prejudice the case against Amgen and Immunex.

*County of Erie v. Abbott Laboratories, Inc., et al.* This case was filed against Amgen and Immunex on March 8, 2005, in the Supreme Court of New York, Erie County. The complaint alleges that all defendants participated in a scheme to market the spread between the true wholesale price (i.e., selling price) and the false and inflated AWP reported, in order to increase market share, thus defrauding the county Medicaid program. On April 15, 2005, defendants filed a notice of removal from the state court to the U.S. District Court for the Western District of New York (the New York District Court ). This case was remanded to state court by order dated January 10, 2006. On September 7, 2006, the state court granted in part, and denied in part, defendants motions to dismiss. Immunex s motion to dismiss was granted and Amgen s motion to dismiss was denied. On October 11, 2006, this case was removed to the New York District Court. On September 1, 2007, the case was remanded to the state court. The State of New York Litigation Coordinating Panel granted defendants motions to coordinate the Erie, Oswego and Schenectady County cases.

*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 21, 2006, Immunex was served with the complaint and on August 24, 2006, Amgen was served with the complaint. On October 11, 2006, this case was removed to the

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U.S. District Court for the Northern District of New York. On September 1, 2007, the case was remanded to the state court. The State of New York Litigation Coordinating Panel granted defendants motions to coordinate the Erie, Oswego and Schenectady County cases.

*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 21, 2006, Immunex was served with the complaint and on August 24, 2006, Amgen was served with the complaint. On October 11, 2006, this case was removed to the U.S. District Court for the Northern District of New York. On September 1, 2007, the case was remanded to the state court. The State of New York Litigation Coordinating Panel granted defendants motions to coordinate the Erie, Oswego and Schenectady County cases.

*State of Kansas, ex rel Steve Six v. Amgen Inc. and Immunex Corporation.* On November 3, 2008, the State of Kansas filed a complaint against Amgen and Immunex in the District Court of Wyandotte County, Kansas, Civil Court Division. Approximately forty other pharmaceutical manufacturers were also sued by the state. Plaintiff Kansas alleges that the manufacturers misrepresented product pricing information reported to the state by falsely inflating those prices. A hearing on defendants motion to dismiss occurred on March 5, 2009, following which the court denied the motion.

*Federal Securities Litigation In re Amgen Inc. Securities Litigation*

The six federal class action shareholder complaints filed against Amgen Inc., Kevin W. Sharer, Richard D. Nanula, Dennis M. Fenton, Roger M. Perlmutter, Brian M. McNamee, George J. Morrow, Edward V. Fritzky, Gilbert S. Omenn and Franklin P. Johnson, Jr., (the Federal Defendants ) in the United States 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 9th Circuit (the 9th Circuit ) under Rule 23(f), regarding the Order on Class Certification and the 9th Circuit granted Amgen s appeal on December 11, 2009. Amgen s brief is due March 29, 2010 and plaintiff s brief is due April 27, 2010. On January 25, 2010, oral argument was heard on Amgen s motion to stay the case in the California Central District Court which was granted on February 2, 2010.

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*State Derivative Litigation*

*Larson v. Sharer, et al.*

The three state shareholder 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 shareholders 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 defendant and removing the causes of action for insider selling and misappropriation of information, violation of California Corporations Code Section 25402 and violation of California Corporations Code Section 25403. On July 14, 2008, the Superior Court dismissed without prejudice the consolidated state derivative class action. The judge also ordered a stay of any re-filing of an amended complaint until the federal court has determined whether any securities fraud occurred.

*Birch v. Sharer, et al.*

On January 23, 2009, a shareholder derivative lawsuit titled *Birch v. Sharer, et al.* was filed in Los Angeles County 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 ( HIPPA ). On February 25, 2009, the case was reassigned to a judge in the Complex Department of the Los Angeles County Superior Court and the initial status conference has been scheduled for May 13, 2009. 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 County 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 Birch 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. The stockholder alleged that the directors and certain executive officers violated their core fiduciary principles, causing Amgen to suffer damages. The stockholder 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 is currently undertaking an investigation into the allegations made by the stockholder.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

On February 8, 2010, plaintiff Shelly Birch filed another shareholder demand lawsuit in the Los Angeles Superior Court against the same defendants in the original lawsuit but also adding Board of Directors members Francois de Carbonnel and Rebecca Henderson. The allegations in the new complaint are nearly identical to those in the previously filed complaint.

*Federal Derivative Litigation*

On May 7, 2007, the shareholder derivative lawsuit of *Durgin v. Sharer, et al.*, was filed in the California Central District Court and named Amgen Inc., Kevin W. Sharer, George J. Morrow, Dennis M. Fenton, Brian M. McNamee, Roger M. Perlmutter, David Baltimore, Gilbert S. Omenn, Judith C. Pelham, Frederick W. Gluck, Jerry D. Choate, J. Paul Reason, Frank J. Biondi, Jr., Leonard D. Schaeffer, Frank C. Herringer, Richard D. Nanula, Edward V. Fritzky and Franklin P. Johnson, Jr. as defendants. The complaint alleges the same claims and requests the same relief as in the three state shareholder 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 shareholder derivative lawsuit of *Rosenblum v. Sharer, et al.*, was filed in the California Central District Court. This lawsuit was brought by the shareholder who previously made a demand on the Amgen Board on May 14, 2007. The complaint alleges that the defendants breached their fiduciary duties, wasted corporate assets and were unjustly enriched. Plaintiffs allege that the defendants failed to disclose and/or misrepresented results of Aranesp® clinical studies, marketed both Aranesp® and EPOGEN® for off-label uses and that these actions or inactions as well as the Amgen market strategy caused damage to the Company resulting in several inquiries, investigations and lawsuits that are costly to defend. The complaint also alleges insider trading by the defendants. The plaintiffs seek treble damages based on various causes of action, reformed corporate governance, equitable and/or injunctive relief, restitution, disgorgement of profits, benefits and other compensation, and legal costs. The case was stayed for all purposes until thirty days after a final ruling on the motion to dismiss by the California Central District Court in the *In re Amgen Inc. Securities Litigation* action.

Thereafter, on May 1, 2008, plaintiff in *Rosenblum v. Sharer, et al.*, filed an amended complaint which removed Dennis Fenton as a defendant and also eliminated the claims for insider selling by defendants. On July 28, 2008, the California Central District Court heard Amgen and the defendants motion to dismiss and motion to stay. On July 30, 2008, the California Central District Court granted Amgen and the defendants motion to dismiss without prejudice and also granted a stay of the case pending resolution of the *In re Amgen Inc. Securities Litigation* action.

*ERISA Litigation*

On August 20, 2007, the ERISA class action lawsuit of *Harris v. Amgen Inc., et al.,* was filed against Amgen and certain members of its Board of Directors in the California Central District Court. Plaintiffs claim that Amgen and various Board members breached their fiduciary duties by failing to inform current and former employees who participated in the Amgen Retirement and Savings Manufacturing Plan and the Amgen Savings Plan 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 9th Circuit, which remains pending before the 9th 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 Fiduciary Committee. Pursuant to the parties stipulation, the Ramos matter has been stayed pending the outcome

**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

of the Harris matter appeal. Oral argument before the 9th 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 9 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 Central District of California 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 but no ruling from the California Central District Court has been issued.

*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 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 District Court of New Jersey. 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 Multi-District Litigation ( MDL ) seeking to have the five third-party payer lawsuits consolidated into one MDL case and assigned to the Northern District of Illinois. Defendants filed an opposition to the MDL consolidation motion on February 3, 2008.

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 have been transferred back to the California Central District Court. The five cases will be transferred back to their respective jurisdictions if and when they are set for trial. On December 17, 2008, the MDL Court granted

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 9th Circuit. Opening briefs were filed by the Plaintiffs in the 9th Circuit on January 4, 2010. Amgen s Opposition Brief will be filed on March 5, 2010. No date for oral argument has been set.

*Qui Tam Actions*

A United States 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. The Massachusetts District Court held a status hearing on May 18, 2009 and ordered that the government make a decision whether or not to intervene in the Massachusetts Qui Tam Action by September 1, 2009.

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. The Massachusetts District Court gave the states and the private relator 60 days from September 1 to file an amended complaint. Amgen filed a motion to unseal the record with regard to the Massachusetts Qui Tam Action on October 23, 2009. 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, a group purchasing organization. The relator s seconded amended complaint also alleges that Amgen retaliated against and wrongfully terminated Westmoreland.

At a status conference on November 17, 2009, the Massachusetts District Court ruled on the motion to unseal, partially granting Amgen s motion and ordering that the relator and states file all complaints by December 17, 2009. The judge also set a trial date of January 2011. On January 20, 2010, the states of Florida and Texas voluntarily dismissed their complaints against Amgen. On February 1, 2010, Amgen filed motions to dismiss both the multi-state complaint and the relator s complaint and a motion to stay and sever the relator s employment claims. 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. Plaintiffs opposition pleadings were filed on February 22, 2010. On February 23, 2010, the state of Delaware voluntarily dismissed its complaint against Amgen. Also, on February 23, 2010, the Massachusetts District Court granted

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Amgen s motion to stay and sever the relator s employment claims. A hearing on the motions to dismiss has been scheduled by the Massachusetts District Court for March 11, 2010.

*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 U.S. District Court for the District of New Jersey 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. Class plaintiff filed its opposition on January 15, 2010 and Amgen filed its reply on February 8, 2010. The District Court has indicated that it will decide the motion without a hearing on or after February 16, 2010.

*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.

On October 25, 2007, Amgen received a subpoena from the U.S. Attorney s Office, Eastern District of New York, seeking documents relating to its products. On July 29, 2009, Amgen was served with a second subpoena from the U.S. Attorney s Office for the Eastern District of New York related to dosing. Amgen continues to fully cooperate with the requests. On January 6, 2010, Amgen was served with a third subpoena from the U.S. Attorney s Office, Eastern District of New York, related to Average Sales Price and on February 5, 2010, Amgen was served with a fourth subpoena from the U.S. Attorney s Office, Eastern District of New York, related to certain clinical trials on dosing. Amgen intends to cooperate fully with the government s requests.

On November 1, 2007, Amgen received a subpoena from the U.S. Attorney s Office, Western District of Washington, for production of documents relating to its products. On July 18, 2008, Amgen received a second subpoena from the U.S. Attorney s Office, Western District of Washington, pursuant to the Health Insurance Portability and Accountability Act of 1996 (18 U.S.C. 3486), which requests documents relating generally to Amgen s collection and dissemination of information regarding clinical research on the efficacy and safety of ESAs. On May 12, 2009, Amgen was served with a third subpoena from the U.S. Attorney s Office for the Western District of Washington related to Johnson and Johnson clinical trials and correspondence with payers. On August 19, 2009, Amgen was served with a fourth subpoena from the U.S. Attorney s Office for the Western District of Washington related to the 219 clinical trial. On December 9, 2009, Amgen received a fifth subpoena from the U.S. Attorney s Office for the Western District of Washington which requested additional information generally related to the compendia, reimbursement and the 219 clinical trial. Amgen is cooperating with the government s document requests. On February 11, 2010, Amgen received a sixth subpoena from the U.S. Attorney s Office for the Western District of Washington which requested documents related to Amgen s products and employees. 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.

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.

In the ordinary course of business, we are involved in various legal proceedings and other matters, including those discussed in this Note. 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.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*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 at December 31, 2009 (in millions):

| Year ending December 31, | Lease commitments |
|---|---|
| 2010 | $ 136 |
| 2011 | 123 |
| 2012 | 108 |
| 2013 | 100 |
| 2014 | 84 |
| Thereafter | 466 |
| Total | 1,017 |
| Less income from subleases | 15 |
| Net minimum operating lease commitments | $ 1,002 |

Included in the table above are future rental commitments for abandoned leases in the amount of $307 million. Rental expense on operating leases, net of sublease rental income, for the years ended December 31, 2009, 2008 and 2007 was $114 million, $120 million and $104 million, respectively. Sublease income for the years ended December 31, 2009, 2008 and 2007 was not material.

In addition, we have minimum contractual purchase commitments with third party manufacturers through 2012 that total $196 million. Amounts purchased under these contractual purchase commitments for the years ended December 31, 2009, 2008 and 2007 were $207 million, $196 million and $153 million, respectively.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**21. Segment information**

We operate in one business segment human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Enterprise-wide disclosures about product sales, revenues and long-lived assets by geographic area, and revenues from major customers are presented below.

*Revenues*

Revenues consisted of the following (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| Product sales: | | | |
| Aranesp® U.S. | $ 1,251 | $ 1,651 | $ 2,154 |
| Aranesp® International | 1,401 | 1,486 | 1,460 |
| EPOGEN® U.S. | 2,569 | 2,456 | 2,489 |
| Neulasta® U.S. | 2,527 | 2,505 | 2,351 |
| NEUPOGEN® U.S. | 901 | 896 | 861 |
| Neulasta® International | 828 | 813 | 649 |
| NEUPOGEN® International | 387 | 445 | 416 |
| ENBREL U.S. | 3,283 | 3,389 | 3,052 |
| ENBREL Canada | 210 | 209 | 178 |
| Sensipar® U.S. | 429 | 412 | 333 |
| Sensipar® International | 222 | 185 | 130 |
| Other U.S. | 175 | 151 | 203 |
| Other International | 168 | 89 | 35 |
| Total product sales | 14,351 | 14,687 | 14,311 |
| Other revenues | 291 | 316 | 460 |
| Total revenues | $ 14,642 | $ 15,003 | $ 14,771 |

*Geographic information*

Outside the United States, we principally sell Aranesp®, Neulasta® and NEUPOGEN® in Europe and ENBREL in Canada only. 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. 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.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Certain geographical information with respect to revenues and long-lived assets are as follows (in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| Revenues: | | | |
| United States | $ 11,421 | $ 11,772 | $ 11,887 |
| International countries | 3,221 | 3,231 | 2,884 |
| Total revenues | $ 14,642 | $ 15,003 | $ 14,771 |

| | December 31, | |
|---|---|---|
| | 2009 | 2008 |
| Long-lived assets: | | |
| United States | $ 3,525 | $ 3,836 |
| Puerto Rico | 1,920 | 1,740 |
| International countries | 293 | 303 |
| Total long-lived assets | $ 5,738 | $ 5,879 |

*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 early 2008, ENBREL s distribution model was converted from primarily being drop shipped directly to pharmacies to a wholesale distribution model similar to our other products. In Europe, Aranesp®, Neulasta® and NEUPOGEN® are principally sold 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, 2009, 2008 and 2007. On a combined basis, these distributors accounted for 71% and 88% of worldwide gross revenues and U.S. gross product sales, respectively, for 2009, as noted in the following table (dollar amounts in millions):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| AmerisourceBergen Corporation: | | | |
| Gross product sales | $ 7,179 | $ 7,099 | $ 6,124 |
| % of total gross revenues | 37% | 37% | 31% |
| % of U.S. gross product sales | 46% | 46% | 39% |
| McKesson Corporation: | | | |
| Gross product sales | $ 3,694 | $ 3,594 | $ 2,398 |
| % of total gross revenues | 19% | 19% | 12% |
| % of U.S. gross product sales | 24% | 23% | 15% |
| Cardinal Health, Inc.: | | | |
| Gross product sales | $ 2,841 | $ 2,823 | $ 2,715 |
| % of total gross revenues | 15% | 15% | 14% |
| % of U.S. gross product sales | 18% | 18% | 17% |

At December 31, 2009 and 2008, amounts due from these three large wholesalers each exceeded 10% of gross trade receivables, and accounted for 53% and 58%, respectively, of net trade receivables on a combined basis. At December 31, 2009 and 2008, 45% and 40%, 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, 2009 and 2008 was not material.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**22. Quarterly financial data (unaudited)**

| | 2009 Quarters ended | | | |
|---|---|---|---|---|
| | December 31 | September 30[1] | June 30[2] | March 31[3] |
| | (In millions, except per share data) | | | |
| 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 |

| | 2008 Quarters ended | | | |
|---|---|---|---|---|
| | December 31[4] | September 30[5] | June 30[6] | March 31 |
| | (In millions, except per share data) | | | |
| Product sales | $ 3,674 | $ 3,784 | $ 3,692 | $ 3,537 |
| Gross profit from product sales | 3,116 | 3,107 | 3,177 | 2,991 |
| Net income | 925 | 1,121 | 906 | 1,100 |
| Earnings per share: | | | | |
| Basic | $ 0.88 | $ 1.06 | $ 0.84 | $ 1.01 |
| Diluted | $ 0.87 | $ 1.05 | $ 0.84 | $ 1.01 |

(1) 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.

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

(3) 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.

(4) We recorded charges of $97 million ($68 million, net of tax) primarily for asset impairments, loss accruals for leases for certain facilities that will not be used in our business, staff separation costs and certain cost saving initiatives associated with our restructuring plan.

(5) We recorded a charge of $84 million ($64 million, net of tax) related to the write-off of inventory resulting from a strategic decision to change manufacturing processes.

(6) We recorded a charge of $263 million ($200 million, net of tax) for loss accruals for settlements of certain commercial legal proceedings.
See Notes 5, 9, 10 and 12 for further discussion of the items described above.

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**SCHEDULE II**

**AMGEN INC.**

**VALUATION ACCOUNTS**

**Years ended December 31, 2009, 2008 and 2007**

**(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, 2009 | $ 38 | $ (6) | $ | $ | $ 32 |
| Year ended December 31, 2008 | $ 39 | $ 1 | $ | $ 2 | $ 38 |
| Year ended December 31, 2007 | $ 38 | $ | $ 3 | $ 2 | $ 39 |