

AMGEN INC  
Form 10-K  
February 27, 2009  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington D.C. 20549

**Form 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2008

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**

(State or other jurisdiction of  
incorporation or organization)

**One Amgen Center Drive,  
Thousand Oaks, California**

(Address of principal executive offices)

**95-3540776**

(I.R.S. Employer  
Identification No.)

**91320-1799**

(Zip Code)

**(805) 447-1000**

(Registrant's telephone number, including area code)

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

**Common stock, \$0.0001 par value; preferred share purchase rights**

(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 ☒ No ☐

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

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

Indicate by check mark 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 ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was \$49,808,027,303 as of June 30, 2008(A)

(A) Excludes 1,077,968 shares of common stock held by directors and officers, and any stockholders whose ownership exceeds five percent of the shares outstanding, at June 30, 2008. 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.

**1,033,964,089**

(Number of shares of common stock outstanding as of February 13, 2009)

### DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2009 Annual Meeting of stockholders to be held May 6, 2009 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 ) was incorporated in 1980 and is a global biotechnology company organized as a Delaware corporation that discovers, develops, manufactures and markets human therapeutics based on advances in cellular and molecular biology. We operate in one business segment human therapeutics.

We market human therapeutic products primarily in the areas of supportive cancer care, nephrology and inflammation. Our principal products include Aranesp® (darbepoetin alfa), EPOGEN® (Epoetin alfa), Neulasta® (pegfilgrastim), NEUPOGEN® (Filgrastim) and Enbrel® (etanercept). Aranesp® and EPOGEN® stimulate the production of red blood cells to treat anemia and belong to a class of drugs referred to as erythropoiesis-stimulating agents ( ESAs ). Aranesp® is used for the treatment of anemia both in supportive cancer care and in nephrology. EPOGEN® is used to treat anemia associated with chronic renal failure ( CRF ). Neulasta® and NEUPOGEN® selectively stimulate the production of neutrophils, one type of white blood cell that helps the body fight infections. ENBREL blocks the biologic activity of tumor necrosis factor ( TNF ) by inhibiting its binding to TNF receptors, a substance induced in response to inflammatory and immunological responses, such as rheumatoid arthritis ( RA ) and psoriasis. For the years ended December 31, 2008, 2007 and 2006, our principal products represented 94%, 95% and 97% of total product sales, respectively.

We operate in a highly regulated industry and various U.S. and foreign regulatory bodies have substantial authority over how we conduct our business in those countries. Government authorities in the United States and in other countries regulate the manufacturing and marketing of our products and our ongoing research and development ( R&D ) activities. (See *Government Regulation.* ) For example, prior to obtaining regulatory approval to market a product, we must conduct extensive clinical studies designed to establish the safety and effectiveness of the product candidate for use in humans in the indications sought. Furthermore, in order to maintain regulatory approval to market a product, we may be required to conduct further clinical trials and to provide additional information on safety and effectiveness. 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 the safety of therapeutic products, which may lead to fewer products being approved by the FDA or other regulatory bodies or additional safety-related requirements. Safety signals, trends, adverse events or results from clinical trials, studies or meta-analyses (a meta-analysis is the review of studies using various statistical methods to combine results from previous separate, but related, studies) performed by us or by others (including our licensees or independent investigators) or from the marketed use of our products may expand safety labeling, restrict the use of our approved products or may result in additional regulatory requirements, such as requiring risk management activities, including a risk evaluation and mitigation strategy ( REMS ), and/or additional or more extensive clinical trials as part of postmarketing commitments ( PMCs ) or a pharmacovigilance program. (See *Postmarketing Safety Activities.* )

Most patients receiving our products are covered by either government and/or private payor healthcare programs. The reimbursement environment is evolving with greater emphasis on cost containment and in demonstrating the economic value of products. Therefore, sales of our products are and will continue to be affected by the availability and extent of reimbursement from third-party payors, including government and private insurance plans and administration of those programs. 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 providers or patients in response to ongoing initiatives to reduce or reallocate healthcare expenditures. Further, safety signals, trends, adverse events or results from clinical trials, studies or meta-analyses or from the marketed use of our products may negatively impact worldwide reimbursement for our products. (See *Reimbursement.* )

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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. We market ENBREL under a co-promotion agreement with Wyeth in the United States and Canada (see *Joint Ventures and Business Relationships* Wyeth ). In addition, we have entered into licensing agreements, which we deem to be necessary or desirable for the use or sale of our products, and/or co-promotion agreements to market our products in certain geographic areas. These agreements generally require us to pay royalties or share profits on product sales. In the United States, we sell primarily to wholesale distributors of pharmaceutical products. Outside the United States, we sell principally to hospitals and/or wholesalers depending upon the distribution practice in each country.

We focus our R&D efforts on novel therapeutics for the treatment of grievous illness in the areas of oncology, inflammation, bone, metabolic disorders and neuroscience. Our research takes a modality-independent approach to drug discovery in which we choose the best possible approach to block a specific disease process before considering the type of drug (modality) that may be required to pursue that approach. We study molecules across a range of modalities in the areas of proteins (sometimes referred to as large molecules ), including monoclonal antibodies and peptibodies, as well as small molecules. We have major R&D centers in several locations throughout the United States and in the United Kingdom, as well as smaller R&D centers in certain other countries throughout the world. To augment our internal R&D efforts, we acquire companies, acquire and license certain product and technology rights and establish R&D collaborations with third parties. 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.

Our manufacturing operations consist of bulk manufacturing, formulation, fill and finish activities which produce Aranesp®, Epoetin alfa, Neulasta®, NEUPOGEN®, ENBREL and other marketed products and product candidates for both commercial and clinical purposes. We operate commercial and clinical manufacturing facilities in several locations throughout the United States and in Puerto Rico as well as perform certain finishing activities in the Netherlands. Third-party contractors manufacture some or all of certain of our marketed products and/or product candidates.

The competitive environment among biotechnology, pharmaceutical and other companies that research, develop, manufacture or market biologics and pharmaceuticals is intense and increasing. We compete with these entities in all areas of our business. In addition, certain of these companies may have greater expertise and/or financial resources, which may provide them certain advantages in the discovery, development and commercialization of new or existing products. (See *Item 1A. Risk Factors* Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do. )

## **Key Developments**

The following is a summary of selected key developments affecting our business that occurred during 2008 and early 2009, including regulatory and reimbursement developments associated with our ESA products and other developments regarding certain of our other marketed products and product candidates.

### *ESA Regulatory and Reimbursement Developments*

The ESA regulatory and reimbursement developments in 2008 reflect a continuation of events that began in late 2006 that affected the class of ESA products, including Aranesp® and EPOGEN®. Certain of the developments discussed below have had a material adverse impact on sales of our ESA products, in particular Aranesp® sales in the U.S. supportive cancer care setting.

Beginning in late 2006, adverse safety results involving ESA products were observed in various studies that were performed by us and by others (including our licensees or independent investigators) that explored the use of ESAs in settings different from those outlined in the FDA approved label, including targeting higher hemoglobin ( Hb ) levels and/or use in non-approved patient populations. The results of these studies culminated in significant regulatory and reimbursement developments affecting the class of ESA products, including

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Aranesp® and EPOGEN®. For example, in February 2007, following the reported results from our Anemia of Cancer phase 3 study (the AoC 103 study), the United States Pharmacopoeia Dispensing Information ( USP DI ) Drug Reference Guides removed Aranesp from the treatment of anemia of cancer ( AoC ). Thereafter, Aranesp use in AoC essentially ceased. In addition, during 2007, we had discussions with the FDA and other regulatory authorities and meetings with certain of the FDA's advisory panels, which led to further developments. For example, in March 2007, the product labeling information for the class of ESAs was updated, including a boxed warning in the prescribing information ( PI ). In addition, in November 2007, following our meeting with the Oncologic Drugs Advisory Committee ( ODAC ) in May 2007, various additional safety-related revisions were again made to the ESA label. Further, in July 2007, the Centers for Medicare and Medicaid Services ( CMS ) issued its National Coverage Decision Memorandum for Use of Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions (the Decision Memorandum ). The Decision Memorandum established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for chemotherapy-induced anemia ( CIA ) with ESAs. We believe that the restrictions in the Decision Memorandum changed the way ESAs are used in clinical practice by decreasing the number of treated patients, the average dose and duration of ESA therapy.

Discussions with regulatory authorities, including the FDA, regarding safety concerns with respect to the administration of ESA products in various settings continued throughout 2008, resulting in further regulatory developments. The following is a summary of selected key regulatory and related developments that occurred in 2008.

During 2008, the ESA labeling information was further revised to reflect various safety concerns, beginning in March 2008, with an updated boxed warning in the labeling information in the United States. This updated box warning states that ESAs shorten overall survival and/or time-to-tumor progression in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid and cervical cancers when dosed to a target Hb level of greater than or equal to 12 grams per deciliter ( g/dL ). Additionally, on August 6, 2008, we revised the ESA product labeling, as the FDA directed, based on a complete response letter, received on July 30, 2008, from the FDA to the revisions to the ESA labeling we proposed following the March 13, 2008 ODAC meeting. The revised labeling included, among other things, (i) the addition to the boxed warning of a statement that ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome of such therapy is cure, (ii) the addition of a statement in the DOSAGE and ADMINISTRATION section of the label that ESA therapy should not be initiated at Hb levels  $\geq 10$  g/dL and that dose should be adjusted to maintain the lowest Hb level sufficient to avoid red blood cell transfusions and (iii) the removal of reference to the upper safety limit of 12 g/dL. Further, following the closed meeting by the Scientific Advisory Group on Oncology ( SAG-O ) in May 2008, we received notification in October 2008 that the European Commission had approved updates to the Aranesp® product information. 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. This assessment should take into account the specific clinical context, including the type of tumor and its stage, the degree of anemia, life-expectancy, the environment in which the patient is being treated and patient preference.

In addition, on January 1, 2008, the CMS' revisions to its Erythropoietin Monitoring Policy ( EMP ) became effective, which require a 50% reduction in Medicare reimbursement if a patient's Hb level is above 13 g/dL for three or more consecutive months. In addition, the 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. We believe that the EMP implementation in January 2008 has significantly affected physician behavior resulting in declines in dosing trends as particularly noted in the quarter of implementation. However, this dose decline subsequently stabilized in 2008 but may further fluctuate in the future.

Further, on September 30, 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

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the European Agency for the Evaluation of Medical Products ( EMEA ). These results were also presented by the Cochrane Haematological Malignancies Group in December at the 2008 American Society of Hematology ( ASH ) Congress.

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.

The analyses on all cancer patients were based on 53 previously conducted studies involving 13,933 patients. None of these studies utilized ESAs according to current label guidance. The overall survival results corroborate an earlier review by the Cochrane Collaboration, published in 2006, which is included in the WARNINGS section of the current U.S. PI (Hazard Ratio ( HR ): 1.08 [95% Confidence Interval ( CI ) 0.99 - 1.18]). The ESA treatment arm had increased on-study deaths (HR: 1.17 [95% CI 1.06 - 1.30]) and decreased overall survival (HR: 1.06 [95% CI 1.00 - 1.12]) compared to controls. The analyses on patients undergoing chemotherapy, the cancer indication for which ESAs are approved, were based on 38 studies with 10,441 patients. None of these studies utilized ESAs according to current label guidance. The ESA treatment arm had increased on-study deaths (HR: 1.10 [95% CI 0.98 - 1.24]) and decreased overall survival (HR: 1.04 [95% CI 0.97 - 1.11]) compared to controls. While neither of these results is statistically significant, they do not exclude the potential for adverse outcomes when ESAs are prescribed according to the current label. The final report on these endpoints is expected in 2009.

Our ESA products will continue to face future challenges. For example, we continue to work with the FDA to finalize a new protocol for a clinical trial to determine the effects of ESAs on survival and tumor outcomes in anemic patients with metastatic cancer receiving concomitant myelosuppressive chemotherapy. We have submitted an Aranesp® study protocol to the FDA and plan to initiate the study in 2009. In addition, in response to the FDA's request under authority prescribed by the Food and Drug Administration Amendments Act of 2007 (the FDAAA ), we continue to work closely with the FDA to develop a REMS program for the class of ESA products. We have submitted a proposed REMS in response to the FDA's requests. The components of the REMS approved by the FDA could be different for the use of ESAs in the oncology and nephrology indications. We believe that a REMS program for our ESA products could have a material adverse impact on the future sales of Aranesp®, especially in the U.S. supportive cancer care setting. Additionally, future Aranesp® sales could also be materially adversely impacted by further changes in reimbursement, including as a result of future regulatory developments.

### *Other Regulatory Developments*

#### *ENBREL*

On March 17, 2008, we and Wyeth Pharmaceuticals, a division of Wyeth, announced updates to the FDA approved labeling for ENBREL, in which the U.S. PI now contains a boxed warning relating to the risk of infections, including tuberculosis. This information in the boxed warning includes additional language regarding screening and monitoring patients for tuberculosis, including patients who tested negative for latent tuberculosis infection. As part of this labeling update, the FDA also required the implementation of a REMS for ENBREL in the form of a medication guide. Additionally, following the FDA web-alert on September 4, 2008 regarding their review of histoplasmosis and other opportunistic fungal infections in patients treated with TNF-blockers, the FDA requested that the boxed warning and WARNINGS sections of the U.S. PI and the medication guide for ENBREL (and other TNF-blockers) be strengthened to include the risk of unrecognized histoplasmosis and other invasive fungal infections with the goal of increasing timely diagnosis and treatment. The FDA also requested that the approved REMS for ENBREL be modified with a communication plan to healthcare providers regarding the risk of unrecognized fungal infections. In December 2008, we agreed with the FDA on the required revisions to the U.S. PI, and we continue to work with the FDA to finalize the requested updates to the ENBREL REMS.

In addition, there are several other outstanding regulatory matters that may also negatively impact future ENBREL product sales. For example, on June 4, 2008, the FDA issued an Early Communication regarding an ongoing safety review of TNF-blockers and the possible association between the use of these medicines and the

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development of lymphoma and other cancers in children and young adults and stated that it had decided to conduct further analyses to evaluate the risk and benefits of TNF-blockers in pediatric patients. Furthermore, following the June 18, 2008 Dermatologic and Ophthalmic Drugs Advisory Committee ( DODAC ) meeting, on July 24, 2008, we received notification from the FDA through a complete response letter that they would like additional information from us regarding the use of ENBREL in pediatric patients with chronic moderate to severe plaque psoriasis. We continue to work with the FDA to provide it with the above-noted requested information.

### *Nplate® (romiplostim)*

On August 22, 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® is the first FDA approved peptibody protein, works by raising and sustaining platelet counts. As part of the approval for Nplate®, a REMS was developed with the FDA to assure the safe use of Nplate® while minimizing risk. The Nplate® REMS involves, among other things, healthcare provider and patient enrollment registries, tracking of patient medical history and data and follow-up safety questionnaires to healthcare providers, all of which require extensive discussion with and education of healthcare providers. In addition, on February 6, 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 European Union ( EU ), Nplate® may also be considered as second line treatment for adult non-splenectomized ITP patients where surgery is contra-indicated.

### *Vectibix® (panitumumab)*

At the ODAC meeting on December 16, 2008, we discussed the clinical utility of the KRAS gene as a predictive biomarker in patients with metastatic colorectal cancer ( mCRC ) treated with anti-Epidermal Growth Factor Receptors ( EGFr ) antibody, Vectibix®. We believe that data shared with the ODAC supports the suggestion that KRAS is a predictive biomarker for the anti-EGFr class of drugs in the monotherapy setting. In March 2008, the *Journal of Clinical Oncology* published results from an analysis of the first randomized, controlled clinical trial ( Study 408 ), which showed that mCRC patients with mutated KRAS tumors do not respond to Vectibix® monotherapy. Conversely, patients with wild-type KRAS tumors treated with Vectibix® have a better response rate and prolonged progression-free survival ( PFS ).

### *Clinical Developments*

#### *Denosumab*

Denosumab is the first fully human monoclonal antibody in late stage clinical development 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). Denosumab is being investigated for its potential to inhibit all stages of osteoclast activity through a targeted mechanism. In December 2008, we submitted a biologics license application ( BLA ) to the FDA for denosumab for the treatment and prevention of postmenopausal osteoporosis ( PMO ) in women and bone loss in patients undergoing hormone ablation for either prostate or breast cancer. On February 18, 2009, the FDA accepted our BLA and informed us that it will target an FDA action within ten months of the BLA's submission date, resulting in a Prescription Drug User Fee Act ( PDUFA ) action date of October 19, 2009. The FDA indicated that it intends to simultaneously review the data we submitted for both the PMO and bone loss in patients undergoing hormone ablation for prostate or breast cancer indications due to the interdependency of the data across the indications from more than 11,000 patients included in support of the BLA. Additionally, in January 2009, we submitted an application to the EMEA for the approval of denosumab for treatment of PMO in women and treatment of bone loss associated with hormone ablation therapy in patients with breast and prostate cancer. In addition, during 2008, we announced results of the following key trials involving denosumab.

#### *Osteoporosis*

On September 16, 2008 at the American Society of Bone and Mineral Research ( ASBMR ) annual meeting, we presented detailed results from the pivotal fracture trial ( Study 216 ) evaluating denosumab in the

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treatment of PMO. In this pivotal, three-year, international, phase 3 study of approximately 7,800 women with osteoporosis, patients were randomized to receive either denosumab, given by subcutaneous injection once every six months, or placebo injections. For the primary endpoint, treatment with denosumab resulted in a statistically significant reduction (68%) in the incidence of new vertebral fractures compared with placebo treatment (2.3% for denosumab versus 7.2% for placebo,  $p=0.0001$ ). In addition, women receiving denosumab experienced a statistically significant reduction (20%) in the incidence of new non-vertebral fractures compared with placebo treatment (6.5% for denosumab versus 8.0% for placebo,  $p=0.011$ ) and a statistically significant reduction (40%) in the incidence of hip fractures compared with placebo treatment (0.7% for denosumab versus 1.2% for placebo,  $p=0.036$ ), each a secondary endpoint. The incidence and types of both adverse and serious adverse events observed in this study, including serious infections and neoplasms, were similar between the denosumab and placebo groups. The most common adverse events across both treatment arms were arthralgia, back pain, hypertension and nasopharyngitis.

In addition to the detailed results of Study 216, we presented the results of two non-pivotal phase 3 studies of denosumab in osteoporosis at the ASBMR meeting. The first was a phase 3 head-to-head, double-blind trial known as the Study of Transitioning from Alendronate to Denosumab trial ( STAND ) ( Study 234 ). The results of this study demonstrated that subcutaneous injections of denosumab every six months achieved significantly greater increases in bone mineral density ( BMD ) versus those achieved with alendronate ( ALN ) at all sites measured. For the primary endpoint, denosumab resulted in significant increases in BMD at the total hip compared with ALN (1.9% for denosumab versus 1.05% for ALN,  $p<0.0001$ ). Treatment with denosumab also resulted in significant increases in BMD compared with continued ALN treatment at all secondary endpoints, including the lumbar spine, femoral neck, hip trochanter and 1/3 radius. The incidence and types of adverse events observed in the study, including neoplasms and infection, were similar between the denosumab and ALN treatment groups. The most common adverse events across both treatment arms were back pain, arthralgia and nasal pharyngitis. The second non-pivotal study was a head-to-head trial comparing denosumab to weekly oral ALN, also known as the Determining Efficacy: Comparison of Initiating Denosumab versus Alendronate trial ( DECIDE ) ( Study 141 ). As a part of this study, patients were given a questionnaire after 12 months of treatment to gauge preference on mode of administration as well as satisfaction with frequency of dosing of twice-yearly subcutaneous injections versus weekly oral tablet. More than three-quarters of patients in both study arms preferred subcutaneous injection over oral pills (77% versus 23%,  $p<0.0001$ ). In addition, significantly more patients were more satisfied with twice-yearly dosing compared to weekly dosing (80% placebo injection versus 20% weekly oral ALN, and 79% for denosumab versus 21% weekly placebo tablet,  $p<0.0001$  for both study groups).

### *Oncology*

On July 14, 2008, we announced findings from a three-year pivotal phase 3 placebo-controlled trial evaluating denosumab in the treatment of bone loss in men undergoing androgen deprivation therapy ( ADT ) for non-metastatic prostate cancer ( Study 138 ). In this study of more than 1,400 men, denosumab treatment produced statistically significantly greater increases in BMD at the lumbar spine (primary endpoint) and non-vertebral sites compared with placebo at multiple time points. These improvements in BMD were consistent with those seen in other denosumab studies evaluating BMD in women with breast cancer receiving aromatase inhibitor ( AI ) therapy, and in postmenopausal women with low bone mass. During the 36-month evaluation period, men receiving denosumab experienced less than half the incidence of new vertebral fractures (a secondary endpoint) compared with those receiving placebo, a statistically significant finding. Furthermore, in the denosumab arm there were fewer non-vertebral fractures over the 36-month period. The incidence and types of adverse events observed in this study were generally similar between the denosumab and placebo groups. The most common adverse events across both treatment arms were arthralgia, back pain, constipation and pain in extremity. Serious adverse infectious events occurred in approximately 5% of men receiving placebo treatment as compared with approximately 6% of those receiving denosumab.

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### *Competitive Developments*

Certain of our marketed products are under increased competitive pressures, including from biosimilar and other products in Europe, which compete or are expected to compete with Aranesp<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup>, as well as our marketed products in the United States, including ENBREL. For example, as a result of final regulatory guidelines issued by the EMEA in 2006 related to the development and approval of biosimilar products, we have experienced and expect to continue to experience increased competition throughout Europe, including from a number of biosimilar erythropoietin products, which compete with Aranesp<sup>®</sup>. In addition, a number of granulocyte colony-stimulating factor ( G-CSF ) biosimilar products have received marketing authorization from the European Commission in 2008 and early 2009 and have been or are expected to be launched and compete with Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup>. Further in the United States, ENBREL will continue to face increased competition primarily due to the expected launch of new products.

### *Litigation Developments*

On October 17, 2008, the Massachusetts District Court entered judgment that the patents in suit are valid and enforceable, and that the patents, identified below as the subject of the permanent injunction, would be infringed by the import, use and sale of F. Hoffmann-La Roche Ltd. ( Roche ) pegylated erythropoietin product in the United States. The Massachusetts District Court 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. See Note 10, *Contingencies Roche Matters Amgen Inc. v. F. Hoffman-La Roche Ltd. et al.* for further discussion of this legal proceeding.

On July 11, 2008, we announced that we had reached an agreement to settle our antitrust litigation with Ortho Biotech Products L.P., a subsidiary of Johnson & Johnson (hereafter referred to as Ortho Biotech or J&J ), which had alleged that discounts offered to oncology clinics on our NEUPOGEN<sup>®</sup> and Neulasta<sup>®</sup> and Aranesp<sup>®</sup> products violated antitrust laws. Under terms of the agreement, we paid Ortho Biotech \$200 million and the pending litigation in New Jersey District Court was dismissed with prejudice.

### *Economic and Political Developments*

Capital and credit markets have been experiencing extreme volatility and disruption, particularly during the latter part of 2008 and the beginning of 2009. We are working to manage our business effectively despite the unprecedented conditions in the financial markets both in the United States and around the world. To date, these macro economic challenges have not affected us to a large degree. The extent and/or the duration of any potential adverse economic impact that such financial disruption may have on our third-party payors, including governments and private insurance plans, wholesale distributors, customers, service providers and suppliers is unclear. However, it may result in reduced demand for our products. (See *Item 1A. Risk Factors The volatility of the current financial markets and the general economic slowdown may magnify certain risks that affect our business.* )

Further, beginning in late 2008 and continuing into 2009, foreign currency rates have also been experiencing extreme volatility. Changes in foreign currency rates result in increases or decreases in our reported international product sales. However, the benefit or detriment of any resulting increases or decreases that movements in foreign currency exchange rates have on our international product sales are largely offset by corresponding increases or decreases in our international operating expenses and as a result of 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.

In addition, we believe the new U.S. presidential administration, together with Congress, will shape U.S. healthcare policy in the coming months and years, and we expect that healthcare reform efforts could include long-term changes to coverage and reimbursement that may have a significant impact on our business. Furthermore, due to the increasing expectations and demands of healthcare payors, we believe that we and others in our industry will be under increased pressure to further demonstrate the efficacy and economic value of our products.

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### *Other Developments*

In February 2008, we entered into a license agreement with Takeda Pharmaceutical Company Limited ( Takeda ), which provided them the exclusive rights to develop and commercialize for the Japanese market up to 12 clinical stage molecules from our pipeline across a range of therapeutic areas, including oncology and inflammation. The molecules covered by the license agreement primarily include: AMG 108, AMG 317, AMG 386, AMG 479, AMG 655 and Vectibix®. 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 motesanib (AMG 706). Each party has the right to participate in the commercialization of motesanib in the other party's territory. In connection with these agreements, Takeda acquired our subsidiary in Japan, Amgen K.K.

As a result of the challenges facing certain of our products and, in particular, the regulatory and reimbursement developments involving our marketed ESA products that began in 2007, as discussed above, and their resulting impact on our operations, 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. Through December 31, 2008, we have completed substantially all of the actions initially included in our restructuring plan, including the divestiture of certain less significant marketed products discussed below. During 2008, 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. The estimated cost of these additional initiatives is \$95 million to \$135 million. The total charges currently estimated to be incurred in connection with our restructuring plan, including related implementation costs, is \$950 million to \$985 million. Through December 31, 2008, we have incurred \$887 million of these costs and currently estimate that all remaining costs will be substantially incurred in 2009.

In September 2008, we entered into an agreement with Biovitrum AB ( Biovitrum ) whereby they acquired from us the marketed biologic therapeutic products Kepivance® (palifermin) and Stemgen® (ancestim), and also obtained from us a worldwide exclusive license to Kineret® (anakinra) for its current approved indication. In connection with the disposal of these less significant marketed products, we incurred a \$10 million loss. For the year ended December 31, 2008, the worldwide product sales for these marketed products were approximately \$70 million.

### **Marketed Products and Selected Product Candidates**

We market our principal products in the areas of supportive cancer care, nephrology and inflammation. Our principal products include Aranesp®, EPOGEN®, Neulasta®, NEUPOGEN® and ENBREL. 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 products 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 by competitors or new information about existing products may result in increased competition for our marketed products, even for those protected by patents, or reduction in the price we receive from selling our products. Further, the development of new treatment options or standards of care may require less use of our products, particularly in supportive cancer care. For example, the development of new treatments for cancer, such as targeted therapies, including monoclonal antibodies, or chemotherapy regimens that are less myelosuppressive, may require less Aranesp® or Neulasta®/NEUPOGEN®. In addition, we expect to continue to face increasingly intense competition, including from new and existing product technologies and competitive pressures associated with biosimilar and other products. In 2006, the EMEA developed and issued final regulatory guidelines related to the development and approval of biosimilar products and, as a result, we have begun to experience and expect to continue to experience increased competition from biosimilar products throughout the EU. Further, although there is currently no legal pathway for abbreviated approval of BLAs for biosimilars in the United States, given the continuing interest by Congress on this issue and on healthcare reform in general, it

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is likely that legislation on biosimilars will be introduced in 2009 and possibly passed into law. The new U.S. presidential administration has also expressed an interest in passing legislation regarding biosimilars.

We operate in a highly regulated industry and various U.S. and foreign regulatory bodies have substantial authority over how we conduct our business in those countries. The regulatory environment is evolving and there is increased scrutiny on drug safety and increased authority being granted to regulatory bodies to assist in ensuring the safety of therapeutic products. Certain regulatory developments discussed above in the *Key Developments* section, have and will continue to impact future sales of certain of our products.

### *Aranesp® (darbepoetin alfa)*

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 CRF, both in patients on dialysis and not on dialysis. Anemia can also result from chemotherapy treatments for patients with non-myeloid malignancies.

We were granted an exclusive license by Kirin-Amgen, Inc. ( *KA* ), a joint venture between Kirin Holdings Company, Limited ( *Kirin* ) and Amgen (see *Joint Ventures and Business Relationships* *Kirin Holdings Company, Limited* ), to manufacture and market darbepoetin alfa in the United States, all European countries, Canada, Australia, New Zealand, Mexico, all Central and South American countries and certain countries in Central Asia, North 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 CIA in patients with non-myeloid malignancies.

Worldwide Aranesp® sales for the years ended December 31, 2008, 2007 and 2006 were \$3.1 billion, \$3.6 billion and \$4.1 billion, respectively. As a result of certain of the regulatory and reimbursement developments discussed above in the *Key Developments* section, worldwide Aranesp® sales and, in particular, sales in the U.S. supportive cancer care setting, have and will continue to be materially adversely affected.

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

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

<sup>(1)</sup> 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 and other companies may receive approval for and market biosimilar or other products to compete with Aranesp® in Europe, presenting additional competition, as further discussed below.

Any products or technologies that are directly or indirectly successful in addressing anemia associated with chemotherapy and nephrology could negatively impact product sales of Aranesp®. The following table reflects companies and their currently marketed products that primarily compete with Aranesp® in the United States and Europe in the supportive cancer care and nephrology segments, unless otherwise indicated.

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| <b>Territory</b> | <b>Competitor Marketed Product</b>                                                     | <b>Competitor</b>                                                                                                      |
|------------------|----------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| U.S.             | PROCRIT <sup>®(1)</sup>                                                                | J&J                                                                                                                    |
| Europe           | EPREX <sup>®</sup> /ERYPO <sup>®</sup>                                                 | Janssen-Cilag <sup>(2)</sup>                                                                                           |
| Europe           | NeoRecormon <sup>®</sup>                                                               | Roche                                                                                                                  |
| Europe           | Retacrit <sup>(3)</sup> /Silapo <sup>®(3)</sup>                                        | Hospira Enterprises B.V. ( Hospira )/Stada Arzneimittel AG ( Stada )                                                   |
| Europe           | Binocrit <sup>®(3)</sup> /Epoetin alfa Hexal <sup>®(3)</sup> /Abseamed <sup>®(3)</sup> | Sandoz GmbH ( Sandoz )/Hexal Biotech Forschungs GmbH ( Hexal )/Medice Arzneimittel Pütter GmbH & Company KG ( Medice ) |
| Europe           | MIRCERA <sup>®(4)</sup>                                                                | Roche                                                                                                                  |
| Europe           | Dynepo <sup>®(5)</sup>                                                                 | Shire Pharmaceutical Group Plc ( Shire )                                                                               |

(1) In the United States, Aranesp<sup>®</sup> competes with PROCRT<sup>®</sup> 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<sup>®</sup> in the nephrology segment only.

(5) Shire announced in the second quarter of 2008 that it had decided to stop the commercialization of Dynepo<sup>®</sup>.

In the United States, Aranesp<sup>®</sup> also competes with EPOGEN<sup>®</sup>, 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<sup>®</sup> in the future. Affymax Inc. ( Affymax ) and Takeda are co-developing Hematide , an ESA for the treatment of anemia in renal patients. FibroGen 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 chronic kidney disease ( CKD ). Ratiopharm is developing a biosimilar ESA, EpoTheta, expected to launch in the EU in 2009. 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<sup>®</sup> (Epoetin alfa)*

EPOGEN<sup>®</sup> 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<sup>®</sup> (darbepoetin alfa)* ). People with CRF suffer from anemia because they do not produce sufficient amounts of erythropoietin, which is normally produced in healthy kidneys.

We were granted an exclusive license to manufacture and market recombinant human erythropoietin in the United States under a licensing agreement with KA. We have retained exclusive rights to market EPOGEN<sup>®</sup> in the United States for dialysis patients. We granted Ortho Pharmaceutical Corporation (which has assigned its rights under the Product License Agreement to Ortho Biotech) a license to commercialize recombinant human erythropoietin as a human therapeutic in the United States in all markets other than dialysis (see *Joint Ventures and Business Relationships Johnson & Johnson* ).

We launched EPOGEN<sup>®</sup> in the United States in 1989 for the treatment of anemia associated with CRF for patients who are on dialysis. We market EPOGEN<sup>®</sup> for the treatment of anemic adult and pediatric patients with CRF who are on dialysis. EPOGEN<sup>®</sup> 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<sup>®</sup> sales in the United States were \$2.5 billion for each of the three years ended December 31, 2008.

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

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

Any products or technologies that are directly or indirectly successful in addressing anemia associated with CRF could negatively impact product sales of EPOGEN®. In the United States, EPOGEN® and Aranesp® compete with each other, primarily in the U.S. hospital dialysis clinic setting, and there was a conversion from EPOGEN® to Aranesp® in this setting, however we believe that the conversion has stabilized. In addition, Affymax and Takeda are co-developing Hematide, an ESA for the treatment of anemia in renal patients. FibroGen is developing FG-2216 and FG-4592, orally active ESAs for the treatment of anemia. Additionally, in December 2008, 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.

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

Neulasta® is our registered trademark for a pegylated protein that selectively stimulates production of certain white blood cells known as neutrophils and is based on the Filgrastim molecule. Neutrophils defend against infection. NEUPOGEN® is our registered trademark for our recombinant-methionyl human G-CSF, a protein that also 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 pegfilgrastim and G-CSF in the United States, Europe, Canada, Australia and New Zealand under a licensing agreement with KA (see *Joint Ventures and 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 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

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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, 2008, 2007 and 2006 were \$3.3 billion, \$3.0 billion and \$2.7 billion, respectively. Worldwide NEUPOGEN® sales for the years ended December 31, 2008, 2007 and 2006 were \$1.3 billion, \$1.3 billion and \$1.2 billion, respectively.

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

| <b>Territory</b>      | <b>General Subject Matter</b> | <b>Expiration</b> |
|-----------------------|-------------------------------|-------------------|
| U.S.                  | Pegylated G-CSF               | 10/20/2015        |
| Europe <sup>(1)</sup> | Pegylated G-CSF               | 2/8/2015          |

<sup>(1)</sup> 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.

| <b>Territory</b> | <b>General Subject Matter</b>                 | <b>Expiration</b> |
|------------------|-----------------------------------------------|-------------------|
| 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 and other companies may receive approval for and market biosimilar products and other products to 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, 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 segment.

| <b>Territory</b> | <b>Competitor Marketed Product</b>                                  | <b>Competitor</b>                               |
|------------------|---------------------------------------------------------------------|-------------------------------------------------|
| U.S.             | Leukine®                                                            | Bayer HealthCare Pharmaceuticals                |
| Europe           | Granocyte®                                                          | Chugai Pharmaceuticals Co., Ltd./Sanofi-Aventis |
| Europe           | Ratiograstim <sup>®(1)</sup> /Filgrastim Ratiopharm <sup>®(1)</sup> | Ratiopharm                                      |
| Europe           | Biograstim <sup>®(1)</sup>                                          | CT Arzneimittel                                 |
| Europe           | Tevagrastim <sup>®(2)</sup>                                         | Teva                                            |
| Europe           | Zarzio <sup>®(3)</sup> /Filgrastim Hexal <sup>®(3)</sup>            | Sandoz/Hexal                                    |

<sup>(1)</sup> Biosimilar products that received marketing authorization by the European Commission in September 2008 and launched in certain EU countries thereafter.

<sup>(2)</sup> Biosimilar product that received marketing authorization by the European Commission in September 2008 for which Teva has stated that it would begin marketing throughout Europe in 2009.

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<sup>(3)</sup> Biosimilar products that received marketing authorization by the European Commission in February 2009.  
*Enbrel® (etanercept)*

ENBREL is our registered trademark for our TNF receptor fusion protein that inhibits its binding to TNF receptors, which can result in a significant reduction in inflammatory activity. TNF is one of the chemical

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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 and deactivates certain TNF molecules before they can trigger inflammation.

We acquired the rights to ENBREL in July 2002 as part of our acquisition of Immunex Corporation ( Immunex ).

We market ENBREL under a co-promotion agreement with Wyeth in the United States and Canada (see *Joint Ventures and Business Relationships* Wyeth ). The rights to market ENBREL outside of the United States and Canada are reserved to Wyeth. ENBREL was initially launched in November 1998 by Immunex for the treatment of 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 in adult 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-course juvenile RA in patients who have had an inadequate response to one or more disease-modifying medicines.

ENBREL sales for the years ended December 31, 2008, 2007 and 2006 were \$3.6 billion, \$3.2 billion and \$2.9 billion, respectively.

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

| <b>Territory</b> | <b>General Subject Matter</b>                             | <b>Expiration</b> |
|------------------|-----------------------------------------------------------|-------------------|
| U.S.             | Methods of treating TNF dependent inflammatory response   | 9/5/2009          |
| U.S.             | TNFR proteins and pharmaceutical compositions             | 9/5/2009          |
| 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 juvenile RA and psoriatic arthritis; and dermatology, which includes ankylosing spondylitis and 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.

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.

| <b>Territory</b> | <b>Therapeutic Area</b>    | <b>Competitor Marketed Product</b> | <b>Competitor</b>                                          |
|------------------|----------------------------|------------------------------------|------------------------------------------------------------|
| U.S. & Canada    | Rheumatology & Dermatology | REMICADE®                          | Centocor, Inc. <sup>(1)</sup> /Schering Plough Corporation |
| U.S. & Canada    | Rheumatology & Dermatology | HUMIRA®                            | Abbott Laboratories ( Abbott )                             |
| U.S. & Canada    | Rheumatology & Dermatology | Trexall                            | Duramed Pharmaceuticals, Inc. <sup>(2)</sup>               |
| 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®                           | Genentech, Inc. ( Genentech )                              |
| U.S. & Canada    | Dermatology                | Raptiva®                           | Genentech                                                  |
| U.S. & Canada    | Dermatology                | Amevive®                           | Biogen IDEC Inc. ( Biogen )                                |
| U.S. & Canada    | Dermatology                | Neoral®                            | Novartis AG ( Novartis )                                   |
| U.S. & Canada    | Dermatology                | Soriatane®                         | Connetics Corporation <sup>(3)</sup>                       |

<sup>(1)</sup> A subsidiary of J&J.

<sup>(2)</sup> A subsidiary of Barr Pharmaceuticals, Inc. ( Barr )

<sup>(3)</sup> A subsidiary of Stiefel Laboratories, Inc.

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In addition to competition from the above-noted marketed products, various companies are developing products which may compete with ENBREL in the future, including the following. In December 2007, J&J filed a BLA with the FDA and a market authorization application (MAA) with the EMEA for CNTO 1275 (ustekinumab) to treat adults with moderate to severe plaque psoriasis. Although the DODAC unanimously recommended CNTO 1275 for approval, in December 2008, the FDA declined approval and requested additional information from J&J. J&J is also developing CNTO 148 (golimumab) for the treatment of RA. Additionally, a number of companies have cytokine inhibitors in development, including GlaxoSmithKline plc (GlaxoSmithKline), Pfizer Inc. (Pfizer), Repligen Corporation and Taisho Pharmaceutical Co., Ltd. Roche filed a BLA for its RA candidate Actemra (tocilizumab) in November 2007 and received a complete response letter from the FDA in September 2008, requesting additional data on the labeling and manufacture of the drug. Abbott is developing ABT-874, which is a psoriasis drug, and is in phase 3 trials. UCB has partnered with Nektar Therapeutics to develop Cimzia® (PEGylated anti-TNF) for the treatment of RA. On January 5, 2009, the FDA issued a complete response letter relating to the BLA of Cimzia® for treatment of RA requesting additional information.

### 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, 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. We market Sensipar®/Mimpara® primarily in the United States and Europe.

Sensipar® sales for the years ended December 31, 2008, 2007 and 2006 were \$597 million, \$463 million and \$321 million, respectively.

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

| Cinacalcet            | General Subject Matter            | Expiration |
|-----------------------|-----------------------------------|------------|
| U.S. <sup>(1)</sup>   | Calcium receptor-active molecules | 10/23/2015 |
| U.S. <sup>(1)</sup>   | Calcium receptor-active molecules | 12/14/2016 |
| U.S. <sup>(1)</sup>   | Methods of treatment              | 12/14/2016 |
| Europe <sup>(2)</sup> | Calcium receptor-active molecules | 10/23/2015 |

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

<sup>(2)</sup> 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.

| Territory | Competitor Marketed Product | Competitor                    |
|-----------|-----------------------------|-------------------------------|
| U.S.      | Zemplar®                    | Abbott                        |
| U.S.      | Hectorol®                   | Genzyme Corporation (Genzyme) |
| U.S.      | Rocaltrol®                  | Roche                         |
| Europe    | Zemplar®                    | Abbott                        |
| Europe    | Renegel®                    | Genzyme                       |
| Europe    | Fosrenol®                   | Shire                         |

Europe

OsvaRen®

Fresenius Medical Care

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On July 25, 2008, we filed a lawsuit against Teva and Barr for infringement of four Sensipar® patents. The lawsuit is based on the Abbreviated New Drug Application ( ANDA ) filed by Teva and Barr which seeks approval to market generic versions of Sensipar® (See Note 10, *Contingencies* to the Consolidated Financial Statements.) These generic versions could compete with Sensipar® in the future.

### *Vectibix® (panitumumab)*

Vectibix® is our trademark for our first entirely 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 an entirely 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 entirely human monoclonal antibodies is to offer effective targeted therapies with lessened risk of immune response against these agents. Vectibix® received FDA approval in September 2006. On December 5, 2007, the European Commission granted a conditional marketing authorization for Vectibix®, which was renewed in December 2008, as a monotherapy for the treatment of patients with EGFr expressing mCRC with non-mutated (wild-type) KRAS genes after failure of standard chemotherapy regimens. We acquired full ownership of Vectibix® as part of our acquisition of Abgenix, Inc. ( Abgenix ) in April 2006.

### *Nplate® (romiplostim)*

On August 22, 2008, the FDA approved Nplate®, the first platelet producer for the treatment of thrombocytopenia in splenectomized (spleen removed) and non-splenectomized adults with chronic ITP. Nplate®, the first FDA approved peptibody protein, works by raising and sustaining platelet counts. On February 6, 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 also be considered as second line treatment for adult non-splenectomized ITP patients where surgery is contra-indicated.

### *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. For example, the bone loss setting, in which denosumab would compete, is currently comprised of three therapeutic classes: bisphosphonates, selective estrogen receptor modulators and anabolic agents. Competitive intensity will increase in the bone loss setting with the expected approval of new agents. If denosumab is approved, we would need to significantly expand our sales and marketing capabilities to support its successful launch.

The following table reflects other companies and their currently marketed products that will compete with denosumab, if approved:

| Amgen Product Candidate | Therapeutic Area | Competitor Marketed Product | Potential Competitor                |
|-------------------------|------------------|-----------------------------|-------------------------------------|
| Denosumab               | PMO              | FOSAMAX®                    | Merck                               |
| Denosumab               | PMO              | Actonel®                    | Procter & Gamble/Aventis            |
| Denosumab               | PMO              | Boniva®/Bonviva®            | Roche/GlaxoSmithKline               |
| Denosumab               | PMO              | Evista®                     | Eli Lilly and Company ( Eli Lilly ) |
| Denosumab               | PMO              | Forteo®/Forsteo             | Eli Lilly                           |
| Denosumab               | PMO              | Miacalcin®                  | Novartis                            |
| Denosumab               | PMO              | Aclasta®/Reclast®           | Novartis                            |
| Denosumab               | PMO              | generic ALN                 | Teva                                |
| Denosumab               | Oncology         | Zometa®                     | Novartis                            |
| Denosumab               | Oncology         | Aredia®                     | Novartis                            |

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Merck's patent covering the use of FOSAMAX<sup>®</sup> to treat bone loss expired in the United States in February 2008. Following the patent expiry, generic ALN became available from Teva, as noted in the table above, and has also become available from other companies.

### Postmarketing Safety Activities

We must conduct extensive clinical trials designed to establish the safety and efficacy of our product candidates in order to file for regulatory approval to market a product. 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 postmarketing 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 minimization activities such as physician education initiatives and patient 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; such trials are sometimes referred to as PMCs. Regulatory agencies may also request or require that we conduct specific studies in order to identify or assess possible safety risks of our marketed products that are observed or suggested by available scientific data.

#### *Certain ESA Postmarketing Commitments*

Following the ODAC meeting in May 2004, we proposed a pharmacovigilance program comprised of five ongoing studies for Aranesp<sup>®</sup>, which sought 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. One of the five studies, the 20010145 ( 145 ) study, was an Amgen sponsored study, with the other four studies being investigator-sponsored studies. The following table summarizes the five studies:

| Sponsor             | Study                     | Tumor Type         | Target Hb (g/dL)                  | Study Results                                                                                                                                                                      |
|---------------------|---------------------------|--------------------|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Amgen               | 20010145                  | Small cell lung    | 13                                | At median follow-up of 2 1/2 years, ESA and placebo group had similar PFS and overall survival; PFS based on blinded central review similar between ESA and placebo <sup>(1)</sup> |
| DAHANCA             | DAHANCA-10 <sup>(2)</sup> | Head and neck      | 14-15.5                           | 5-year locoregional control poorer in ESA group; No significant difference in overall survival <sup>(1)</sup>                                                                      |
| AGO                 | PREPARE                   | Neoadjuvant breast | 12.5-13                           | Decreased 3-year relapse-free and overall survival in the ESA group <sup>(1)</sup>                                                                                                 |
| GELA <sup>(3)</sup> | LNH-03-6B                 | NHL <sup>(4)</sup> | 13-15 initially, amended to 13-14 | At 1 year, ESA and control groups had similar overall survival and event-free survival <sup>(5)</sup>                                                                              |
| WSG <sup>(6)</sup>  | ARA-03/ARA Plus           | Adjuvant breast    | 13-14                             | Interim safety results published <sup>(7)</sup>                                                                                                                                    |

(1) Final results are expected in 2009.

(2) Danish Head and Neck Cancer ( DAHANCA )

(3) Groupe d Etudes de Lymphomes de L Adulte ( GELA )

(4) Non-Hodgkin's Lymphoma ( NHL )

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- (5) The final study report is expected in 2010. Late in 2007, an independent Data Safety Monitoring Committee recommended continuation of the study unchanged.
- (6) West German Study Group ( WSG )
- (7) Interim safety results presented at the 31st annual San Antonio Breast Cancer Symposium, December 13, 2008, San Antonio, TX. The final study report is expected in 2011.

In addition, Johnson and Johnson Pharmaceutical Research & Development ( J&JPRD ), a subsidiary of J&J, and/or its investigators have conducted numerous studies proposed at the 2004 ODAC meeting including: the EPO-GBR-7 and RTOG-9903 studies in head and neck cancer ( HNC ), the EPO-GER-22 and EPO-CAN-20 studies in non-small cell lung cancer ( NSCLC ), the EPO-CAN-17 and EPO-GER-7 studies in breast cancer and the EPO-GER-8/AGO-NOGGO study in cervical cancer. All of the above 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 an 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. We have submitted an Aranesp® study protocol to the FDA and plan to initiate the study in 2009.

### *Other Postmarketing Commitments*

In addition to our ESA products, we have ongoing PMC studies for all of our marketed products. In particular, we have several large, ongoing studies involving ENBREL, which include trials to evaluate the safety and efficacy of its long-term use.

### *Other Safety Activities*

The FDAAA gave the FDA authority to require us and other companies to develop and 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. A REMS may include a medication guide, patient package insert, a plan for communication with healthcare providers or other elements the FDA deems are necessary to assure safe use of the product, which could include imposing certain restrictions on distribution or use of a product. A REMS must include a timetable for submission of assessments of the strategy at specified time intervals. 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 ENBREL and Nplate®. Additionally, in response to the FDA's request under authority prescribed by the FDAAA, we have submitted a proposed REMS program for the class of ESAs and an update to the existing REMS for ENBREL.

## **Marketing and Distribution**

We maintain sales and marketing forces primarily in the United States, Europe and Canada to support our currently marketed products. 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. 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, such as physicians or their clinics, dialysis centers, hospitals and pharmacies. 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. Outside the United States, Aranesp®, Neulasta® and NEUPOGEN® are principally distributed to hospitals and/or wholesalers depending upon the distribution practice in each country for which the product has been launched. 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, 2008, 2007 and 2006. On a combined basis, these distributors accounted for 71% and 87% of worldwide gross revenues and U.S. gross product sales, respectively, for 2008, as noted in the following table (dollar amounts in millions):

|                                      | Years ended December 31, |          |          |
|--------------------------------------|--------------------------|----------|----------|
|                                      | 2008                     | 2007     | 2006     |
| <b>AmerisourceBergen Corporation</b> |                          |          |          |
| Gross product sales                  | \$ 7,099                 | \$ 6,124 | \$ 6,523 |
| % of total gross revenues            | 37%                      | 31%      | 35%      |
| % of U.S. gross product sales        | 46%                      | 39%      | 42%      |
| <b>McKesson Corporation</b>          |                          |          |          |
| Gross product sales                  | \$ 3,594                 | \$ 2,398 | \$ 2,427 |
| % of total gross revenues            | 19%                      | 12%      | 13%      |
| % of U.S. gross product sales        | 23%                      | 15%      | 15%      |
| <b>Cardinal Health, Inc.</b>         |                          |          |          |
| Gross product sales                  | \$ 2,823                 | \$ 2,715 | \$ 2,490 |
| % of total gross revenues            | 15%                      | 14%      | 13%      |
| % of U.S. gross product sales        | 18%                      | 17%      | 16%      |

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 *Joint Ventures and Business Relationships* Johnson & Johnson ). Under a co-promotion agreement with Wyeth, we and Wyeth market ENBREL in the United States and Canada for all approved indications. 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.

**Reimbursement**

Sales of all of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payors, including governments and private insurance plans. Most patients receiving our products are covered by government and/or private payor healthcare programs. 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 providers or patients in response to ongoing initiatives to reduce or reallocate healthcare expenditures. An increasing 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 the new U.S. presidential administration, together with Congress, will shape U.S. healthcare policy in the coming months and years, and we expect that healthcare reform efforts could include long-term changes to coverage and reimbursement that may have a significant impact on our business.

*U.S. Reimbursement System*

In the United States, healthcare providers, including doctors, hospitals and other healthcare professionals and facilities, are reimbursed for their services by the government through Medicare and other forms of public health insurance and private insurers, which are funded primarily through the payment of premiums from individuals, businesses and the government and taxes from individuals and businesses. The public and private components of this multi-payor system are described below.

*Medicare and Other Forms of Public Health Insurance*

Medicare is a federal program administered and reimbursed by the federal government that covers individuals age 65 and over as well as those with certain disabilities and chronic illnesses. The CMS administer

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Medicare (as well as Medicaid, described below) and are responsible for issuing Medicare National Coverage Determinations Manual instructions as well as manual policy updates, codes for drugs and local coverage decisions. Generally, a national coverage determination ( NCD ) is a national policy statement granting, limiting or excluding Medicare coverage for a specific medical item or service. 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 offers an outpatient prescription drug benefit.

*Medicare Part B.* Medicare Part B provides limited benefits for fee-for-service outpatient drugs 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 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 an FDA approval. Many of our primary products, including EPOGEN®, Aranesp®, Neulasta® and NEUPOGEN®, are currently covered under Medicare Part B (as well as other government programs). In addition, most patients with end stage renal disease ( ESRD ), regardless of age, are eligible for coverage of their dialysis treatment through the ESRD Program under Medicare Part B, the primary payor for dialysis treatment. Because Medicare Part B is the primary payor for dialysis treatment, reimbursement for products, such as EPOGEN®, that are typically administered in dialysis centers is particularly sensitive to changes in Medicare reimbursement policy.

*Medicare Part D.* Medicare Part D provides a voluntary prescription drug benefit for elderly and disabled people who are eligible for Medicare. This coverage is available through various 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 a required range of prescription drugs and biologicals needed by Medicare beneficiaries. To encourage competition, the Medicare Prescription Drug Improvement and Modernization Act ( MMA ) stipulates that Part D plans have at least two drugs in each unique therapeutic category, subject to certain exceptions. Medicare patients who access ENBREL and Sensipar® under retail coverage where they are primarily accessed are covered by Medicare Part D.

*Medicaid.* Medicaid is a state-administered program designed for the low-income and disabled. Under federal law, states must cover low-income children, pregnant women, parents, disabled and seniors, and states have the option of expanding eligibility beyond these groups of patients. Medicaid is financed jointly by the states and federal government through taxes. Medicaid offers a broad set of benefits, including prescription drugs. Certain drug rebates for our products may be available to state governments under Medicaid. (See *Item 1A. Risk Factors* Our sales depend on coverage and reimbursement from third-party payors, and to the extent that access to and reimbursement for products is reduced, this could negatively impact the utilization of our products. )

### *Private Health Insurance*

*Employer-sponsored insurance.* Employer-sponsored insurance represents the main avenue 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.

*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. The plans are administered by private insurance companies. Individuals pay an insurance premium out-of-pocket for coverage, and benefits vary widely according to plan specifications.

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### *Reimbursement of Our Principal Products*

*Aranesp<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup>.* Medicare and Medicaid payment policies for drugs and biologicals are subject to various laws and regulations. The Medicare program covers Aranesp<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup>, when administered in the physician clinic setting and the hospital outpatient and dialysis settings, under Part B, and reimburses providers using a payment methodology developed under the MMA 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. (See *Items 1A. Risk Factors* *Our sales depend on coverage and reimbursement from third-party payors, and to the extent that access to and reimbursement for products is reduced, this could negatively impact the utilization of our products.* )

As of January 1, 2008, Medicare payment in the hospital outpatient setting reimbursed each product at 105% of its ASP (sometimes referred to as ASP+5%). For 2009, and effective January 1, 2009, CMS established the payment rate in the hospital outpatient setting at ASP+4% and CMS has the regulatory authority to further reduce the outpatient hospital payment formula in future years. The extent to which commercial payors 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.* Dialysis providers in the United States are primarily reimbursed for EPOGEN<sup>®</sup> by the federal government through the ESRD Program. The ESRD Program reimburses approved 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 monitored and implemented by CMS. Medicare reimburses for separately billable dialysis drugs administered in both free-standing and hospital-based dialysis centers, including EPOGEN<sup>®</sup> and Aranesp<sup>®</sup>, at ASP+6%, using the same payment amount methodology used in the physician clinic setting. Any changes to the ASP calculations directly affect the Medicare reimbursement for our products administered in the physician clinic setting, dialysis facility and hospital outpatient setting. These 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. For example, partially as a result of our methodology changes, our ASP reimbursement rate for EPOGEN<sup>®</sup> was reduced for the third quarter of 2007.

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

*Recent Medicare Reforms.* On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 (the MIPPA) became law. The MIPPA 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. The new bundled rate will include dialysis services covered under the current composite rate, including all injectable drugs commonly provided during dialysis treatment, including ESAs, intravenous (IV) iron, and IV vitamin D, as well as oral equivalent forms of these IV drugs. The bundled reimbursement rate will be phased in over a four year period in equal increments starting in 2011. It is possible that individual providers could elect to permanently move to a full Medicare bundled payment in 2011. CMS will also be required to establish a quality incentive program that begins concurrently with bundling in 2011 and which subjects facilities 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.

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*ESA Reimbursement Developments.* Since April 1, 2006, the Medicare reimbursement for ESAs administered to dialysis patients has been subject to a revised 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 IUs of EPOGEN®, from 500,000 IUs, and to 1,200 mcgs of Aranesp®, from 1,500 mcgs. The implementation of the revised EMP and ESA labeling changes led to a decline in EPOGEN® sales for the first quarter of 2008 compared to the first quarter of 2007 primarily due to a decline in both overall utilization and as well as average dosing per patient. However, this dose decline subsequently stabilized. (See *Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations EPOGEN®.* )

On March 14, 2007, CMS announced that the agency began 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 an NCD. 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 its Decision Memorandum which was substantially altered from the proposed NCD. On January 14, 2008, CMS issued changes to its Medicare NCD Manual, adding the ESA Decision Memorandum, effective for claims with dates of service on and after July 30, 2007 with an implementation date of April 7, 2008. The Decision Memorandum 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 Decision Memorandum 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 reimbursement of ESAs in the Decision Memorandum has had a material adverse effect on the use, reimbursement and sales of Aranesp®, and our business and results of operations. In addition, based on our knowledge, although no private payors have fully implemented the Decision Memorandum to date, many private payors have implemented portions of the Decision Memorandum that most commonly reflect the prescriber package insert. Further, 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 and 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 proposed in the Decision Memorandum for treatment of anemia in oncology with ESAs, would negatively affect use, reduce reimbursement and coverage, negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations.

### *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 payor of healthcare costs of patients. Over the past several years, the reimbursement environment in Europe has become very challenging, with the advent of Health Technology Assessment organizations (e.g., National Institute for Health and Clinical Excellence ( NICE ) in the United Kingdom) that make determinations of coverage and reimbursement based upon both the clinical value as well as cost-effectiveness of a product. With increased budgetary constraints, payors in many countries employ a variety of cost-containment measures that can include reference pricing (i.e., setting the reimbursement rate for a given class of agents at the lowest price within the class), generic substitution and mandatory price cuts. In many countries, the influence of regional and hospital payors also contributes to the level of product access that is afforded

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to patients. In the future, these trends are likely to continue. Additionally, we anticipate that many payors will request manufacturers to provide alternative pricing mechanisms (e.g., payment caps) that facilitate greater predictability of payor budgets.

### **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, inflammation, bone, metabolic disorders and neuroscience. We take a modality-independent approach to R&D—that is, we identify targets, and then choose the modality best suited to address a specific target. As such, our discovery research programs may yield targets that lead to the development of human therapeutics delivered as proteins, including monoclonal 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 our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of geographic locations where we have more limited experience conducting clinical trials, including Russia, India, East Asia and some Central and South American countries. *(See Item 1A. Risk Factors—Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected. )*

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 ). As part of our restructuring efforts, we have also moderated expansion of certain R&D facilities throughout the United States, including abandoning leases for certain R&D facilities that will no longer be used in our operations.

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, which enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. (See Note 8, *Acquisitions* to the Consolidated Financial Statements and Item 1A. Risk Factors—*We may not be able to develop commercial products.* )

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 our 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.

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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 6, 2009. 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.)

| <b>Molecule</b>            | <b>Disease/Condition</b>                                                                                                                                       | <b>Therapeutic Area</b> |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| <b>Phase 3 Programs</b>    |                                                                                                                                                                |                         |
| Cinacalcet                 | Cardiovascular disease in patients with secondary hyperparathyroidism and chronic kidney disease undergoing maintenance dialysis                               | Nephrology              |
| Darbepoetin alfa           | Anemia in heart failure                                                                                                                                        | Nephrology              |
| Darbepoetin alfa           | Patients with chronic kidney disease, anemia and type 2 diabetes                                                                                               | Nephrology              |
| Denosumab                  | Postmenopausal 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                  | 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     |
| Panitumumab                | First- and second-line colorectal cancer                                                                                                                       | Hematology/Oncology     |
| Panitumumab                | Metastatic and/or recurrent head and neck cancer                                                                                                               | Hematology/Oncology     |
| <b>Phase 2 Programs</b>    |                                                                                                                                                                |                         |
| AMG 102                    | Various cancer types                                                                                                                                           | Hematology/Oncology     |
| AMG 108                    | Rheumatoid arthritis                                                                                                                                           | Inflammation            |
| AMG 222                    | Type 2 diabetes                                                                                                                                                | General Medicine        |
| AMG 223                    | Hyperphosphatemia                                                                                                                                              | Nephrology              |
| AMG 317                    | Asthma                                                                                                                                                         | Inflammation            |
| AMG 386                    | Various cancer types                                                                                                                                           | Hematology/Oncology     |
| AMG 479                    | Various cancer types                                                                                                                                           | Hematology/Oncology     |
| AMG 655                    | Various cancer types                                                                                                                                           | Hematology/Oncology     |
| Denosumab                  | Rheumatoid arthritis                                                                                                                                           | Inflammation            |
| Motesanib                  | First-line breast cancer                                                                                                                                       | Hematology/Oncology     |
| Panitumumab                | Locally advanced head and neck cancer                                                                                                                          | Hematology/Oncology     |
| rhApo2L/TRAIL              | Various cancer types                                                                                                                                           | Hematology/Oncology     |
| Romiplostim <sup>(1)</sup> | Chemotherapy-induced thrombocytopenia in non-small cell lung cancer and lymphoma                                                                               | Hematology/Oncology     |
| Romiplostim <sup>(1)</sup> | Myelodysplastic syndromes                                                                                                                                      | Hematology/Oncology     |
| <b>Phase 1 Programs</b>    |                                                                                                                                                                |                         |
| AMG 191                    | Inflammatory diseases                                                                                                                                          | Inflammation            |
| AMG 208                    | Various cancer types                                                                                                                                           | Hematology/Oncology     |
| AMG 221                    | Type 2 diabetes                                                                                                                                                | General Medicine        |
| AMG 477                    | Type 2 diabetes                                                                                                                                                | General Medicine        |
| AMG 557                    | Systemic lupus erythematosus                                                                                                                                   | Inflammation            |
| AMG 745                    | Muscle wasting disorders                                                                                                                                       | Hematology/Oncology     |
| AMG 747                    | Neuroscience                                                                                                                                                   | General Medicine        |
| AMG 761                    | Asthma                                                                                                                                                         | Inflammation            |
| AMG 811                    | Systemic lupus erythematosus                                                                                                                                   | Inflammation            |
| AMG 827                    | Inflammatory diseases                                                                                                                                          | Inflammation            |
| AMG 853                    | Asthma                                                                                                                                                         | Inflammation            |
| AMG 888                    | Various cancer types                                                                                                                                           | Hematology/Oncology     |
| Sclerostin Ab (AMG 785)    | Bone-related conditions                                                                                                                                        | Bone                    |

<sup>(1)</sup> Program previously identified as AMG 531.

**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.

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**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 are in human clinical trials.

### *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 PMO and treatment-induced bone loss (prostate and breast cancer) phase 3 studies having met primary and key secondary endpoints. The following chart is an overview of the phase 3 clinical development program for denosumab:

| Program Area | Indication                                            | Enrollment Status | Project 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                           |
| 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 <sup>(1)</sup>                |
| Oncology     | Skeletal-Related Events-Breast Cancer                 | Complete          | 3rd Quarter of 2009 <sup>(1)</sup> |
| Oncology     | Skeletal-Related Events-Solid Tumors/multiple myeloma | Complete          | 4th Quarter of 2009 <sup>(1)</sup> |
| Oncology     | Skeletal-Related Events-Prostate Cancer               | Complete          | 2010 <sup>(1)</sup>                |

<sup>(1)</sup> Event-driven study and consequently data availability may vary as a result  
*Postmenopausal Osteoporosis Trials*

In a three-year phase 3 pivotal study of approximately 7,800 women with PMO (Study 216), twice-yearly subcutaneous injections with denosumab resulted in a statistically significant reduction in the incidence of new vertebral fractures compared with placebo treatment. In addition, women receiving denosumab experienced a statistically significant reduction in the incidence of new non-vertebral and hip fractures compared with those receiving placebo.

In a two-year pivotal phase 3 study of 332 postmenopausal women with low bone mass (osteopenia), treatment with denosumab increased BMD at all sites measured compared with placebo.

In a one-year non-pivotal phase 3, head-to-head, double-blind study in 1,189 postmenopausal women comparing the effects of denosumab versus weekly oral ALN (FOSAMAX®), treatment with denosumab resulted in significantly greater BMD gains at all sites measured compared with ALN.

In a one-year phase 3 head-to-head, double-blind study (Study 234) comparing the effects of denosumab in 504 women with PMO transitioned from weekly oral ALN versus continued ALN therapy, treatment with denosumab resulted in significantly greater BMD gains at all sites measured compared with continued treatment with ALN.

In all four PMO studies, the incidence and types of adverse events were generally similar across the treatment groups. The most common adverse events included back pain, arthralgia and nasopharyngitis.

### *Treatment-Induced Bone Loss Trials*

In a pivotal phase 3 study of more than 1,400 men undergoing ADT for non-metastatic prostate cancer (Study 138), denosumab treatment produced statistically significantly greater increases in BMD across the



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skeleton compared with placebo. During the 36-month evaluation period, men receiving denosumab experienced less than half the incidence of new vertebral fractures compared with those receiving placebo, a statistically significant finding. Furthermore, in the denosumab arm there were fewer non-vertebral fractures over the 36-month period.

In the pivotal phase 3 trial of 252 women with non-metastatic breast cancer and low bone mass receiving AI therapy, patients experienced significant increases in BMD across the skeleton when given denosumab once every six months irrespective of duration of AI therapy.

In both studies, the incidence and types of adverse and serious adverse events observed generally were similar between the denosumab and placebo groups. The most common adverse events across the treatment arms included arthralgia, back pain, constipation, and pain in extremity.

License applications for PMO and patients undergoing hormone ablation for either prostate or breast cancer were submitted with the FDA in December 2008 and EMEA in January 2009.

### *Other Settings*

Denosumab is also being studied in patients with breast cancer, prostate cancer, other solid tumors or multiple myeloma for treatment to prevent skeletal-related events ( SRE ). The Company expects to review the complete data set for SREs in breast cancer and solid tumors in the second half of 2009. The phase 3 study evaluating denosumab in patients with non-metastatic prostate cancer to prevent bone metastases is ongoing.

### *Vectibix® (panitumumab)*

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

In December 2008, we presented data to the ODAC regarding the utility of KRAS as a predictive biomarker for Vectibix® monotherapy. We performed a biomarker analysis which indicated that in mCRC patients who have failed all other chemotherapeutic regimens, the efficacy of Vectibix® monotherapy is confined to patients with non-mutated (wild-type) KRAS tumors. Specifically, patients with non-mutated KRAS tumors treated with Vectibix® monotherapy have shown a significantly prolonged PFS compared to best supportive care alone. Indeed, patients whose tumors contained KRAS mutations did not seem to benefit from Vectibix® treatment. As a result of our KRAS analyses, the statistical analysis plans of the phase 3 studies of Vectibix® in the treatment of first and second line colorectal cancer, which were initiated in 2006, have been amended. These study changes are expected to allow the Company to assess the utility of Vectibix® in patients according to tumor KRAS mutational status; data from these phase 3 studies are expected to be available in 2009.

In December 2007, we announced that the European Commission has granted a conditional marketing authorization for Vectibix® as monotherapy for the treatment of patients with EGFr expressing metastatic colorectal carcinoma with non-mutated (wild-type) KRAS after failure of fluoropyrimidine-, oxaliplatin- and irinotecan-containing chemotherapy regimens. In December 2008, the European Committee for Medicinal Products for Human Use ( CHMP ) adopted a positive opinion for the renewal of this conditional marketing authorization.

In May 2008, we presented data from the phase 2 Panitumumab Regimen Evaluation in Colorectal Cancer to Estimate Primary Response to Treatment ( PRECEPT ) trial and phase 1 data evaluating panitumumab in head and neck cancer at the annual meeting of the American Society of Clinical Oncology ( ASCO ) and in July 2008, we disclosed that the phase 2 Skin Toxicity Evaluation Protocol with Panitumumab ( STEPP ) study showed that preemptive treatment reduced the incidence rate of skin toxicities without additional side effects. 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 panitumumab in combination with chemoradiotherapy or with radiotherapy alone. Panitumumab is also being investigated in combination with other investigational anti-cancer therapies.

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### *Nplate® (romiplostim)*

Romiplostim (Nplate®) is a peptibody agonist of the thrombopoietin ( 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 August 2008, Nplate® became the first FDA-approved peptibody protein, which works by raising and sustaining platelet counts representing a novel approach for the treatment of this chronic disease.

We are also evaluating romiplostim in pediatric ITP, myelodysplastic syndromes ( MDS ), and chemotherapy-induced thrombocytopenia ( CIT ). Phase 2 studies in each setting were initiated in 2006. The trials are currently ongoing and we continue to evaluate the safety and efficacy of romiplostim in these settings.

### *Sensipar® (cinacalcet)*

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

The phase 3 EVOLVE (EValuation Of Cinacalcet Therapy to Lower CardioVascular Events) 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 EVOLVE study completed enrollment in January 2008.

### *Aranesp® (darbepoetin alfa)*

Darbepoetin alfa (Aranesp®) is a recombinant protein agonist of the erythropoietic receptor.

The Reduction of Events with Darbepoetin alfa in Heart Failure ( RED-HF ) Trial phase 3 study, initiated in 2006, is a large (2,600 patient), 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 patients.

The Trial to Reduce Cardiovascular Events with Aranesp® Therapy ( TREAT ) phase 3 study, initiated in 2004, is a large (4,000 patient), multi-center, randomized, double-blind, controlled trial designed to determine the impact of anemia therapy with darbepoetin alfa on mortality and non-fatal cardiovascular events in patients with CKD, anemia and type 2 diabetes. In December 2007, the TREAT study completed enrollment. In November 2008, we disclosed that the independent Data Safety Monitoring Committee ( DSMC ) completed a pre-specified, unblinded review of the data at a point where 80% of the targeted number of fully adjudicated events had been recorded and recommended that the study continue without modification.

### *AMG 102*

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

Phase 2 studies of single agent AMG 102 initiated in 2006 for renal cell carcinoma ( RCC ) and glioblastoma multiforme ( GBM ) are ongoing. An interim analysis of the GBM study was presented at ASCO 2008 in which AMG 102 was administered as a single agent to 40 patients with recurrent GBM to assess its safety and efficacy. We expect the final results from the phase 2 studies in RCC and GBM to be available in the first half of 2009. In 2008, data were presented at ASCO from a separate trial in which AMG 102 was combined with bevacizumab or motesanib. We also initiated in 2008, four separate phase 2 studies for the treatment of gastric, prostate, colorectal and small cell lung cancer.

### *AMG 108*

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



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In April 2008, we discussed results from the phase 2 study in RA. AMG 108 appeared to be well tolerated and showed a statistically significant improvement in the signs and symptoms of RA. However, the efficacy profile based on the results of this study was not comparable to the current standard of care for biologic therapies. Amgen is evaluating other options for the overall development program.

### *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.

A phase 2a study is ongoing in this disease setting in collaboration with Servier. We expect the results from the phase 2a study to be available in the first half of 2009.

### *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.

The results for AMG 223 from its recently completed phase 1 study in normal healthy subjects and phase 2 study in subjects with CKD on hemodialysis with hyperphosphatemia have been obtained. AMG 223 appeared to be well tolerated and showed a statistically significant reduction in serum phosphorus compared with placebo. While these results were consistent with what is required for registration of a phosphate-binding therapy, in the context of our overall development portfolio, the Company will be reviewing other options for the commercialization of this investigational product.

### *AMG 317*

AMG 317 is a fully human monoclonal antibody that is under investigation for its ability to block the actions of interleukin-4 ( IL-4 ) and interleukin-13 ( IL-13 ), cytokines that may play a role in asthma.

In 2008, a phase 2 dose ranging study in moderate to severe asthma was completed. An interim analysis showed evidence of biological activity; however, the overall clinical efficacy did not meet expectations. Complete study results will be presented in a peer-reviewed forum in 2009.

### *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, we initiated four phase 2 studies of AMG 386 for the treatment of RCC, metastatic breast cancer, ovarian cancer and gastric cancer. We expect the results from the phase 2 gastric study to be available in the second half of 2009.

### *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.

### *AMG 655*

AMG 655 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.

Phase 2 studies in pancreatic cancer, NSCLC, colorectal cancer ( CRC ) and soft tissue sarcoma are ongoing. We expect the results from the phase 2 NSCLC and soft tissue sarcoma studies to be available in the second half of 2009.



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### *Motesanib*

Motesanib is an orally-administered small molecule antagonist of vascular endothelial growth factor receptors 1, 2 and 3 ( VEGFR1-3 ), platelet-derived growth factor receptor ( PDGFR ) and stem cell factor receptor ( c-kit ). It is being investigated as a cancer treatment. We are developing this product in collaboration with Takeda.

In 2008, we completed enrollment in phase 2 studies of motesanib versus bevacizumab in the treatment of metastatic breast cancer and NSCLC and we expect the results from these studies to be available in the first half of 2009.

In November 2008, Amgen and Millennium: The Takeda Oncology Company, a subsidiary of Takeda announced that enrollment in the phase 3 MONET1 trial evaluating motesanib in combination with paclitaxel and carboplatin for the first-line treatment of advanced NSCLC has been temporarily suspended following a planned safety data review of 600 patients by the study's independent Data Monitoring Committee ( DMC ). The study's DMC also recommended that patients with squamous NSCLC immediately discontinue motesanib therapy but did not recommend discontinuation of motesanib therapy for patients with non-squamous NSCLC. In February 2009, the DMC recommended the trial resume enrollment of patients with non-squamous NSCLC. Amgen, Millennium and Takeda plan to follow this recommendation, which will require modifications to the trial's study design. Enrollment is expected to resume once these changes are sanctioned by appropriate global health authorities.

### *rhApo2L/TRAIL*

rhApo2L/TRAIL is a recombinant human protein that targets death receptors 4 and 5 ( DR4 and DR5 ) and induces apoptosis in sensitive tumor cells. It is being investigated as a cancer treatment. We are developing this product in collaboration with Genentech.

Phase 2 studies in NSCLC and NHL are ongoing. We expect the results to be available in the second half of 2009.

## **Manufacturing, Distribution and Raw Materials**

### *Manufacturing*

Our manufacturing operations consist of bulk manufacturing, formulation, fill and finish and distribution activities for Aranesp®, Epoetin alfa, Neulasta®, NEUPOGEN®, ENBREL, Vectibix®, Nplate®, denosumab and other products and product candidates for both commercial and clinical purposes. Bulk manufacturing includes fermentation and cell culture, which are the processes in 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 the vials or syringes. Finally, in the finish process, our products are packaged for distribution. 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 contractors.

We actively manage our inventory produced at our manufacturing facilities and supply produced by our third-party contract manufacturers. We expect to continue to use third-party contract manufacturers to produce or assist in the production of certain of our existing products and a number of our clinical product candidates.

(See *Item 1A. Risk Factors* We must continue to build the framework for our future growth, and if we fail to execute on our initiatives our business could be adversely affected. )

In general, we have obtained licenses from various parties that we deem to be necessary or desirable for the manufacture of our products. These licenses generally require us to pay royalties to the parties on product sales.

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### *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.

In addition to commercial quantities of bulk ENBREL produced at our Rhode Island facility, we and Wyeth also have a contract manufacturing agreement with Boehringer Ingelheim Pharma KG ( *BI Pharma* ) for the production of additional supply of ENBREL. We also have a global supply agreement with Wyeth related to the manufacture, supply and allocation of bulk supplies of ENBREL. Under this agreement, we and Wyeth share the total worldwide bulk supply of ENBREL produced by our Rhode Island manufacturing facility, *BI Pharma* 's manufacturing facility in Germany and Wyeth 's manufacturing facility in Ireland.

Our supply of ENBREL is significantly dependent on product manufactured by *BI Pharma*, and, accordingly, we have made significant purchase commitments to *BI Pharma*. Under our supply agreements, *BI Pharma* has reserved a specified level of production capacity for ENBREL and we are committed to using at least that level of capacity. We are required to submit a rolling three-year forecast for manufacturing the bulk drug for ENBREL and a rolling forecast for a shorter period for the number of finished vials of ENBREL. We would be responsible for substantial payments to *BI Pharma* if we were not to use the minimum production capacity that *BI Pharma* has reserved for ENBREL each calendar year or if the *BI Pharma* supply agreement is terminated prematurely under specified conditions. (See Note 9, *Commitments* to the Consolidated Financial Statements.)

In addition to producing our own commercial quantities of Epoetin alfa, we also supply Epoetin alfa in the United States to J&J under a supply agreement (see *Joint Ventures and 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 ENBREL and Nplate®, we perform substantially all of the commercial formulation, fill and finish activities for our proteins in Puerto Rico. In addition to the formulation, fill and finish of ENBREL performed by us in Puerto Rico or by *BI Pharma* for the ENBREL they manufacture and supply to us, fill and finish of a certain portion of ENBREL is also performed by other 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 manufacturing, 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 to perform manufacturing activities for certain of our clinical products.

### *Distribution*

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

### *Other*

In addition to the manufacturing and distribution activities noted above, our operations in the United States and Puerto Rico perform key manufacturing support functions, including quality control, process development, procurement, distribution and production scheduling. Our global supply of our principal products is significantly dependent on the uninterrupted and efficient operation of our manufacturing facilities.

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### *Manufacturing Initiatives*

We have a number of key ongoing initiatives to assist in meeting our future manufacturing needs. 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 adequately prepare to launch a number of our late-stage product candidates, in particular denosumab, we must successfully implement a number of manufacturing projects on schedule, 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. Key manufacturing projects include: (i) construction, qualification and licensure of a new formulation and filling facility at our Puerto Rico site and (ii) expansion and the related qualification and licensure of our existing bulk protein facilities at our Puerto Rico site for the production of our late-stage product candidate, denosumab. (See *Item 1A. Risk Factors – Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing of supply may also be affected by operation of our distribution and logistics centers and providers.* )

### *Raw Materials and Medical Devices*

Certain raw materials, medical devices and components needed for manufacturing are proprietary products provided by single-source third-party suppliers. Certain of these raw materials, medical devices and components are cited in our drug application with regulatory agencies so that they must be obtained from the specified sole source. 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 raw materials required for commercial and clinical manufacturing of our products are derived from biological sources, including mammalian tissues, bovine serum and human serum albumin ( HSA ). Some of our manufacturing processes currently use biological sources and 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, certain countries in which we market our products may restrict the use of biologically derived substances in the manufacture of drugs. A material shortage, contamination, recall and/or restriction of the use of biologically derived substances in the manufacture of our products could disrupt our commercial manufacturing of products, or could result in a mandated withdrawal of products from the market. (See *Item 1A. Risk Factors – We rely on single third-party suppliers for some of our raw materials, medical devices and components; if these third-parties fail to supply these items, we may be unable to supply our products.* )

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.

### **Joint Ventures and Business Relationships**

From time to time, we may enter into joint ventures and other business relationships to provide additional development, manufacturing and marketing capabilities. In addition to our internal R&D efforts, we have acquired certain product rights and have established R&D collaborations to enhance our R&D capabilities and internally developed product pipeline. Our R&D collaborations generally provide for non-refundable, upfront license fees, R&D and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. Additionally, these collaborations may include manufacturing and co-promotion arrangements. 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 collaboration and licensing agreements to execute confidentiality agreements upon the commencement of the collaboration or licensing arrangement with us. However, others could either develop independently the same or similar information or obtain access to our information.

**Table of Contents***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, North 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 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 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, Taiwan and Korea and (iii) recombinant human erythropoietin in Japan. Kirin markets darbepoetin alfa in Japan under the brand name NESP®. Kirin markets G-CSF and recombinant human erythropoietin in China under a separate agreement with KA. Kirin markets its G-CSF product in its respective territories under the trademark GRAN®. Kirin markets its recombinant human erythropoietin product in Japan under the trademark ESPO®.

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 4, *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 markets other than dialysis. 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. dialysis market. Pursuant to the license agreement with J&J, we earn a 10% royalty on net sales of PROCrit® by J&J in the United States.

Outside the United States, with the exception of China and Japan, J&J was granted rights to manufacture and commercialize recombinant human erythropoietin as a human therapeutic for all uses under a licensing agreement with KA. With respect to its sales outside of the United States, J&J manufactures and commercializes its own brand of Epoetin alfa which is then sold by 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.

*Wyeth*

Amgen and Wyeth market and sell ENBREL under a co-promotion agreement in the United States and Canada for all approved indications. The rights to market ENBREL outside of the United States and Canada are reserved to Wyeth. Under the co-promotion agreement, a management committee comprised of equal representation from Wyeth and Amgen 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

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responsible for all sales activities. Further, pursuant to the co-promotion agreement, Wyeth and Amgen each pay a defined percentage of all selling and marketing expenses approved by the management committee. In addition, we pay Wyeth a percentage of the annual gross profits on our ENBREL sales, which reflect the sharing of manufacturing costs 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. Under the co-promotion agreement, Wyeth is required to reimburse Amgen for: (i) certain clinical and regulatory expenses we incur in connection with the filing and approval of any new indications for ENBREL in the United States and Canada, (ii) certain specified patent expenses related to ENBREL and (iii) certain costs, expenses and liabilities associated with the manufacture, use or sale of ENBREL in the United States and Canada.

We also have a global supply agreement with Wyeth related to the manufacture, supply and allocation of bulk supplies of ENBREL. Under this agreement, we and Wyeth share the total worldwide bulk supply of ENBREL produced by our Rhode Island manufacturing facility, BI Pharma's manufacturing facility in Germany and Wyeth's manufacturing facility in Ireland.

Our agreements with Wyeth do not include a change of control provision.

### *Fresenius Medical Care North America, Inc.*

In October 2006, we entered into a five-year sole sourcing and supply agreement with an affiliate of Fresenius Medical Care North America, Inc. (Fresenius), 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' 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.

### *Daiichi Sankyo Company, Limited*

In July 2007, we entered into a collaboration and license agreement with Daiichi Sankyo Company, Limited (Daiichi Sankyo), which provided them the exclusive rights to develop and commercialize denosumab in Japan in PMO and oncology with the potential for additional indications. As part of the agreement, Amgen received exclusive worldwide rights to certain Daiichi Sankyo intellectual property to the extent applicable to denosumab.

### *Takeda Pharmaceutical Company Limited*

In February 2008, we entered into a license agreement with Takeda, which provided them the exclusive rights to develop and commercialize for the Japanese market up to 12 clinical stage molecules from our pipeline across a range of therapeutic areas, including oncology and inflammation. The molecules covered by the license agreement primarily include: AMG 108, AMG 317, AMG 386, AMG 479, AMG 655 and Vectibix®. 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 motesanib (AMG 706). Each party has the right to participate in the commercialization of motesanib in the other party's territory. In connection with these agreements, Takeda acquired our subsidiary in Japan, Amgen K.K.

## **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 FDAAA, as amended, 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

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requirements may subject a company 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.* 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 (see *Item 1A. Risk Factors* *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.* , *Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.* , *We may not be able to develop commercial products.* and *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.* ). 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, the IND sponsor 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, denosumab, one of our late-stage product candidates, requires large trials that require 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 the ethical principles contained in the Declaration of Helsinki (as embodied in FDA regulations) and applicable laws and regulations of the country in which the research was conducted. 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, reevaluate, 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* *Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.* )

*Applications.* The results of preclinical and clinical trials are submitted to the FDA in the form of a BLA for biologic products subject to the Public Health Service Act or a new drug application ( NDA ) for drugs subject to the approval provisions of the FDCA. The submission of the application is no guarantee that the FDA will find it complete and accept it for filing. If an application is accepted for filing, following the FDA's review, the FDA may grant marketing approval, request additional information, or deny the application if it determines that the application does not provide an adequate basis for approval. As a condition of approval, the FDA may require postmarketing clinical trials or other studies to confirm the product's safety and efficacy for its intended use. 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.* Under 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

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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. A REMS may include a medication guide, patient package insert, a plan for communication with healthcare providers, or other elements as the FDA deems are necessary to assure safe use of the product, which could include imposing certain restrictions on distribution or use of a product. A REMS must include a timetable for submission of assessments of the strategy at specified time intervals. 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.

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. (See *Item 1A. Risk Factors Recent labeling changes or risk mitigation activities required by regulatory authorities, as well as the results or meta-analyses of clinical trials, may adversely impact the use, sales and reimbursement of our ESAs.* ) Failure to implement FDA-mandated changes may result in civil or criminal penalties. (See *Item 1A. Risk Factors Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.* )

**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 advertising and 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 also reviews 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 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.

**Approval and Post-Approval Regulation Ex-US.** 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

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marketing authorization application to the EMEA 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 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 EMEA, 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 has 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 payors (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 were to allege against or convict us of violating these laws, 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 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) pharmaceutical pricing program. Under the Medicaid 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 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 of the quarter's AMP and best price for each of our products to the CMS. The terms of our participation in the program impose an obligation to correct the prices reported in previous quarters, as may be necessary. Any such corrections could result in an overage or underage in our rebate liability for past quarters, depending on the direction of the correction. In addition to retroactive rebates, if we were found to have knowingly submitted false information to the government, in addition to other penalties available to the government, the statute provides for civil monetary penalties in the amount of \$100,000 per item of false information. Under the Medicare program our products are reimbursed under a Medicare Part B payment methodology that reimburses each product at a specified percentage of its ASP (sometimes referred to as ASP+6%). ASP is calculated by the manufacturer

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based on a statutorily defined formula and submitted to CMS and similar civil monetary penalties apply for knowingly submitting false information. (See *Item 1A. Risk Factors Our sales depend on coverage and reimbursement from third-party payors, and to the extent access to and reimbursement for our products is reduced, this could negatively impact the utilization of our products.* )

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.

(See *Item 1A. Risk Factors Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.* and *Our sales depend on coverage and reimbursement from third-party payors, and to the extent that access to and reimbursement for our products is reduced, this could negatively impact the utilization of our products.* )

## **Human Resources**

As of December 31, 2008, we had approximately 16,900 staff members, which include approximately 200 part-time staff members. Of the total staff members as of December 31, 2008, approximately 7,850 were engaged in R&D, approximately 3,050 were engaged in selling and marketing, approximately 3,600 were engaged in commercial manufacturing activities and approximately 2,400 were engaged in other activities. There can be no

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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, 2009 are as follows:

Mr. Kevin W. Sharer, age 60, has served as a director of the Company since November 1992. Since May 2000, Mr. Sharer has been Chief Executive Officer and President of the Company and has also been Chairman of the Board of Directors since December 2000. From October 1992 to May 2000, Mr. Sharer served as President and Chief Operating Officer of the Company. From April 1989 to October 1992, Mr. Sharer was President of the Business Markets Division of MCI Communications Corporation ( 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.

Mr. David W. Beier, age 60, 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 62, 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 46, 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 59, 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 52, 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 56, 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

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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 56, 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 48, became Senior Vice President and Chief Compliance Officer in June 2008. From December 2003 to June 2008, Ms. Richo served as Vice President, Law. Prior to Amgen, she spent 12 years at Baxter Healthcare Corporation in roles of increasing responsibility in law, including Vice President, Law, for Baxter's BioScience Division. Also, for more than five years, Ms. Richo served on the Board of Directors of Cytoc Corporation and was a member of the Audit and Finance Committees.

Mr. David J. Scott, age 56, 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 11, *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 such material electronically or otherwise furnishing it to the Securities and Exchange Commission (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 450 Fifth Street, N.W., 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.

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*Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.*

We and certain of our licensees and partners conduct research, preclinical testing and clinical trials for our product candidates and marketed products for both their existing indications as well as for new and/or expanded indications. In addition, we manufacture and contract manufacture, and certain of our licensees and partners manufacture our products and product candidates, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, such as the EMEA in European countries and similar regulatory bodies in Canada and Australia. Currently, we are required in the United States and in foreign countries to obtain approval from those countries' regulatory authorities before we can manufacture (or have our third-party manufacturers produce), market and sell our products in those countries. The FDA and other U.S. and foreign regulatory agencies have substantial authority to fail to approve commencement of, suspend or terminate clinical trials, require additional testing, delay or withhold registration and marketing approval, mandate product withdrawals and require changes in labeling (including eliminating certain therapeutic indications) of our products. In 2007, the FDAAA was signed into law significantly adding to the FDA's authority including allowing the FDA to (i) require sponsors of marketed products to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk; (ii) mandate labeling changes to products, at any point in a product's lifecycle, based on new safety information and (iii) require sponsors to implement a REMS for a product which could include a medication guide, patient package insert, a communication plan to healthcare providers, or other elements as the FDA deems are necessary to assure safe use of the drug, which could include imposing certain restrictions on distribution or use of a product. Failure to comply with the new requirements, if imposed on a sponsor by the FDA under the FDAAA, could result in significant civil monetary penalties. Further, regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain or maintain approval of our existing or future products or require significant additional costs to obtain or maintain such approvals.

In our experience, obtaining regulatory approval has been and continues to be increasingly difficult and costly and takes many years, and, after it is obtained, is increasingly costly to maintain. With the occurrence of a number of high profile safety events relating to certain pharmaceutical products, regulatory authorities, and, in particular, the FDA, members of Congress, the U.S. Government Accountability Office (GAO), Congressional committees, private health/science foundations and organizations, medical professionals, including physicians and investigators, and the general public are increasingly concerned about potential or perceived safety issues associated with pharmaceutical and biological products, whether under study for initial approval or already marketed. For example, we have received letters from both the House Subcommittee on Oversight and Investigation, Committee on Energy and Commerce and the United States Senate Committee on Finance with inquiries with respect to our ESA studies, promotion of our ESAs and other products, our rebates and contracting strategies and our pharmacovigilance program, to which we have fully cooperated by submitting our responses and meeting with Congressional staff. To the extent that there is resulting legislation or changes in CMS or FDA policy or regulatory activity as a result of Congressional concerns, such changes could have a material adverse effect on the use of our ESA products that are the subject of such changes.

As a result of this increasing concern, potential or perceived safety signals and safety concerns, from clinical trials, use by the market or other sources, are receiving greater scrutiny, which may lead to (i) fewer treatments being approved by the FDA or other regulatory bodies, (ii) revised labeling of an approved product or a class of products for safety reasons, potentially including a boxed warning or additional limitations on the use of approved products in specific therapeutic areas (possibly until additional clinical trials can be designed and completed), (iii) mandated PMCs or pharmacovigilance programs for approved products and/or (iv) requirement of risk management activities (including a REMS) related to the promotion and sale of a product. In addition, significant concerns about the safety and effectiveness of our products could ultimately lead to the revocation of

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marketing approval of the products within particular therapeutic areas, or in total, which would have a material adverse effect on the use, sales and reimbursement of the affected products and on our business and results of operations. (See *Our sales depend on coverage and reimbursement from third-party payors, and to the extent that access to and reimbursement for our products is reduced, this could negatively impact the utilization of our products.* )

Certain specific labeling or label changes of our approved products or product candidates may be necessary or required for a number of reasons, including: the identification of actual or theoretical safety or efficacy concerns concerning any of our products by regulatory agencies, 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 or meta-analysis of clinical trials or clinical data performed by us or others. Label changes may also be required as a result of new legislation. Under new FDA legislation implemented in 2006, the Physician's Labeling Rule ( PLR ) requires 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. In addition, before or after any of our products are approved for commercial use, regulatory bodies could decide that the product labels need to include certain warning language as part of an evolving label change to a particular class of products. For example, in March and November 2007, and in March and August 2008, the U.S. labels for the class of ESA products, including Aranesp® and EPOGEN®, were updated to include revised boxed warnings, restrictions on the use of ESAs in specific therapeutic areas and other safety-related product labeling changes. (See *Recent labeling changes or risk management activities required by regulatory authorities, as well as the results or meta-analyses of clinical trials, may adversely impact the use, sales and reimbursement of our ESAs.* ) On March 17, 2008, we and Wyeth announced updates to the FDA-approved labeling for ENBREL in which the U.S. PI now contains a boxed warning relating to the risk of infections, including tuberculosis. This information in the boxed warning includes additional language regarding screening and monitoring patients for tuberculosis, including patients who tested negative for latent tuberculosis infection. Further, on September 4, 2008, the FDA issued a web-alert regarding their review of histoplasmosis and other opportunistic fungal infections in patients treated with TNF-blockers. The FDA requested that the boxed warning and WARNINGS sections of the U.S. PI and the medication guide for ENBREL (and other TNF-blockers) be strengthened to include the risk of unrecognized histoplasmosis and other invasive fungal infections with the goal of increasing timely diagnosis and treatment. The FDA also requested that the approved REMS for ENBREL be modified with a communication plan to healthcare providers regarding the risk of unrecognized fungal infections. In December 2008, we agreed with the FDA on the required revisions to the U.S. PI, and we continue to work with the FDA to finalize the requested updates to the ENBREL REMS.

Additionally, on June 4, 2008, the FDA issued an Early Communication regarding the ongoing safety review of TNF-blockers and the possible association between the use of these medicines and the development of lymphoma and other cancers in children and young adults and stated that it had decided to conduct further analyses to evaluate the risk and benefits of TNF-blockers in pediatric patients. On June 18, 2008, we participated in a meeting of the DODAC to review data supporting the supplemental BLA submitted by us for the use of ENBREL in treating pediatric patients with chronic moderate to severe plaque psoriasis, who are inadequately controlled with topical therapy or who have received systemic therapy or phototherapy and the DODAC recommended, with an 8-5 vote, to approve ENBREL in the treatment of chronic moderate to severe plaque psoriasis in children. On July 24, 2008, we received notification from the FDA through a complete response letter that the FDA would like additional information from us regarding the use of ENBREL in pediatric patients with chronic moderate to severe plaque psoriasis. We cannot predict what the result of the FDA's analysis of TNF-blockers and the development of lymphoma or other cancers in children and young adults may be, nor can we speculate on the effect of that analysis on the supplemental BLA. However, further revisions to the ENBREL label or other actions by the FDA, including additional advisory committee meetings, could have a material adverse impact on the use and sales of ENBREL which could have a material adverse effect on our business and results of operations.

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A revision of product labeling or the regulatory actions described above could be required even if there is no clearly established connection between the product and the safety or efficacy concerns that have been raised or if the product is not indicated for a particular use. For example, in October 2007 we announced that we and the FDA adopted changes to the U.S. labeling for Vectibix<sup>®</sup> based on the results of the Panitumumab Advanced Colorectal Cancer Evaluation ( PACCE ) trial highlighting to clinicians the greater risk seen when Vectibix<sup>®</sup> is combined with Avastin<sup>®</sup> and the specific chemotherapy used in the PACCE trial to treat patients with first-line mCRC. Vectibix<sup>®</sup> is not indicated for the first-line treatment of mCRC and the additional safety information applies to an unapproved use of Vectibix<sup>®</sup>.

If we or others identify safety concerns before approval of the product or after a product is on the market, the regulatory agencies such as the FDA or EMEA may impose risk management activities upon us (including a REMS) which may require substantial costs and resources to negotiate, develop and implement, including sales force time to educate physicians on REMS requirements and compliance, and/or may require additional or more extensive clinical trials as part of a pharmacovigilance program of our product or for approval of a new indication. Further, risk management activities, including a REMS, required by regulatory agencies such as the FDA could also modify, restrict or otherwise impact the ability of healthcare providers to prescribe, dispense or use our products, limit patient access to our products or affect our ability to compete against products that do not have a REMS, any of which could have a negative effect on our ability to launch our affected products and could have a material adverse effect on sales of the affected products and on our business and results of operations. For example, as part of the approval for Nplate<sup>®</sup>, a REMS was developed with the FDA to assure the safe use of Nplate<sup>®</sup> while minimizing risk. The Nplate<sup>®</sup> REMS involves, among other things, healthcare provider and patient enrollment registries, tracking of patient medical history and data and follow-up safety questionnaires to healthcare providers, all of which require extensive discussion with and education of healthcare providers which has limited our ability to promote Nplate<sup>®</sup>. Further, as part of the update to the boxed warning and warnings sections of the U.S. PI and the medication guide for ENBREL, the FDA stated that it would require us and the other makers of TNF-blockers to educate healthcare providers about the risk of unrecognized histoplasmosis. Our efforts to comply with the requirements of our existing REMS and any additional REMS or other risk management activities required of us in the future could restrict or otherwise impact our existing promotional activities for our other products as well. In addition, we have ongoing PMC studies for all of our marketed products. These clinical trials must be conducted by us to maintain regulatory approval and marketing authorization. For example, 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. (See *Recent labeling changes or risk management activities required by regulatory authorities, as well as the results or meta-analyses of clinical trials, may adversely impact the use, sales and reimbursement of our ESAs.* ) Additionally, the original approvals of Vectibix<sup>®</sup> in both the United States and EU were conditioned on us conducting additional clinical trials of the use of Vectibix<sup>®</sup> as a therapy in treating mCRC. Our conditional approval of Vectibix<sup>®</sup> in the EU is reviewed annually by the CHMP, and in December 2008 we agreed as a condition of the renewal of the conditional approval to conduct an additional clinical trial in the existing approved indication. If results from clinical trials as part of a PMC or pharmacovigilance program are negative, it could result in the revocation of the marketing or conditional marketing approvals or revised labeling of our products, which could have a material adverse effect on sales of the affected products and on our business and results of operations.

Substantially all of our marketed products are currently approved in the United States and most are approved in Europe and in other foreign countries for specific uses. However, later discovery of unknown problems with our products could result in the regulatory activities described above or even the potential withdrawal of the product in certain therapeutic areas or certain product presentations, or completely, from the market. If new medical data suggest an unacceptable safety risk or previously unidentified side-effects, we may voluntarily withdraw, or regulatory authorities may mandate we withdraw, such product in certain therapeutic areas, or completely recall a product presentation from the market for some period or permanently. For example in 2006, we initiated a voluntary recall of the Neulasta<sup>®</sup> SureClick<sup>®</sup> pre-filled pen in Europe because of the potential risk to patients of receiving an incomplete dose and we conducted a voluntary wholesaler recall of a limited number of lots of ENBREL as a result of a small number of reports of missing, detached or loose rubber caps on the needleless syringe filled with diluent liquid by a third-party contract manufacturer and packaged with the vials of

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ENBREL. In addition in August 2008, we voluntarily recalled two manufacturing lots of EPOGEN® and our licensee, Ortho Biotech, voluntarily recalled one manufacturing lot of PROCRIT® (Epoetin alfa) that was manufactured in our manufacturing facilities after having identified cracks in the necks of a small number of vials upon post-manufacturing inspection. Although there have been no observable adverse event trends associated with the Neulasta® SureClick pre-filled pen, with the reports of missing, detached or loose rubber caps on the needleless syringe packaged with the ENBREL vials or with the cracks in the neck of vials of Epoetin alfa, we may experience the same or other problems in the future resulting in broader product recalls or adverse event trends. Additionally, if other parties (including our licensees, such as J&J and Wyeth, 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, regulatory approval may be withdrawn for a product for the therapeutic area in question, or completely, or other risk management activities may be required by regulators.

If regulatory authorities determine that we or our licensees or partners conducting R&D activities on our behalf have not complied with regulations in the R&D of a product candidate, new indication for an existing product or information to support a current indication, then they may not approve the product candidate or new indication or maintain approval of the current indication in its current form or at all, and we will 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. Additionally, 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. (See *Our sales depend on coverage and reimbursement from third-party payors, and to the extent that access to and reimbursement for our products is reduced, this could negatively impact the utilization of our products.* and *Guidelines and recommendations published by various organizations can reduce the use of our products.* )

*Recent labeling changes or risk management activities required by regulatory authorities, as well as the results or meta-analyses of clinical trials, may adversely impact the use, sales and reimbursement of our ESAs.*

On March 9, 2007, based upon data from our AoC 103 Study, J&J's Correction of Hemoglobin and Outcomes in Renal Insufficiency ( CHOIR ) study, and preliminary data from the third-party investigator DAHANCA 10 Study, among others, the FDA approved updated safety information, including a boxed warning, in the labeling for the class of ESAs, including Aranesp® and EPOGEN®. On May 10, 2007, the ODAC held a panel meeting to discuss the safety/efficacy profile of ESA use in oncology. Responding to questions posed by the FDA, the ODAC recommended that more restrictions be added to ESA labeling and that additional clinical trials be conducted by companies with currently approved ESAs, including us, although no specific restrictions or studies were recommended at the ODAC meeting. The committee is advisory and FDA officials are not bound to or limited by its recommendations, although the FDA has commonly followed the recommendations of its advisory panels. The FDA also held a joint meeting of the CRDAC and the DSaRMAC on September 11, 2007, which evaluated the safety data on ESA use in renal disease. On November 8, 2007, in recognition of the input from the May 2007 ODAC and September 2007 joint CRDAC/DSaRMAC meetings, we announced additional updates to the Aranesp® and EPOGEN®/PROCRIT® labeling which reflected ongoing interactions with the FDA regarding the safety and benefit/risk profile of ESAs and included modifications to the boxed warnings of the ESA labeling. Additionally, based on safety data from the Preoperative Epirubicin Paclitaxel Aranesp® ( PREPARE ) interim study results in neo-adjuvant breast cancer and the data from the Gynecologic Oncology Group 191 ( GOG-191 ) study in cervical cancer, on March 7, 2008, we announced that the FDA approved updated safety information, including the boxed warning in the labeling information for the class of ESAs, including Aranesp® and EPOGEN®. On March 13, 2008, the FDA held a follow-up ODAC panel meeting to discuss cumulative data, including recent study results, on the risks of ESAs when used in the oncology setting.

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On July 30, 2008, we received a complete response letter from the FDA to the revisions to the ESA labeling we proposed following the March 13, 2008 ODAC meeting. The letter included, among other things, (i) the addition to the boxed warning of a statement that ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome of such therapy is cure, (ii) the addition of a statement in the DOSAGE and ADMINISTRATION section of the label that ESA therapy should not be initiated at Hb levels  $\geq 10$  g/dL and that dose should be adjusted to maintain the lowest Hb level sufficient to avoid red blood cell transfusions and (iii) the removal of reference to the upper safety limit of 12 g/dL. We revised the ESA labeling on August 6, 2008, as the FDA directed, and have experienced a reduction in our ESA sales, in particular Aranesp® sales in the U.S. supportive cancer care setting, since that time. Although we cannot predict what further impact the revised ESA labels may have on our business, the revised ESA labeling or any future labeling changes, including any required in connection with our ongoing discussions with the FDA regarding the conversion of the format of our ESA U.S. labels in accordance with the PLR, could have a material adverse impact on the reimbursement, use and sales of our ESA products, which would have a material adverse effect on our business and results of operations.

Additionally, we continue to work closely with the FDA to develop a REMS program for the class of ESA products under authority prescribed by the FDAAA. We have submitted a proposed REMS in response to the FDA's requests, although we cannot predict what risk management activities the FDA may require of us, and the components of the REMS could be different for the use of ESAs in the oncology and nephrology indications. A REMS program for our ESA products could have a material adverse impact on the reimbursement, use and sales of our ESA products, 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 of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market and Our sales depend on coverage and reimbursement from third-party payors, and to the extent that access to and reimbursement for our products is reduced, this could negatively impact the utilization of our products.* ) We also continue to work with the FDA to finalize a new protocol for a clinical trial to determine the effects of ESAs on survival and tumor outcomes in anemic patients with metastatic cancer receiving concomitant myelosuppressive chemotherapy. We have submitted an Aranesp® study protocol to the FDA and plan to initiate the study in 2009. The addition of these clinical trials to our pharmacovigilance program and any additional clinical trials required by the FDA could result in substantial additional expense, and their 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 ESA products. (See *Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.* )

Further on March 5, 2008, we announced that the European Commission reached its decision to amend the product labeling for the class of ESAs, including Aranesp®, based on the positive opinion from the CHMP in January 2008, which was consistent with the EMEA's October 23, 2007 press release stipulating a uniform target Hb range for all ESAs of 10 g/dL to 12 g/dL with guidance to avoid sustained Hb levels above 12 g/dL. Following the March 13, 2008 ODAC, we have continued to share additional ESA safety data with the EMEA as it has become available. On May 15, 2008, we and other ESA marketing authorization holders participated in a closed meeting of the SAG-O. The marketing authorization holders were asked to provide an overview on studies that have been initiated or conducted since July 2007, as well as any other new data that can help to elucidate recent issues on the impact of ESAs on tumor progression and survival in cancer patients. These data included previously disclosed interim results from the PREPARE study in neo-adjuvant breast cancer therapy; follow-up data from the GOG-191 study in cervical cancer, which were published in the February 2008 issue of Gynecologic Oncology; and the February 2008 meta-analysis by Bennett et al, which was published in the Journal of the American Medical Association. Scientific Advisory Groups ( SAGs ) are established by the EMEA to deliver answers, on a consultative basis, to specific questions addressed to them by the CHMP. On June 26, 2008 the

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EMA, based upon the CHMP's opinion which took into account the position expressed by the SAG-O, recommended updating the product information for ESAs with a new warning for their use in cancer patients. In July 2008, the EMA requested that further clarity around the product information be provided by regulatory agencies in each European Member State country through the publication of a Dear Healthcare Professional Communication, following which we followed the necessary regulatory procedure to update the Aranesp® product information. In October 2008, we received notification that the Aranesp® product information update was approved by the European Commission. 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, which should take into account the specific clinical context and that factors that should be considered in the assessment should include the type of tumor and its stage, the degree of anemia, life-expectancy, the environment in which the patient is being treated and patient preference. Although we cannot predict what impact the final EU ESA product information will have on our business, the reimbursement, use and sales of Aranesp® in Europe could be materially adversely affected, which would have a material adverse effect on our business and results of operations.

Further, we continue to receive results from meta-analyses or previously initiated clinical trials using ESAs. For example, on September 30, 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. These results were also presented by the Cochrane Haematological Malignancies Group in December at the 2008 ASH Congress. 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. The analyses on all cancer patients were based on 53 previously conducted studies involving 13,933 patients. None of these studies utilized ESAs according to current label guidance. The overall survival results corroborate an earlier review by the Cochrane Collaboration, published in 2006, which is included in the WARNINGS section of the current U.S. PI (HR: 1.08 [95% CI 0.99-1.18]). The ESA treatment arm had increased on-study deaths (HR: 1.17 [95% CI 1.06-1.30]) and decreased overall survival (HR: 1.06 [95% CI 1.00-1.12]) compared to controls. The analyses on patients undergoing chemotherapy, the cancer indication for which ESAs are approved, were based on 38 studies with 10,441 patients. None of these studies utilized ESAs according to current label guidance. The ESA treatment arm had increased on-study deaths (HR: 1.10 [95% CI 0.98-1.24]) and decreased overall survival (HR: 1.04 [95% CI 0.97-1.11]) compared to controls. While neither of these results is statistically significant, they do not exclude the potential for adverse outcomes when ESAs are prescribed according to the current label. The final report on these endpoints is expected in 2009. Additionally, our TREAT study, a large 4,000 patient multi-center, randomized, double-blind, controlled phase 3 trial designed to determine the impact of anemia therapy with Aranesp® on mortality and non-fatal cardiovascular events in patients with CKD, anemia and type 2 diabetes, continues to progress. Although we cannot predict the results of meta-analyses 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 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.

*Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.*

Before we can sell any products, we must conduct clinical trials which demonstrate that our product candidates are safe and effective for use in humans for the indications sought or our existing products are safe and effective for use in humans in new indications sought. Additionally, we may be required to conduct additional trials as a condition of the approval of our label or as a result of perceived or existing safety concerns. The results of these clinical trials are used as the basis to obtain regulatory approval from regulatory authorities such as the FDA. Clinical trials are experiments conducted using our products or product candidates in human patients hav-

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ing the diseases or medical conditions we are trying to address. Conducting clinical trials is a complex, time-consuming and expensive process. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims we are seeking or to support our existing label. The length of time, number of trial sites and patients required for clinical trials vary substantially according to the type, complexity, novelty and intended use of the product candidate or the extent of the safety concerns, post-marketing issues and/or exposure to patients and therefore, we may spend several years and incur substantial expense in completing certain trials. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval, availability of clinical study material and the rate of patient enrollment in clinical trials. Patient enrollment is a function of several factors, including the size and location of the patient population, enrollment criteria and competition with other clinical trials for eligible patients. As such, there may be limited availability of patients who meet the criteria for certain clinical trials. Delays in planned clinical trials can result in increased development costs, delays in regulatory approvals, associated delays in product candidates reaching the market and revisions to existing product labels. In addition, in order to increase the number of patients available for enrollment for our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, India, 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, our clinical trials and corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates altogether 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 (<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.)

Patients may also suffer adverse medical events or side effects in the course of our, our licensees, partners or independent investigator's clinical trials of our products or product candidates that may delay the clinical program, require additional or longer trials to gain approval, prohibit regulatory approval of our product candidates or additional indications for our currently approved products, or may render the product candidate commercially unfeasible or limit our ability to market existing products in certain therapeutic areas or at all. For example, as a result of observing an increased frequency of cholecystitis (inflammation of the gall bladder) in patients treated with our late-stage product candidate motesanib, we delayed our phase 3 trial in first-line NSCLC, which was previously expected to begin in the fourth quarter of 2006, until the second half of 2007. 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. Of course, even if we successfully manage our clinical trials, we may not obtain favorable clinical trial results and may not be able to obtain regulatory approval for new product candidates, product label extensions 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.

In connection with our efforts to improve our cost structure, we refocused our spending on critical R&D and operational priorities and sought greater efficiencies in how we conduct our business, including optimizing ongoing clinical trials and trial initiation. To the extent future sales are negatively affected as a result of additional regulatory and reimbursement developments or other challenges, we may be required to further adjust our R&D investment plans. Such actions could result in delays in obtaining approval or reductions in the number of indications and market potential of our product candidates.

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*Our sales depend on coverage and reimbursement from third-party payors, and to the extent that access to and reimbursement for our products is reduced, this could negatively impact the utilization of our products.*

Sales of all of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payors, including governments and private insurance plans. Generally, in Europe and other countries outside the United States, the government-sponsored healthcare system is the primary payor of healthcare costs of patients. Governments may regulate access to, prices or reimbursement levels of our products to control costs or to affect levels of use of our products. Worldwide use of our products may be affected by these 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. It is possible that applicable statutes, such as the MMA, could be modified or new legislation or regulation introduced in 2009 and later that could include a focus on reducing drug costs and change coverage and reimbursement methodologies for government healthcare programs that could have a significant impact on our business. Although we cannot predict when legislation or regulation affecting reimbursement from third-party payors may be proposed or enacted in the future or the specific effect any such legislation or regulation would have on our business, any such legislation or regulations changing and/or reducing the coverage and reimbursement of our products or the way our products are used or prescribed may cause our sales to decrease and our revenues to decline.

Further, adverse events or results from clinical trials or studies performed by us or by others or from the marketed use of our drugs may expand the safety information in the labeling for our approved products and may negatively impact worldwide reimbursement for our products. For example, on January 14, 2008, CMS issued changes to its Medicare National Coverage Determinations Manual that resulted in the reduced use of ESAs in clinical practice. A more detailed discussion of the Decision Memorandum follows below. (See also *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.* and *Guidelines and recommendations published by various organizations can reduce the use of our products.* )

An increasing focus on cost containment by public and private insurers has resulted, and could result in the future, in lower reimbursement rates for our products. Most patients receiving Aranesp®, Neulasta® and NEUPOGEN® for approved indications are covered by government and/or private payor healthcare programs. Medicare and Medicaid government healthcare programs' payment policies for drugs and biologicals are subject to various laws and regulations. Effective January 1, 2009 in the hospital outpatient setting, our products are reimbursed under a Medicare Part B payment methodology that reimburses each product at 104% of its ASP (sometimes referred to as ASP+4% ). The rate of reimbursement in the hospital outpatient setting has been reduced twice since its inception (with reimbursement rates set at ASP+5% for 2008 and ASP+6% from 2005 to 2007). Effective January 1, 2009, in the physician office setting, Aranesp®, Neulasta® and NEUPOGEN® are reimbursed under a Medicare Part B payment methodology that reimburses each product at ASP+6%. CMS has the regulatory authority to alter or maintain the Medicare payment rates for Part B drugs and biologicals in the future for the hospital outpatient setting. A product's ASP is calculated and reported to CMS on a quarterly basis and 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. For example, the ASP based payment rate for Aranesp® that will be in effect for the second quarter of 2009 will be based in part on certain historical sales and sales incentive data for Aranesp® from January 1, 2008 through December 31, 2008.

In the dialysis setting, our products may also be subject to downward pressure on reimbursement rates. 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 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 monitored and implemented by CMS. Currently, the payment mechanism for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN® and

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Aranesp<sup>®</sup>, is reimbursed by Medicare at ASP+6%. Although we cannot predict the payment levels of EPOGEN<sup>®</sup> in future quarters or the extent to which Medicare payments for dialysis drugs may be modified by future federal regulation or legislation, a decrease in the reimbursement rate for EPOGEN<sup>®</sup> may have a material adverse effect on our business and results of operations. Any changes to the ASP calculations directly affect the Medicare reimbursement for our products administered in the physician clinic setting, dialysis facility and hospital outpatient setting. These calculations are regularly reviewed for completeness and based on such review, and we have revised our reported ASPs to reflect calculation changes both prospectively and retroactively. For example, partially as a result of our methodology changes, our ASP reimbursement rate for EPOGEN<sup>®</sup> was reduced for the third quarter of 2007.

Since April 1, 2006, the Medicare reimbursement for ESAs administered to dialysis patients has been subject to a revised EMP, the Medicare payment review mechanism used by CMS to monitor EPOGEN<sup>®</sup> and Aranesp<sup>®</sup> 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 IUs of EPOGEN<sup>®</sup>, from 500,000 IUs, and to 1,200 mcgs of Aranesp<sup>®</sup>, from 1,500 mcgs. The implementation of the revised EMP and ESA labeling changes led to a decline in EPOGEN<sup>®</sup> sales for the first quarter of 2008 compared to the first quarter of 2007 primarily due to a decline in both overall utilization and as well as average dosing per patient. While this dose decline subsequently stabilized in 2008, it may further fluctuate in the future, which could have a material adverse effect on sales of EPOGEN<sup>®</sup> and our business and results of operations.

On July 15, 2008, the MIPPA became law with 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. The new bundled rate will include dialysis services covered under the current composite rate, as well as all injectable drugs commonly provided during dialysis treatment, and currently billed separately, including ESAs, IV iron, and IV vitamin D, as well as oral equivalent forms of these IV drugs. The bundled reimbursement rate will be phased in over a four year period in equal increments starting in 2011. It is possible that some providers could elect to move to a full Medicare bundled payment in 2011. CMS will also be required to establish a quality incentive program that begins concurrently with bundling in 2011 and which subjects facilities 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. We are in the process of evaluating the potential impact of the new Medicare legislation on our business and at this time cannot predict the impact a bundled payment system for outpatient dialysis might have on sales of EPOGEN<sup>®</sup> or Aranesp<sup>®</sup>.

We face risks relating to the calculation of ASP. ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. MedPAC has recommended that ASP reporting requirements be clarified to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug. Under the current ASP system, we allocate our discounts based on the prices paid for individual drugs, according to the terms of our contracts with physicians and other purchasers, and we believe that the resulting ASPs reflect the transaction prices for individual drugs. Moreover, in the Medicare Physician Fee Schedule Final Rule for 2008, the agency clarified that in the absence of specific guidance, manufacturers may continue to make reasonable assumptions in the calculation of ASP, consistent with the general requirements and the intent of the Medicare statute and regulations and their customary business practices. The agency stated that it will continue to monitor this issue and may provide more specific guidance in the future.

Other initiatives reviewing the coverage or reimbursement of our products, including those related to safety, could result in less extensive coverage or lower reimbursement and could negatively affect sales of some of our marketed products. For example, on March 14, 2007, shortly after the March 9, 2007 FDA labeling changes for all ESAs, CMS announced that the agency had begun reviewing all Medicare policies related to the administration of ESAs in non-renal disease applications as part of a NCA which is generally CMS' first step toward developing a NCD. Generally, an NCD is a national policy statement granting, limiting or excluding Medicare

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coverage or reimbursement for a specific medical item or service. 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 its Decision Memorandum which was substantially altered from the proposed NCD. On January 14, 2008, CMS issued changes to its Medicare NCD Manual, adding the ESA Decision Memorandum, effective for claims with dates of service on and after July 30, 2007 with an implementation date of April 7, 2008. In the Decision Memorandum, CMS 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 this restriction on reimbursement of ESAs in the Decision Memorandum has had and may continue to have a material adverse effect on the use, reimbursement and sales of Aranesp®, and our business and results of operations. Additionally, to our knowledge, although no private payors have fully implemented the Decision Memorandum to date, many private payors have implemented the portions of the restrictions included in the Decision Memorandum that most commonly reflect the prescriber package insert. Further, we believe many healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage. While we cannot fully predict the further impact of the Decision Memorandum on how, or under what circumstances, healthcare providers will prescribe or administer our ESAs, it had a significant impact to our business in 2007 and 2008 and we believe that it may continue to impact us in the future.

In addition, the FDA held a joint meeting of the CRDAC and the DSaRMAC on September 11, 2007 to evaluate 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. 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®. CMS has not announced whether it will proceed to a NCD for ESAs in ESRD or CKD, or for thrombopoiesis stimulating agents, and we cannot predict whether either ESAs in the renal setting or thrombopoiesis stimulating agents 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 proposed in Decision Memorandum for treatment of anemia in oncology with ESAs, would negatively affect use, reduce reimbursement and coverage, negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations.

If, and when, reimbursement rates or availability for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our current or future products, healthcare providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales, which could have a material adverse effect on us and our results of operations. For example, the use of EPOGEN® in the United States in connection with treatment for ESRD is funded primarily by the U.S. federal government. In early 1997, CMS, formerly known as Healthcare Financing Administration ( HCFA ), instituted a reimbursement change for EPOGEN®, which materially and adversely affected our EPOGEN® sales until the policies were revised. In addition, following the update to the ESA labeling and associated revisions in compendia, nearly all Medicare contractors dropped reimbursement for Aranesp® for anemia of cancer. (See *Guidelines and recommendations published by various organizations can reduce the use of our products.* ) Also, we believe the increasing emphasis on cost-containment initiatives in the United States, Europe and other countries has and will continue to put pressure on the price and usage of our products, which may adversely impact product sales. In addition, we believe the new U.S. presidential administration, together with Congress, will shape U.S. healthcare policy in the coming months and years, and we expect that healthcare reform efforts could include long-term changes to coverage and reimbursement that may have a significant impact on our business. Further, when a new therapeutic product is approved, the governmental and/or private coverage and reimbursement for that product is uncertain and a failure to demonstrate clear clinical and/or comparative value associated with the use of a new therapeutic product as compared to existing therapeutic products or practices may result in inadequate or no reimbursement. We cannot predict the availability or amount of reimbursement for our approved products or product candidates, including those at a late stage of development, and current reimbursement policies for marketed products may change at any time. Sales of all our products are and will be affected by government and

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private payor reimbursement policies. Reduction in reimbursement for our products could have a material adverse effect on our product sales and 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.*

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. To date, there has emerged no consistent policy regarding breadth of claims allowed in such companies' patents. 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 prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude or delay commercialization of products. We are currently, and in the future may be, involved in patent litigation. However, 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. For example, on July 25, 2008, we, NPS Pharmaceuticals and Brigham and Women's Hospital, filed a lawsuit against Teva and Barr for infringement of four Sensipar® patents. The lawsuit is based on ANDAs filed by Teva and Barr which seek approval to market generic versions of Sensipar® before expiration of the patents. This lawsuit is described in Note 10, *Contingencies* to the Consolidated Financial Statements. If we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities; required to enter into third-party licenses for the infringed product or technology or 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.

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. We have filed applications for a number of patents and have been granted patents or obtained rights relating to erythropoietin, natural and recombinant G-CSF, darbepoetin alfa, pegfilgrastim, etanercept, cinacalcet, panitumumab, romiplostim and our product candidates. We market our erythropoietin, recombinant G-CSF, darbepoetin alfa, pegfilgrastim, etanercept, cinacalcet, panitumumab and romiplostim products as EPOGEN® (Epoetin alfa), NEUPOGEN® (Filgrastim), Aranesp® (darbepoetin alfa), Neulasta® (pegfilgrastim), Enbrel® (etanercept), Sensipar®/Mimpara® (cinacalcet), Vectibix® (panitumumab) and Nplate® (romiplostim), respectively. With respect to our material patents, we have had a number of G-CSF patent expiries in the United States.

We also have been granted or obtained rights to patents in Europe relating to erythropoietin, G-CSF, pegfilgrastim (pegylated G-CSF), etanercept, darbepoetin alfa, cinacalcet, panitumumab and romiplostim. Our principal European patent relating to erythropoietin expired on December 12, 2004 and our principal European patent relating to G-CSF expired on August 22, 2006. As these patents have expired, some companies have and we believe others may receive approval for and market biosimilar (as they are generally known in the EU) and other products to compete with these products in the EU presenting additional competition to our products. (See *Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do.* )

*We may experience difficulties, delays or unexpected costs and not achieve or maintain anticipated cost savings from our restructuring plan.*

As a result of various regulatory and reimbursement developments that began in 2007 and, in particular those affecting our marketed ESA products, on August 15, 2007, we announced a plan to restructure our world-

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wide 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 the restructuring plan, 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. Through December 31, 2008, we have completed substantially all of these actions and reduced costs in 2008. Our ability to maintain these savings is dependent upon various future developments, some of which are beyond our control. During 2008, we identified certain additional initiatives designed to further assist in improving our cost structure. We may not realize, in full or in part, the anticipated benefits and savings from our recent restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to achieve or maintain all of the resulting savings or benefits to our business or other unforeseen events occur, our business and results of operations may be adversely affected. Further, if we were to experience additional changes to our business or redesign certain processes to achieve increased efficiencies, we may face further restructuring and/or reorganization activities in the future.

In addition, our reduction of staff was completed through a combination of a voluntary transition program and an involuntary reduction in force. In order to be successful and build our framework for future growth, we must continue to execute and deliver on our core business initiatives with fewer human resources and losses of intellectual capital. We must also attract, retain and motivate key employees including highly qualified management, scientific, manufacturing and sales and marketing personnel who are critical to our business. We may not be able to attract, retain or motivate qualified employees in the future and our inability to do so may adversely affect 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 payors, 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 payors. (See *Our sales depend on coverage and reimbursement from third-party payors, and to the extent that access to and reimbursement for our products is reduced, this could negatively impact the utilization of our products.* ) Organizations like these have in the past made recommendations about our products. 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 August 30, 2007, the National Kidney Foundation (the 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 s Anemia Work Group conducted an extensive review of results from 26 new and existing randomized controlled trials, comparing the risks and benefits of a range of Hb therapeutic targets in CKD patients. Based on this review, 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.

On February 2, 2007, following the reported results from our AoC 103 Study, the USP DI Drug Reference Guides removed Aranesp® in the treatment of AoC. Thereafter, Aranesp® use in AoC essentially ceased.

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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*We may not be able to develop commercial products.*

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

the product candidate is not cost effective in light of existing therapeutics

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, we announced that 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. We believe that the safety concerns around our ESAs expressed by the FDA must be addressed to the agency's satisfaction before new indications or expanded labeling of our ESA products will likely be approved.

Further, several of our product candidates have failed or been discontinued at various stages in the product development process, including, but not limited to, Brain Derived Neurotrophic Factor (BDNF), Megakaryocyte Growth and Development Factor (MGDF) and Glial Cell Lined-Derived Neurotrophic Factor (GDNF). For example, in 1997, we announced the failure of BDNF for the treatment of amyotrophic lateral sclerosis, or Lou Gehrig's Disease, because the product candidate, when administered by injection, did not produce acceptable clinical results for a specific use after a phase 3 trial, even though BDNF had progressed successfully through preclinical and earlier clinical trials. In addition, in 1998, we discontinued development of MGDF, a novel platelet growth factor, at the phase 3 trial stage after several people in platelet donation trials developed low platelet counts and neutralizing antibodies. Also, in June 2004, we announced that the phase 2 study of 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 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, in the fall of 2004 we discontinued clinical development of GDNF in patients with advanced Parkinson's disease after several patients in the phase 2 study developed neutralizing antibodies and new preclinical data in rhesus monkeys showed that GDNF caused irreversible damage to the area of the brain critical to movement control and coordination. On February 11, 2005, we confirmed our previous decision to halt clinical trials of GDNF and, as a part of that decision and based on thorough

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scientific review, we also concluded that we will not provide GDNF to the 48 patients who participated in clinical trials that were terminated in the fall of 2004. Of course, there may be other factors that prevent us from marketing a product. We cannot guarantee we will be able to produce or manufacture commercially successful products. (See *Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit*

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*supply of our products and limit our product sales; timing of supply may also be affected by operation of our distribution and logistics centers and providers. ; Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market. and Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected. )*

*Our business may be affected by government investigations or litigation.*

We and certain of our subsidiaries are involved in legal proceedings relating to various patent matters, government investigations, our business operations, government requests for information and other legal proceedings that arise from time to time in the ordinary course of our business. Matters required to be disclosed by us are set forth in Note 10, *Contingencies* to the Consolidated Financial Statements and are updated as required in subsequently filed Form 10-Qs. Litigation is inherently unpredictable, and the outcome can result in excessive verdicts and/or injunctive relief that affects how we operate our business. Consequently, it is possible that we could, in the future, 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.

We have received subpoenas from a number of government entities, including the U.S. Attorney's Offices for the Eastern District of New York and the Western District of Washington, as well as the Attorneys General of New York and New Jersey. The federal subpoenas have been issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (18 U.S.C. 3486), 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. To the extent it is alleged in a proceeding that we are in violation of the various federal and state laws that govern the sales and marketing of its products, then a decision adverse to our interests 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. In addition, as current macroeconomic conditions place increasing fiscal pressure on governments, 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.

*We may be required to defend lawsuits or pay damages for product liability claims.*

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.

*Our revenues may fluctuate and our operating results are subject to fluctuations and these fluctuations could cause financial results to be below expectations and our stock price is volatile, which could adversely affect your investment.*

Our revenues and operating results may fluctuate from period to period for a number of reasons, some of which we cannot control. For example, primarily as a result of various regulatory and reimbursement developments involving ESA products that began in 2007, our anemia product sales, in particular sales of Aranesp®, for 2007 were materially adversely impacted. Even a relatively small revenue shortfall may cause financial results for a period to be below our expectations or projections as some of our operating expenses are fixed in the short term and cannot be reduced within a short period of time to offset reductions in revenue. Further, primarily as a

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result of the various regulatory and reimbursement developments impacting ESA products, on August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure. As of December 31, 2008, we have completed substantially all of the actions initially included in our restructuring plan and have incurred approximately \$887 million in charges. During 2008, we identified certain additional initiatives designed to further assist in improving our cost structure. The estimated cost of these additional initiatives is \$95 million to \$135 million. As a result of these initiatives and certain minor changes in expected costs associated with the actions initially included in our restructuring plan, the amount of total charges currently expected to be incurred in connection with our restructuring plan, including implementation costs, is \$950 million to \$985 million. Our operating results have and may continue to fluctuate and be adversely impacted as a result of these restructuring charges. (See *We may experience difficulties, delays or unexpected costs and not achieve or maintain anticipated cost savings from our restructuring plan.* ) In addition, in the event that the actual restructuring charges exceed our latest estimate, this may cause our operating results for a period to be below our expectations or projections. As a result of the above or other challenges, including further label revisions to our ESAs, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Changes in credit ratings issued by nationally recognized statistical ratings organizations could adversely affect our cost of financing and have an adverse effect on the market price of our securities. Additionally, our stock price, like that of other biotechnology companies, is volatile. For example, in the fifty-two weeks prior to December 31, 2008, the trading price of our common stock has ranged from a high of \$66.51 per share to a low of \$39.16 per share.

Our revenues, operating results and stock price may be affected by a number of factors, such as:

adverse developments regarding the safety or efficacy of our products

changes in the government's or private payors' reimbursement policies, particularly for supportive cancer care products, or prescribing guidelines for our products

current volatility and disruption of the financial markets

evolving medical care in treating cancer requiring less use of supportive cancer care products and/or changes in chemotherapy usage patterns

inability to maintain regulatory approval of marketed products or manufacturing facilities

actual or anticipated clinical trial results of ours or our licensees, partners or independent investigators

business development or licensing activities

product development or other business announcements by us or our competitors

regulatory matters or actions, such as label changes or risk management activities, including a REMS

lower than expected demand for our products or a change in product mix either or both of which may result in less than optimal utilization of our manufacturing facilities and the potential to incur excess capacity or impairment charges

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changes in our product contracting and related pricing strategies

changes in wholesaler buying patterns

increased competition from new or existing products

fluctuations in foreign currency exchange rates

announcements in the scientific and research community

intellectual property and legal matters

actual or anticipated product supply constraints

broader economic, industry and market trends unrelated to our performance

Of course, there may be other factors that affect our revenues, operating results and stock price in any given period. In addition, if our revenues, earnings or other financial results in any period fail to meet the investment community's expectations, there could be an immediate adverse impact on our stock price.

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*Current levels of market volatility are unprecedented and adverse capital and credit market conditions may affect our ability to access cost-effective sources of funding and our investment in marketable securities may be subject to market, interest and credit risk that could reduce their value.*

The capital and credit markets have been experiencing extreme volatility and disruption which, particularly during the latter part of 2008 and the beginning of 2009, has led to uncertainty and liquidity issues for both borrowers and investors. We currently have sufficient cash to repay the \$1.0 billion of our 4.00% notes due in November 2009. 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 future, 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.

We have some exposure to financial institutions which have come under pressure as a result of the current credit crisis. For example, we have historically had 16 financial institutions participate in our \$2.5 billion revolving credit facility including a subsidiary of Lehman Brothers Holdings Inc. (Lehman), which had a \$178 million commitment. Lehman declared bankruptcy on September 15, 2008, and the subsidiary participant in our credit facility subsequently declared bankruptcy on October 5, 2008. Although we have never drawn on our credit facilities and do not currently anticipate any need to do so, we would not anticipate the ability to access this specific commitment provided by Lehman in the future. Additionally, the conversion feature of our 0.125% Convertible Senior Notes due 2011 and our 0.375% Convertible Senior Notes due 2013 are hedged pursuant to transactions entered into with two financial institutions. We have also entered into interest rate swap agreements for certain of our outstanding debt and routinely enter into foreign currency exchange contracts with financial institutions as counterparties. Additional bankruptcies in the financial sector could limit our ability to replace these transactions on favorable terms, or at all, or to manage the risks inherent in our business which could have a material adverse effect on our business and results of operations.

Additionally, we maintain a significant portfolio of fixed-income based 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 seek to mitigate these risks with the help of our investment advisors by generally investing in high quality securities and continuously monitoring the overall risk of our portfolio. To date, we have not realized any material impairments within our investment portfolio.

*The volatility of the current financial markets and the general economic slowdown may magnify certain risks that affect our business.*

Sales of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payors, including governments and private insurance plans. (See *Our sales depend on coverage and reimbursement from third-party payors, and to the extent that access to and reimbursement for our products is reduced, this could negatively impact the utilization of our products.* ) As a result of the volatility of the current financial markets and the general economic slowdown, our third-party payors may delay or be unable to satisfy their reimbursement obligations. A reduction in the availability or extent of reimbursement from government programs, including Medicare and Medicaid, and/or private payor healthcare programs could have a material adverse affect on the sales of our products, our business and results of operations.

In addition, as a result of the volatile financial markets and economic slowdown, 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 changes 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 reductions may affect patients' ability to afford healthcare and/or cause them to forego or postpone treatment to reduce out-of-pocket healthcare costs as a result of increased co-pay or deductible obligations or for other reasons. These changes may result in reduced demand for our products, which could adversely affect our business

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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 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. For example, current markets 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. In addition, 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 rely on single third-party suppliers for some of our raw materials, medical devices and components; if these third-parties fail to supply these items, we may be unable to supply our products.*

Certain raw materials necessary for commercial and clinical manufacturing and formulation of our products are provided by single-source unaffiliated third-party suppliers. Also, certain medical devices and components necessary for 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 that specific sole source and could not be obtained from another supplier unless and until the regulatory agency approved that other supplier.

We would be unable to obtain these raw materials, medical devices or components for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including:

regulatory requirements or action by regulatory agencies or others

adverse financial developments at or affecting the supplier

unexpected demand for or shortage of raw materials, medical devices or components

labor disputes or shortages, including the effects of an avian or pandemic flu outbreak or otherwise

failure to comply with our quality standards which results in quality 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 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, 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 are investigating alternatives to certain biological sources and alternative manufacturing processes that do not require the use of certain 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 drug manufacturing process.

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



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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 biological sources 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.

*Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing of supply may also be affected by operation of our distribution and logistics centers and providers.*

We currently manufacture and market all of our principal products, and we plan to manufacture and market many of our product candidates. Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. (See *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.* )

We currently manufacture our products and product candidates at our manufacturing facilities located in Thousand Oaks and Fremont, California; Boulder and Longmont, Colorado; West Greenwich, Rhode Island; Bothell, Washington and Juncos, Puerto Rico. (See *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.* )

Additionally, 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. (See *We are dependent on third parties for a significant portion of our bulk supply and the formulation, fill and finish of ENBREL.* ) 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 is impacted by many manufacturing variables including:

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 an avian or pandemic flu outbreak

compliance with regulatory requirements

changes in forecasts of future demand

timing and actual number of production runs

production success rates and bulk drug yields

timing and outcome of product quality testing

If we have problems in one or more of these or other manufacturing variables, we may experience delayed shipments, supply constraints, stock-outs and/or recalls of our products. For example, in the second quarter of 2002, the prior co-marketers with respect to ENBREL experienced a brief period where no ENBREL was available to fill new patient prescriptions, primarily due to variation in the expected production yield from BI Pharma. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients,

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physicians may elect to prescribe competing therapeutics instead of our products, and sales of our products will be adversely affected, which could materially and adversely affect our product sales and results of operations.

We manufacture and contract manufacture, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, including European countries, Canada, Australia and Japan. Although we have obtained regulatory approval for our marketed products, these products and 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 adequately prepare to launch a number of our late-stage product candidates, in particular denosumab, we must successfully implement a number of manufacturing projects on schedule, 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. Key manufacturing projects include: (i) construction, qualification and licensure of a new formulation and filling facility at our Puerto Rico site and (ii) expansion and the related qualification and licensure of our existing bulk protein facilities at our Puerto Rico site for the production of our late-stage product candidate, denosumab.

If regulatory authorities determine that we or our third-party contract manufacturers or 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 our third-party contract manufacturers or third-party service providers comply, or indefinitely. Because our third-party contract manufacturers and third-party service providers are subject to FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and service providers may not be available on a timely basis or at all. If we or our third-party contract manufacturers and 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 for any reason, we may experience delayed shipments, supply constraints, stock-outs and/or recalls of our products. If we are unable to manufacture, market and sell our products, our business and results of operations would be materially and adversely affected. 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®, some 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. 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

breakdown, failure or substandard performance of equipment

improper installation or operation of equipment

labor disputes or shortages, including the effects of an avian or pandemic flu outbreak

inability of third-party suppliers to provide raw materials and components



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natural or other disasters, including hurricanes

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

For example, this facility in Puerto Rico 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 in the past. Although these experiences in Puerto Rico have not impacted our ability to supply product in the past, 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 adversely affect our product sales and operating results materially. (See *Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing of supply may also be affected by operation of our distribution and logistics centers and providers.* )

*We are dependent on third parties for a significant portion of our bulk supply and the formulation, fill and finish of ENBREL.*

Under a collaboration and global supply agreement, we and Wyeth share the total worldwide bulk supply of ENBREL produced by our Rhode Island manufacturing facility, BI Pharma's manufacturing facility in Germany and Wyeth's manufacturing facility in Ireland. (See also *We face uncertainties related to the recently announced Wyeth / Pfizer merger.* ) Our ENBREL supply forecasts rely on certain assumptions of how much ENBREL each of these manufacturing facilities is expected to produce. If any of these manufacturing facilities are unable to produce in accordance with our or Wyeth's expectations, the worldwide supply of ENBREL could be adversely affected materially. In such cases, we may be required to allocate supply for Wyeth's benefit. To the extent that there is a shortfall in worldwide production, our supply of ENBREL could be adversely affected. Additionally, the costs associated with a shortfall or failure in production of ENBREL would be borne by both parties.

We currently produce a substantial portion of the annual ENBREL supply at our Rhode Island manufacturing facility. However, we also depend on third parties for a significant portion of our ENBREL bulk supply as well as for some of the formulation, fill and finish of ENBREL that we manufacture. BI Pharma is our third-party contract manufacturer of ENBREL bulk drug; accordingly, our U.S. and Canadian supply of ENBREL is currently significantly dependent on BI Pharma's production schedule for ENBREL. We would be unable to produce ENBREL in sufficient quantities to substantially offset shortages in BI Pharma's scheduled production if BI Pharma or other third-party contract manufacturers used for the formulation, fill and finish of ENBREL bulk drug were to cease or interrupt production or services or otherwise fail to supply materials, products or services to us for any reason, including labor shortages or disputes, regulatory requirements or action or contamination of product lots or product recalls.

For example, in the second quarter of 2002, the prior co-marketers with respect to ENBREL experienced a brief period where no ENBREL was available to fill new patient prescriptions, primarily due to variation in the expected production yield from BI Pharma. We cannot guarantee that an alternative third-party contract manufacturer would be available on a timely basis or at all. This in turn could materially reduce our ability to satisfy demand for ENBREL, which could materially and adversely affect our operating results.

Among the factors that could affect our actual supply of ENBREL at any time include, without limitation, BI Pharma's and our Rhode Island facility's bulk drug production scheduling. For example, BI Pharma does not produce ENBREL continuously; rather, it produces the bulk drug substance through a series of periodic campaigns throughout the year. Our Rhode Island manufacturing facility is currently dedicated to ENBREL production. The amount of commercial inventory available to us at any time depends on a variety of factors, including the timing and actual number of BI Pharma's production runs, the actual number of runs at our Rhode Island manufacturing facility, and, for either the Rhode Island or BI Pharma facilities, the level of production yields and success rates, the timing and outcome of product quality testing and the amount of formulation, fill and finish capacity. We are also dependent on third-parties for some formulation, fill and finish of ENBREL bulk

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drug substance manufactured at our Rhode Island facility. If third-party formulation, fill and finish manufacturers are unable to provide sufficient capacity or are otherwise unable to provide services to us, the supply of ENBREL could be adversely affected materially.

*Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do.*

We operate in a highly competitive environment. Our products compete with other products or treatments for diseases for which our products may be indicated. For example, ENBREL competes in certain circumstances with products marketed by J&J, Abbott, Biogen, Barr, Genentech, BMS, Novartis and Sanofi-Aventis and others, as well as the generic drug methotrexate, and may face competition from other potential therapies being developed, including J&J's CNTO 1275 (ustekinumab) and CNTO 148 (golimumab), Roche's Actemra (tocilizumab) and UCB's Cimzia (PEGylated anti-TNF). Additionally, in the first quarter of 2008 Abbott received approval from the FDA to market HUMIRA® as a treatment for adult patients with moderate to severe chronic plaque psoriasis and HUMIRA® now competes with ENBREL in both the rheumatology and dermatology segments and ENBREL has experienced and continues to experience share loss to competitors.

The following table reflects companies and their currently marketed products that primarily compete with Aranesp® in the United States and Europe in the supportive cancer care and nephrology segments, unless otherwise indicated:

| Territory | Competitor Marketed Product                                                            | Competitor                   |
|-----------|----------------------------------------------------------------------------------------|------------------------------|
| U.S.      | PROCRIT® <sup>(1)</sup>                                                                | J&J                          |
| Europe    | EPREX®/ERYPO®                                                                          | Janssen-Cilag <sup>(2)</sup> |
| Europe    | NeoRecormon®                                                                           | Roche                        |
| Europe    | Retacrit <sup>(3)</sup> /Silapo® <sup>(3)</sup>                                        | Hospira/Stada                |
| Europe    | Binocrit® <sup>(3)</sup> /Epoetin alfa Hexal® <sup>(3)</sup> /Abseamed® <sup>(3)</sup> | Sandoz/Hexal/Medice          |
| Europe    | MIRCERA® <sup>(4)</sup>                                                                | Roche                        |
| Europe    | Dynepo® <sup>(5)</sup>                                                                 | Shire                        |

(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.

(5) Shire announced in the second quarter of 2008 that it had decided to stop the commercialization of Dynepo®.

In addition to competition from the above-noted marketed products, a number of companies are developing products that could potentially compete with Aranesp® and/or EPOGEN® in the future. Affymax and Takeda are co-developing Hematide, an ESA for the treatment of anemia in renal patients. FibroGen 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. Ratiopharm is developing a biosimilar ESA, EpoTheta, expected to launch in the EU in 2009. Additionally in December 2008, Merck announced the formation of a new biotech division, Merck Bioventures, which is developing a pegylated ESA (MK-2578), which they have announced they expect to launch in 2012. Further, if our currently marketed products are approved for new uses, or if we sell new products, or our competitors get new or expanded indications, we may face new, additional competition that we do not face today. Further, adverse clinical developments for our current products could limit our ability to compete. (See *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.* ) 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.

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Our principal European patent relating to erythropoietin expired on December 12, 2004 and our principal European patent relating to G-CSF expired on August 22, 2006. As these patents have expired, some companies have and other companies may receive approval for and market biosimilar or other products to compete with our products in the EU, presenting additional competition to our products. For example, in September 2008, the European Commission issued marketing authorizations for the first G-CSF biosimilar products to Ratiopharm's Ratiograstim®/Filgrastim Ratiopharm®, CT Arzneimittel's Biograstim® and Teva's Tevagrastim®. Ratiopharm launched its G-CSF biosimilar product, Ratiograstim®, in the United Kingdom and Germany in October 2008 and in the Netherlands in January 2009, and is expected to launch it in other European markets in 2009. Teva has stated that it would begin marketing Tevagrastim throughout Europe in 2009. In February 2009, the European Commission issued marketing authorizations for two additional G-CSF biosimilar products to Sandoz's Zarzio® and Hexal's Filgrastim Hexal®. If these companies' launch plans are successful, there may be as many as six G-CSF biosimilars available in 2009 on the European market. These G-CSF biosimilar products would compete with Neulasta® and NEUPOGEN®. We cannot predict to what extent the entry of biosimilar products or other competing products will impact future Aranesp®, Neulasta® or NEUPOGEN® 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 2006, the EMEA 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, which guidance recommends that applicants seeking approval of such biosimilar products conduct fairly extensive pharmacodynamic, toxicological, clinical safety studies and a pharmacovigilance program. In the United States, there currently is no legal approval pathway for the abbreviated approval of BLAs for biosimilars. A number of events would need to occur before these products could enter the market, including passage of legislation by Congress to create a new approval pathway and, depending on the specific provisions of any such legislation, promulgation of associated regulations or guidance by the FDA. In 2007, several members of Congress expressed interest in the issue, a number of bills were introduced, the House of Representatives and the Senate held hearings on biosimilars, and the Senate Committee on HELP voted on legislation in June 2007. In 2008, additional legislation was introduced in the House of Representatives, but no final legislation was considered or passed in either chamber of Congress, with all introduced bills expiring at the end of the Congressional session (end of the year). Given the continuing interest of Congress in the issue and in healthcare reform generally, it is likely that legislation on biosimilars will be introduced in 2009 and possibly passed into law. The new U.S. presidential administration has also expressed an interest in passing legislation regarding biosimilars. It is unknown what type of regulatory framework, what legal provisions, and what timeframes for issuance of regulations or guidance any final legislation would contain. Until such legislation is created, we cannot predict when biosimilars could appear in the United States.

Certain of our competitors, including biotechnology and pharmaceutical companies, market products or 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. In the future, we expect that our products will compete with new drugs currently in development, drugs approved for other indications that may be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. As with Merck's recent announcement, pharmaceutical companies and generic manufacturers that have traditionally developed and marketed small molecule pharmaceutical products may elect to expand into the biotechnology field, and some of these companies may seek to develop biosimilar products to compete with our products. Large pharmaceutical corporations may have greater clinical, research, regulatory, manufacturing, marketing, financial and human 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. Business combinations among our competitors may also increase competition and the resources available to our competitors.

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*We must continue to build the framework for our future growth, and if we fail to execute on our initiatives our business could be adversely affected.*

As a result of developments in 2007 and, in particular the regulatory and reimbursement changes to our ESA products, 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. We face a number of risks, some of which we cannot completely control. For example:

we will need to manage complexities associated with a large and geographically diverse organization

we will need to manage and execute large, complex and global clinical trials

we will need to significantly expand our sales and marketing resources to launch our late-stage product candidate, denosumab

we will need to accurately anticipate demand for the products we manufacture and maintain adequate manufacturing capacity for both commercial and clinical supply

we have implemented a new global enterprise resource planning ( ERP ) system to support our increasing complex business and business processes and need to ensure that the new system continues to operate without disruptions to our operations

Of course, there may be other risks and we cannot guarantee that we will be able to successfully manage these or other risks. If we fail to execute on our initiatives in these ways or others, such failure could result in a material adverse effect on our business and results of operations.

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

The substantial majority of our U.S. product sales are made to three pharmaceutical product wholesaler distributors, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation. These distributors, in turn, sell our products to their customers, which include physicians or their clinics, dialysis centers, hospitals and pharmacies. One of these products, EPOGEN®, is primarily sold to free-standing dialysis clinics, which have experienced significant consolidation. Two organizations, DaVita Inc. and Fresenius own or manage a large number of the outpatient dialysis facilities located in the United States and account for a significant 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, 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' 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.

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. The results of these developments may have a material adverse effect on our product sales and results of operations.

*Our marketing of ENBREL is dependent in part upon Wyeth.*

Under a co-promotion agreement, we and Wyeth market and sell ENBREL in the United States and Canada. A management committee comprised of an equal number of representatives from us and Wyeth 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 team, with equal representation from us and Wyeth, 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 Wyeth fails to effectively deliver on its marketing commitments to us or if we and Wyeth fail to coordinate our efforts effectively, our sales of ENBREL may be adversely affected materially. (See also *We face uncertainties related to the recently announced Wyeth/Pfizer merger.* )



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*We face uncertainties related to the recently announced Wyeth/Pfizer merger.*

We are party to a number of agreements with Wyeth relating to the manufacturing, marketing and selling of ENBREL, including a co-promotion agreement and a global supply agreement. On January 26, 2009, Wyeth and Pfizer announced that they have entered into a definitive merger agreement under which Pfizer will acquire Wyeth in a cash-and-stock transaction approved by the boards of directors of both companies. Wyeth and Pfizer stated that the transaction is subject to a number of closing conditions, including the approval of Wyeth's stockholders. While our agreements with Wyeth do not include a change of control provision, if the acquisition transaction is completed, our relationship with Wyeth may be affected in ways we do not anticipate, including changes in Wyeth/Pfizer management, strategy or otherwise.

*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 of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market. and Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing of supply may also be affected by operation of our distribution and logistics centers and providers.* ) 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.

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**Item 1B. UNRESOLVED STAFF COMMENTS**

None.

**Item 2. PROPERTIES**

The following table summarizes our significant properties and their primary functions as of December 31, 2008. For additional information regarding manufacturing initiatives see *Item 1. Business Manufacturing, Distribution and Raw Materials*.

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In addition to these properties, 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; Cork, Ireland 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 have been closed as part of our restructuring plan as further described in Note 2, *Restructuring* to the Consolidated Financial Statements.

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. There are no material encumbrances on our properties. (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 third-party suppliers for some of our raw materials, medical devices and components; if these third-parties fail to supply these items, we may be unable to supply our products.* and *Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing of supply may also be affected by operation of our distribution and logistics centers and providers.* )

### **Item 3. LEGAL PROCEEDINGS**

Certain of our legal proceedings in which we are involved are discussed in Note 10, *Contingences* to our Consolidated Financial Statements in our 2008 Form 10-K and are hereby incorporated by reference.

### **Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of our security holders during the last quarter of our fiscal year ended December 31, 2008.

**Table of Contents****PART II****Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES***Common stock*

Our common stock trades on The NASDAQ Stock Market under the symbol AMGN. As of February 13, 2009, there were approximately 11,392 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:

|                                      | <b>High</b> | <b>Low</b> |
|--------------------------------------|-------------|------------|
| <b>Year ended December 31, 2008:</b> |             |            |
| 4th Quarter                          | \$ 61.55    | \$ 47.76   |
| 3rd Quarter                          | 65.89       | 48.64      |
| 2nd Quarter                          | 47.16       | 41.49      |
| 1st Quarter                          | 48.14       | 39.97      |
| <b>Year ended December 31, 2007:</b> |             |            |
| 4th Quarter                          | \$ 58.17    | \$ 46.44   |
| 3rd Quarter                          | 57.16       | 49.01      |
| 2nd Quarter                          | 65.10       | 53.68      |
| 1st Quarter                          | 75.85       | 55.72      |

**Table of Contents***Performance graph*

The chart set forth below shows the value of an investment of \$100 on December 31, 2003 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.

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

|                           | 12/31/2003 | 12/31/2004 | 12/31/2005 | 12/31/2006 | 12/31/2007 | 12/31/2008 |
|---------------------------|------------|------------|------------|------------|------------|------------|
| Amgen (AMGN)              | \$ 100.00  | \$ 103.82  | \$ 127.63  | \$ 110.55  | \$ 75.16   | \$ 93.46   |
| Amex Biotech (BTK)        | \$ 100.00  | \$ 138.93  | \$ 138.93  | \$ 153.90  | \$ 160.48  | \$ 132.05  |
| Amex Pharmaceutical (DRG) | \$ 100.00  | \$ 96.44   | \$ 99.85   | \$ 110.43  | \$ 111.55  | \$ 93.60   |
| S&P 500 (SPX)             | \$ 100.00  | \$ 110.74  | \$ 116.09  | \$ 134.21  | \$ 141.57  | \$ 89.82   |

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

**Table of Contents***Stock repurchase program*

Repurchases under our stock repurchase program reflect, in part, our confidence in the long-term value of our common stock. Additionally, we believe 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, 2008, we had one outstanding stock repurchase program. A summary of our repurchase activity for the three months ended December 31, 2008 is as follows:

|            |             | <b>Total<br/>Number of<br/>Shares<br/>Purchased</b> | <b>Average<br/>Price Paid<br/>per Share</b> | <b>Total Number<br/>of Shares<br/>Purchased as<br/>Part of<br/>Publicly<br/>Announced<br/>Programs</b> | <b>Maximum \$<br/>Value that May<br/>Yet Be Purchased<br/>Under the<br/>Programs<sup>(1)</sup></b> |
|------------|-------------|-----------------------------------------------------|---------------------------------------------|--------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| October 1  | October 31  |                                                     | \$                                          |                                                                                                        | \$ 4,871,328,709                                                                                   |
| November 1 | November 30 | 3,750,662                                           | 53.33                                       | 3,750,259                                                                                              | 4,671,318,474                                                                                      |
| December 1 | December 31 | 8,845,384                                           | 56.53                                       | 8,845,384                                                                                              | 4,171,328,747                                                                                      |
|            |             | 12,596,046 <sup>(2)</sup>                           | 55.57                                       | 12,595,643 <sup>(2)</sup>                                                                              |                                                                                                    |

<sup>(1)</sup> In July 2007, the Board of Directors authorized us to repurchase up to \$5.0 billion of our common stock. As of December 31, 2008, \$4.2 billion was available for stock repurchases under our stock repurchase program.

<sup>(2)</sup> The difference between total number of shares purchased and the total number of shares purchased as part of publicly announced program is due to shares of common stock withheld by us for the payment of taxes upon vesting of certain employees' restricted stock.

**Table of Contents****Item 6. SELECTED FINANCIAL DATA**

| Consolidated Statement of Income Data:                                              | 2008      | Years ended December 31, |           |           |                                      | 2004     |
|-------------------------------------------------------------------------------------|-----------|--------------------------|-----------|-----------|--------------------------------------|----------|
|                                                                                     |           | 2007                     | 2006      | 2005      | (In millions, except per share data) |          |
| Revenues:                                                                           |           |                          |           |           |                                      |          |
| Product sales                                                                       | \$ 14,687 | \$ 14,311                | \$ 13,858 | \$ 12,022 |                                      | \$ 9,977 |
| Other revenues                                                                      | 316       | 460                      | 410       | 408       |                                      | 573      |
| Total revenues                                                                      | 15,003    | 14,771                   | 14,268    | 12,430    |                                      | 10,550   |
| Operating expenses <sup>(1)(2)</sup> :                                              |           |                          |           |           |                                      |          |
| Cost of sales (excludes amortization of acquired intangible assets presented below) | 2,296     | 2,548                    | 2,095     | 2,082     |                                      | 1,731    |
| Research and development <sup>(3)</sup>                                             | 3,030     | 3,266                    | 3,366     | 2,314     |                                      | 2,028    |
| Selling, general and administrative                                                 | 3,789     | 3,361                    | 3,366     | 2,790     |                                      | 2,556    |
| Amortization of acquired intangible assets <sup>(4)</sup>                           | 294       | 298                      | 370       | 347       |                                      | 333      |
| Write-off of acquired in-process research and development <sup>(5)</sup>            |           | 590                      | 1,231     |           |                                      | 554      |
| Other charges <sup>(6)</sup>                                                        | 380       | 728                      |           | 49        |                                      |          |
| Net income                                                                          | 4,196     | 3,166                    | 2,950     | 3,674     |                                      | 2,363    |
| Diluted earnings per share                                                          | 3.90      | 2.82                     | 2.48      | 2.93      |                                      | 1.81     |
| Cash dividends declared per share                                                   |           |                          |           |           |                                      |          |

| Consolidated Balance Sheet Data:            | 2008      | 2007      | At December 31, |           |               | 2004      |
|---------------------------------------------|-----------|-----------|-----------------|-----------|---------------|-----------|
|                                             |           |           | 2006            | 2005      | (In millions) |           |
| Total assets <sup>(2)</sup>                 | \$ 36,443 | \$ 34,639 | \$ 33,788       | \$ 29,297 |               | \$ 29,221 |
| Total debt <sup>(7)(8)(9)(10)(11)</sup>     | 10,176    | 11,177    | 9,012           | 3,957     |               | 3,937     |
| Stockholders' equity <sup>(9)(10)(12)</sup> | 20,386    | 17,869    | 18,964          | 20,451    |               | 19,705    |

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-Ks 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 2008 and 2007, we incurred restructuring charges of \$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 (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) for a purchase price of approximately \$1.5 billion. Included in operating expenses are acquisition-related charges of \$1 million, \$37 million, \$41 million, \$12 million and \$53 million, in 2008, 2007, 2006, 2005 and 2004, respectively. Acquisition charges, net of tax, for the three years ended December 31, 2008 were \$1 million, \$22 million and \$26 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 R&D expenses for 2008, 2007 and 2006 is the non-cash amortization of acquired R&D technology rights of \$70 million (\$44 million, net of tax), \$71 million (\$44 million, net of tax) and \$48 million (\$30 million, net of tax), respectively.
- (4) Primarily represents the non-cash amortization of acquired product technology rights, primarily ENBREL, related to the Immunex acquisition. Amortization charges, net of tax, for the three years ended December 31, 2008 were \$183 million, \$185 million and \$200 million, respectively.
- (5) As part of the accounting for the acquisitions of Alantox and Ilypsa in 2007, Avidia and Abgenix in 2006 and Tularik in 2004, we recorded charges to write-off acquired in-process R&D ( IPR&D ) of \$270 million and \$320 million in 2007, respectively, \$130 million and \$1.1 billion in 2006, respectively, and \$554 million in 2004. 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.
- (6) 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 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 2008 and 2007, primarily relate to restructuring charges (see Note 2, *Restructuring* to the Consolidated Financial Statements).
- (7) 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 ).
- (8) In 2008, we repaid our \$2.0 billion of floating rate notes.
- (9) 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.
- (10) In February 2006, we issued \$2.5 billion principal amount of convertible notes due in 2011 and \$2.5 billion principal amount of convertible notes due in 2013. 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.
- (11) 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.
- (12) Throughout the five years ended December 31, 2008, we have had share repurchase programs authorized by the Board of Directors through which we have repurchased \$2.3 billion, \$5.1 billion, \$5.0 billion, \$4.4 billion and \$4.1 billion of Amgen common stock in 2008, 2007, 2006, 2005 and 2004, respectively.

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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, 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 the business of Amgen. MD&A is provided as a supplement to, and should be read in conjunction with, our consolidated financial statements and accompanying notes.

We are a global biotechnology company that discovers, develops, manufactures and markets human therapeutics based on advances in cellular and molecular biology. Our mission is to serve patients. As a science-based, patient-focused organization, we discover and develop innovative therapies to treat grievous illness. We operate in one business segment—human therapeutics. Therefore, our results of operations are discussed on a consolidated basis.

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 Wyeth in the United States and Canada. Our international product sales consist principally of European sales of Aranesp® and Neulasta®/NEUPOGEN®. For additional information about our principal products, their approved indications and where they are marketed, see *Item 1. Business—Marketed Products and Selected Product Candidates*.

We operate in a highly regulated industry and various U.S. and foreign regulatory bodies have substantial authority over how we conduct our business in those countries. Government authorities in the United States and in other countries regulate the manufacturing and marketing of our products and our ongoing R&D activities. (See *Government Regulation*.) For example, prior to obtaining regulatory approval to market a product, we must conduct extensive clinical studies designed to establish the safety and effectiveness of the product candidate for use in humans in the indications sought. Furthermore, in order to maintain regulatory approval to market a product, we may be required to conduct further clinical trials and to provide additional information on safety and effectiveness. 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 or

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additional safety-related requirements. Safety signals, trends, adverse events or results from clinical trials, studies or meta-analyses performed by us or by others (including our licensees or independent investigators) or from the marketed use of our products may expand safety labeling, restrict the use for our approved products or may result in additional regulatory requirements, such as requiring risk management activities, including a REMS, and/or additional or more extensive clinical trials as part of PMCs or a pharmacovigilance program. (See *Item 1. Business Key Developments* and *Item 1. Business Postmarketing Safety Activities*.)

Most patients receiving our products are covered by either government and/or private payor healthcare programs. The reimbursement environment is evolving with greater emphasis on cost containment. For example, we believe that the new U.S. presidential administration, together with Congress, will shape U.S. healthcare policy in the coming months and years, and we expect that healthcare reform efforts could include long-term changes to coverage and reimbursement that may have a significant impact on our business. Furthermore, due to the increasing expectations and demands of healthcare payors, we believe that we and others in our industry will be under increased pressure to further demonstrate the efficacy and economic value of our products. Therefore, sales of our products are and will continue to be affected by the availability and extent of reimbursement from third-party payors, including government and private insurance plans and administration of those programs. 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 providers or patients in response to ongoing initiatives to reduce or reallocate healthcare expenditures. Further, safety signals, trends, adverse events or results from clinical trials, studies or meta-analyses or from the marketed use of our products may negatively impact worldwide reimbursement for our products. For additional information on reimbursement and its impact on our business, see *Item 1. Business Reimbursement*.

For the year ended December 31, 2008, our total revenues were \$15.0 billion and net income was \$4.2 billion, or \$3.90 per share on a diluted basis. In addition to the negative impact of the regulatory and reimbursement developments on sales of our ESA products, as discussed below, our results of operations for the year ended December 31, 2008 were negatively impacted by charges of \$288 million for legal settlements and \$148 million in connection with our previously announced restructuring plan.

As of December 31, 2008, cash, cash equivalents and marketable securities were \$9.6 billion, of which approximately \$8.8 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 the United States, we would be required to pay additional U.S. and state income taxes at the applicable marginal tax rates. Our total debt outstanding was \$10.2 billion as of December 31, 2008, of which \$1.0 billion is due in November 2009. Our cash flow from operations was \$6.0 billion for the year ended December 31, 2008.

Our worldwide product sales for the year ended December 31, 2008 were \$14.7 billion representing an increase of \$376 million, or 3%, over product sales for the year ended December 31, 2007. This increase reflects growth primarily in ENBREL and Neulasta®/NEUPOGEN® sales significantly offset by a decline in U.S. Aranesp® sales. Product sales in the United States for the year ended December 31, 2008 totaled \$11.5 billion and were relatively unchanged from 2007 as the decline in Aranesp® sales, in particular in the supportive cancer care setting, was offset by the overall growth in our other products. The decline in sales of Aranesp® reflects a decrease in demand resulting from various regulatory and reimbursement developments which principally occurred in the second half of 2007, additional product label changes in 2008 and, to a lesser extent, loss of segment share as discussed below.

International product sales totaled \$3.2 billion, reflecting an increase of 13% over 2007. International product sales comprised 22% of total product sales in 2008 compared to 20% in 2007 and consisted principally of European sales of Aranesp® and Neulasta®/NEUPOGEN®. Growth in international product sales for the year ended December 31, 2008 was principally driven by favorable foreign currency exchange rate changes, which totaled \$213 million for the year, and sales of Neulasta®/NEUPOGEN®. Excluding the impact of foreign currency exchange rate changes for the year ended December 31, 2008, worldwide product sales increased 1% and international product sales increased 5%.

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Beginning in late 2008 and continuing into 2009, foreign currency rates have also been experiencing extreme volatility. Changes in foreign currency rates result in increases or decreases in our reported international product sales. However, the benefit or detriment of any resulting increases or decreases that movements in foreign currency exchange rates have on our international product sales are largely offset by corresponding increases or decreases in our international operating expenses and as a result of 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.

As discussed in more detail in *Item 1. Business Key Developments*, certain of our products, principally our marketed ESA products, have experienced a number of regulatory and reimbursement challenges, including safety-related revisions to product labels and the loss of or significant restrictions on reimbursement. The developments with respect to our marketed ESA products have had a material adverse impact on Aranesp® sales, in particular, in the U.S. supportive cancer care setting. Furthermore, our ESA products will continue to face future challenges. For example, in response to the FDA's request, we have submitted a proposed REMS for the class of ESA products. We believe that a REMS program for our ESA products could have a material adverse impact on the future sales of Aranesp®, especially in the U.S. supportive cancer care setting. Additionally, future Aranesp® sales could also be materially adversely impacted by further changes in reimbursement, including as a result of future regulatory developments. In addition, certain of our marketed products are also under increased competitive pressures, including from biosimilar and other products in Europe, which compete or are expected to compete with Aranesp®, Neulasta® and NEUPOGEN®, as well as our marketed products in the United States, including ENBREL.

In addition, capital and credit markets have been experiencing extreme volatility and disruption, particularly during the latter part of 2008 and the beginning of 2009. We are working to manage our business effectively despite the unprecedented conditions in the financial markets both in the United States and around the world. To date, these macro economic challenges have not affected us to a large degree. The extent and/or the duration of any potential adverse economic impact that such financial disruption may have on our third-party payors, including governments and private insurance plans, wholesale distributors, customers, service providers and suppliers is unclear. However, it may result in reduced demand for our products. (See *Item 1A. Risk Factors The volatility of the current financial markets and the general economic slowdown may magnify certain risks that affect our business.* )

As a result of the challenges facing certain of our products and, in particular, the regulatory and reimbursement developments involving our marketed ESA products that began in 2007 and their resulting impact on our operations, 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. Key components of our restructuring plan initially included: (i) worldwide staff reductions aggregating approximately 2,500 positions, (ii) rationalization of our worldwide network of manufacturing facilities in order to gain cost efficiencies while continuing to meet future commercial and clinical demand for our products and product candidates 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. Through December 31, 2008, we have completed substantially all of the actions initially included in our restructuring plan, including the divestiture of certain less significant marketed products discussed below. During 2008, 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. The estimated cost of these additional initiatives is \$95 million to \$135 million. As a result of these additional initiatives and certain minor changes in the expected costs for the actions initially included in our restructuring plan, the total charges currently expected to be incurred in connection with our restructuring plan, including related implementation costs, has been increased to \$950 million to \$985 million, as compared to our prior estimate of \$775 million to \$825 million as of December 31, 2007. Through December 31, 2008 we have incurred \$887 million of these costs and estimate that all remaining amounts will be incurred through 2009. Such cost estimates and amounts incurred are net of amounts recovered from our ENBREL co-promotion partner, Wyeth.

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In September 2008, we entered into an agreement with Biovitrum whereby they acquired from us the marketed biologic therapeutic products Kepivance® (palifermin) and Stemgen® (ancestim), and also obtained from us a worldwide exclusive license to Kineret® (anakinra) for its current approved indication. In connection with the disposal of these less significant marketed products, we incurred a \$10 million loss. For the year ended December 31, 2008, worldwide product sales for these marketed products were approximately \$70 million.

There are many factors that affect us and our industry in general, including, among others, those relating to increased complexity and cost of R&D due, in part, to greater scrutiny of clinical trials with respect to safety which may lead to fewer treatments being approved by the FDA or other regulatory bodies and/or safety-related label changes for approved products; increasingly intense competition for marketed products and product candidates; reimbursement changes; healthcare provider prescribing behavior, regulatory or private healthcare organization medical guidelines and reimbursement practices; complex and expanding regulatory requirements; and intellectual property protection. (See *Item 1. Business* and *Item 1A. Risk Factors* for further information on these economic and industry-wide factors and their impact and potential impact on our business.)

## Results of Operations

### Product sales

For the years ended December 31, 2008, 2007 and 2006, worldwide product sales and total product sales by geographic region were as follows (dollar amounts in millions):

|                            | 2008             | Change     | 2007             | Change     | 2006             |
|----------------------------|------------------|------------|------------------|------------|------------------|
| Aranesp®                   | \$ 3,137         | (13)%      | \$ 3,614         | (12)%      | \$ 4,121         |
| EPOGEN®                    | 2,456            | (1)%       | 2,489            | (1)%       | 2,511            |
| Neulasta®/NEUPOGEN®        | 4,659            | 9%         | 4,277            | 9%         | 3,923            |
| ENBREL                     | 3,598            | 11%        | 3,230            | 12%        | 2,879            |
| Sensipar®                  | 597              | 29%        | 463              | 44%        | 321              |
| Other                      | 240              | 1%         | 238              | 131%       | 103              |
| <b>Total product sales</b> | <b>\$ 14,687</b> | <b>3%</b>  | <b>\$ 14,311</b> | <b>3%</b>  | <b>\$ 13,858</b> |
| <b>Total U.S.</b>          | <b>\$ 11,460</b> | <b>0%</b>  | <b>\$ 11,443</b> | <b>0%</b>  | <b>\$ 11,397</b> |
| <b>Total International</b> | <b>3,227</b>     | <b>13%</b> | <b>2,868</b>     | <b>17%</b> | <b>2,461</b>     |
| <b>Total product sales</b> | <b>\$ 14,687</b> | <b>3%</b>  | <b>\$ 14,311</b> | <b>3%</b>  | <b>\$ 13,858</b> |

Product sales are influenced by a number of factors, 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, general economic conditions, new product launches and indications, competitive products, product supply and acquisitions. (See *Item 1. Business* *Marketed Products and Selected Product Candidates* for a discussion of our principal products and their approved indications.)

Total product sales for the year ended December 31, 2008 increased 3%. This increase reflects growth primarily in ENBREL and Neulasta®/NEUPOGEN® sales significantly offset by a decline in U.S. Aranesp® sales. Product sales in the United States for the year ended December 31, 2008 totaled \$11.5 billion and were relatively unchanged from 2007 as the decline in Aranesp® sales was offset by the overall growth in other products. International product sales for the year ended December 31, 2008 totaled \$3.2 billion reflecting an increase of 13% over 2007. International product sales for the year ended December 31, 2008 reflect favorable foreign currency exchange rate changes of \$213 million. Excluding the impact of foreign currency exchange rate changes for the year ended December 31, 2008, total product sales increased 1% and international product sales increased 5%.

**Table of Contents***Aranesp*<sup>®</sup>

For the years ended December 31, 2008, 2007 and 2006, total Aranesp<sup>®</sup> sales by geographic region were as follows (dollar amounts in millions):

|                                    | 2008            | Change       | 2007            | Change       | 2006            |
|------------------------------------|-----------------|--------------|-----------------|--------------|-----------------|
| Aranesp <sup>®</sup> U.S.          | \$ 1,651        | (23)%        | \$ 2,154        | (23)%        | \$ 2,790        |
| Aranesp <sup>®</sup> International | 1,486           | 2%           | 1,460           | 10%          | 1,331           |
| <b>Total Aranesp<sup>®</sup></b>   | <b>\$ 3,137</b> | <b>(13)%</b> | <b>\$ 3,614</b> | <b>(12)%</b> | <b>\$ 4,121</b> |

The decrease in U.S. Aranesp<sup>®</sup> 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<sup>®</sup> 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, discussed in more detail in *Item 1. Business Key Developments*, include (i) the loss of Aranesp<sup>®</sup> for use in the treatment of AoC in 2007 (ii) the March 9, 2007, November 8, 2007, March 7, 2008 and August 6, 2008 product safety-related label changes in the United States, and (iii) the CMS Decision Memorandum issued in July 2007, which significantly restricted Medicare reimbursement for use of Aranesp<sup>®</sup> in CIA and which we believe has also negatively impacted Aranesp<sup>®</sup> use in CIA for patients covered by private insurance plans.

The increase in international Aranesp<sup>®</sup> sales for the year ended December 31, 2008 is 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<sup>®</sup> sales decreased 5%. This decrease reflects dosing conservatism in the oncology segment and pricing pressures across all ESAs in Europe, which has resulted in an overall decrease in the ESA market. Through December 31, 2008, biosimilars and other recently introduced marketed products in Europe have not had a significant impact on total international Aranesp<sup>®</sup> segment share.

The decrease in U.S. Aranesp<sup>®</sup> sales for the year ended December 31, 2007 was principally driven by a decline in demand. This decline primarily reflects physician conformance to label and reimbursement changes that occurred throughout 2007, primarily in the supportive cancer care setting, which are discussed in more detail in *Item 1. Business Key Developments*, and, to a lesser extent, loss of segment share.

The increase in international Aranesp<sup>®</sup> sales for the year ended December 31, 2007 was primarily driven by favorable foreign currency exchange rate changes of \$100 million. Excluding the impact of foreign currency exchange rate changes, international Aranesp<sup>®</sup> sales increased 2%. International sales were negatively impacted in Europe by dosing conservatism in the oncology segment and pricing pressures across all ESAs.

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

regulatory developments, including those resulting from:

- i the proposed REMS for the class of ESAs, which we have submitted to the FDA, or other risk management activities undertaken by us or required by the FDA or other regulatory authorities;
- i product labeling changes occurring in October 2008 in Europe for the class of ESAs, including Aranesp<sup>®</sup>, by the European Commission and the potential for further changes;
- i future product label changes;

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reimbursement developments, including those resulting from:

- i government s and/or third-party payor s reaction to regulatory developments, including the proposed REMS, which we have submitted to the FDA, and recent or future product label changes;

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i current or future cost containment pressures by third-party payors, including governments and private insurance plans;

adverse events or results from clinical trials or studies or meta-analyses performed by us, including our pharmacovigilance clinical trials, or by others (including our licensees or independent investigators), such as those referred to in *Item 1. Business Key Developments*, 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 ability to maintain worldwide segment share and differentiate Aranesp® from current and potential future competitive 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 or are expected to be launched in the future;

our current and future contracting and related pricing strategies;

patient population growth; and

development of new treatments for cancer and future chemotherapy treatments. For example, targeted therapies and other treatments that are less myelosuppressive may require less Aranesp®.

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

See *Item 1. Business Key Developments* 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, 2008, 2007 and 2006, total EPOGEN® sales were as follows (dollar amounts in millions):

|              | 2008     | Change | 2007     | Change | 2006     |
|--------------|----------|--------|----------|--------|----------|
| EPOGEN® U.S. | \$ 2,456 | (1)%   | \$ 2,489 | (1)%   | \$ 2,511 |

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 is related to the ESA label changes and the CMS revision to its EMP, which became effective January 1, 2008, as discussed in more detail in *Item 1. Business Key Developments*. 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.

The decline in EPOGEN® sales for the year ended December 31, 2007 reflects a decrease in demand due to a decline in dose/utilization, partially offset by patient population growth. The decline in dose/utilization was due to physician behavior in making treatment and dosing decisions in response to regulatory and reimbursement developments that occurred throughout 2007, including anticipation of the implementation of the CMS revision to its EMP, as discussed in more detail in *Item 1. Business Key Developments*. The decline in sales for the year ended December 31, 2007 was partially offset by favorable changes in wholesaler inventory and spillover. Spillover is a result of the Company's contractual relationship with J&J (see Note 1, *Summary of significant accounting policies Product sales* to the Consolidated Financial Statements for further discussion).

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In addition to the 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:

- <sup>i</sup> changes in healthcare providers' prescribing behavior resulting in dose fluctuations due to the CMS' revisions to its EMP, which became effective January 1, 2008;

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- i the federal government's reaction to regulatory developments, including recent or future product label changes;
- i changes in reimbursement rates or changes in the basis for reimbursement by the federal and state governments, including Medicare and Medicaid;
- i cost containment pressures from the federal and state governments on healthcare providers;

regulatory developments, including those resulting from:

- i future product label changes;
- i risk management activities, including a REMS, undertaken by us or required by the FDA;

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 or studies or meta-analyses performed by us, including our pharmacovigilance clinical trials, or by others (including our licensees or independent investigators), such as those referred to in *Item 1. Business Key Developments*, 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 current and future contracting and related pricing strategies;

changes in future patient population growth or dose/utilization; and

development of new modalities to treat anemia associated with CRF.

See *Item 1. Business Key Developments* 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, 2008, 2007 and 2006, total Neulasta®/NEUPOGEN® sales by geographic region were as follows (dollar amounts in millions):

|                                       | 2008         | Change    | 2007         | Change    | 2006         |
|---------------------------------------|--------------|-----------|--------------|-----------|--------------|
| Neulasta® U.S.                        | \$ 2,505     | 7%        | \$ 2,351     | 6%        | \$ 2,217     |
| NEUPOGEN® U.S.                        | 896          | 4%        | 861          | 4%        | 830          |
| <b>U.S. Neulasta®/NEUPOGEN® Total</b> | <b>3,401</b> | <b>6%</b> | <b>3,212</b> | <b>5%</b> | <b>3,047</b> |

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|                                         |          |     |          |     |          |
|-----------------------------------------|----------|-----|----------|-----|----------|
| Neulasta® International                 | 813      | 25% | 649      | 32% | 493      |
| NEUPOGEN® International                 | 445      | 7%  | 416      | 9%  | 383      |
| International Neulasta®/NEUPOGEN® Total | 1,258    | 18% | 1,065    | 22% | 876      |
| Total Worldwide Neulasta®/NEUPOGEN®     | \$ 4,659 | 9%  | \$ 4,277 | 9%  | \$ 3,923 |

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 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% versus the prior year.

The increase in U.S. Neulasta®/NEUPOGEN® sales for the year ended December 31, 2007 was driven by demand for Neulasta® primarily due to segment growth and, to a lesser degree, favorable changes in wholesaler inventory levels. The increase in international Neulasta®/NEUPOGEN® sales for the year ended December 31,

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2007 was driven by the continued conversion to Neulasta® from NEUPOGEN® and changes in foreign exchange, which positively impacted the growth in combined international sales by \$74 million. Excluding the impact of foreign currency exchange rate changes, combined international Neulasta®/NEUPOGEN® sales increased 13%.

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

penetration of existing segments;

competitive products or therapies, 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 payors;

adverse events or results from clinical trials or 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;

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;

our current and future contracting and related pricing strategies;

patient population growth; and

development of new treatments for cancer and future chemotherapy treatments. For example, targeted therapies and other treatments that are less myelosuppressive, and changes in chemotherapy usage patterns, may require less Neulasta®/NEUPOGEN®.

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

### ENBREL

For the years ended December 31, 2008, 2007 and 2006, total ENBREL sales by geographic region were as follows (dollar amounts in millions):

|                      | 2008     | Change | 2007     | Change | 2006     |
|----------------------|----------|--------|----------|--------|----------|
| ENBREL U.S.          | \$ 3,389 | 11%    | \$ 3,052 | 12%    | \$ 2,736 |
| ENBREL International | 209      | 17%    | 178      | 24%    | 143      |
| Total ENBREL         | \$ 3,598 | 11%    | \$ 3,230 | 12%    | \$ 2,879 |

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ENBREL sales growth for the year ended December 31, 2008 reflects higher demand principally due to increases in 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, and ENBREL continues to maintain a leading position in both segments.

ENBREL sales growth for the year ended December 31, 2007 was driven by demand due to increases in both patients and average net sales price. While ENBREL continued to maintain a leading position in both rheumatology and dermatology, the sales growth during the year ended December 31, 2007 was affected by slight share declines in the United States in both segments compared to the prior year due to increased competitive activity.

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In addition to the factors mentioned in the *Product sales* section above, future worldwide 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 J&J's CNTO 1275 (ustekinumab) and CNTO 148 (golimumab) (see *Item 1. Business - Marketed Products and Selected Product Candidates*) and, in part, our ability to differentiate ENBREL based on its safety profile and efficacy;

recent or future product label changes;

risk management activities, including a REMS, undertaken by us or required by the FDA or other regulatory authorities;

growth in the rheumatology and dermatology segments;

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

adverse events or results from clinical trials or 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;

current and future contracting and related pricing strategies;

patient population growth; and

penetration of existing segments.

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

### *Selected operating expenses*

The following table summarizes our product sales and operating expenses for the years ended December 31, 2008, 2007 and 2006 (dollar amounts in millions):

|               | 2008      | Change | 2007      | Change | 2006      |
|---------------|-----------|--------|-----------|--------|-----------|
| Product sales | \$ 14,687 | 3%     | \$ 14,311 | 3%     | \$ 13,858 |

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### Operating expenses:

|                                                                     |          |       |          |      |          |
|---------------------------------------------------------------------|----------|-------|----------|------|----------|
| Cost of sales (excludes amortization of acquired intangible assets) | \$ 2,296 | (10)% | \$ 2,548 | 22%  | \$ 2,095 |
| % of product sales                                                  | 16%      |       | 18%      |      | 15%      |
| Research and development                                            | \$ 3,030 | (7)%  | \$ 3,266 | (3)% | \$ 3,366 |
| % of product sales                                                  | 21%      |       | 23%      |      | 24%      |
| Selling, general and administrative                                 | \$ 3,789 | 13%   | \$ 3,361 | 0%   | \$ 3,366 |
| % of product sales                                                  | 26%      |       | 23%      |      | 24%      |
| Amortization of acquired intangible assets                          | \$ 294   |       | \$ 298   |      | \$ 370   |
| Write-off of acquired in-process research and development           | \$       |       | \$ 590   |      | \$ 1,231 |
| Other charges                                                       | \$ 380   |       | \$ 728   |      | \$       |
| <i>Cost of sales</i>                                                |          |       |          |      |          |

Cost of sales, which excludes the amortization of acquired intangible assets, decreased 10% for the year ended December 31, 2008. The decrease was primarily driven by lower restructuring charges incurred in 2008, as

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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 increased 22% for the year ended December 31, 2007, primarily driven by restructuring charges, as discussed below, product mix due to higher sales of ENBREL, excess capacity charges and the write-off of excess inventory related to certain new product presentations and due to changing regulatory and reimbursement environments.

Cost of sales for the year ended December 31, 2008 included \$6 million of restructuring charges. Cost of sales for the year ended December 31, 2007 included \$150 million of restructuring charges, 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 2, *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 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 are recognized as the obligation has been incurred or as we become entitled to the cost recovery.

R&D expenses decreased 7% for the year ended December 31, 2008, 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 decreased 3% for the year ended December 31, 2007, which was primarily attributable to reductions in in-licensing expenses of approximately \$95 million primarily due to our agreement with Cytokinetics entered into in 2006 and a \$50 million benefit in 2007 from our licensing agreement with Daiichi Sankyo. These decreases in R&D expenses for the year ended December 31, 2007 were partially offset by \$19 million of restructuring costs, as discussed below.

For the year ended December 31, 2008, restructuring-related R&D costs totaled \$3 million. R&D expense for the year ended December 31, 2007 include \$19 million of restructuring costs, primarily comprised of \$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.

*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. In connection with a co-promotion agreement, we and Wyeth market and sell ENBREL in the United States and Canada and Wyeth is paid a share of the related profits, as defined. The share of ENBREL's profits owed to Wyeth is included in SG&A expenses.

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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 Wyeth 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. For the years ended December 31, 2008 and 2007, the expense associated with the Wyeth profit share, excluding recoveries recorded as part of our restructuring, as discussed below, was \$1,195 million and \$984 million, respectively.

SG&A remained relatively unchanged for the year ended December 31, 2007. During the year ended December 31, 2007, outside legal costs increased \$53 million and outside marketing costs increased approximately \$59 million. The increase in outside marketing is primarily due to an increase in the expense associated with the Wyeth profit share, partially offset by reductions in promotion and advertising on marketed products. These increases were offset by approximately \$125 million in expense recoveries associated with our restructuring, as discussed below. For the year ended December 31, 2006, the expense associated with the Wyeth profit share was \$837 million. See Note 2, *Restructuring* to the Consolidated Financial Statements for further discussion.

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 certain restructuring charges, principally with respect to accelerated depreciation, in connection with our co-promotion agreement with Wyeth 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 2, *Restructuring* to the Consolidated Financial Statements for further discussion.

### *Amortization of acquired intangible assets*

Amortization of acquired intangible assets relates to products technology rights acquired in connection with the Immunex acquisition. For the years ended December 31, 2007 and 2006, amortization expense also included \$3 million and \$49 million, respectively, 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*

For acquisitions 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 (see *Recent accounting pronouncements* below). In 2007, we wrote-off \$270 million and \$320 million of acquired IPR&D related to the acquisitions of Alantox and Ilypsa, respectively. The Alantox 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. In 2006, we wrote-off \$1.1 billion and \$130 million of acquired IPR&D related to the acquisitions of Abgenix and Avidia, respectively. The Abgenix IPR&D amount is primarily comprised of approximately \$770 million related to the rights which we did not own pursuant to our agreement with Abgenix to jointly develop and commercialize panitumumab and approximately \$330 million 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. 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. Denosumab is a fully human monoclonal antibody that is a key mediator of osteoclast formation, function and survival and was in phase 2/3 clinical trials for various types of bone diseases at the time of the Abgenix acquisition. There were no individually significant IPR&D projects acquired and written off in the acquisition of Avidia.

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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, 77% for the Ilypsa product candidate, and 43% to 85% for the Abgenix product candidates. The incremental R&D expenses assumed to be incurred to obtain necessary regulatory approval for the Alantos and Ilypsa product candidates are immaterial. 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. The elimination of the royalty on potential future sales of denosumab did not result in us incurring any incremental R&D expenses.

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.

At the date of acquisition, we intended to develop panitumumab for treatment of various types of cancer. Panitumumab received FDA approval in late September 2006 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. 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®, such as the results of our PACCE trial and KRAS biomarker analysis. Because of these developments, our expected time to obtain regulatory approvals for the remaining indications has been delayed compared to our original expectations. Our development efforts with respect to denosumab are continuing. In December 2008, we submitted a BLA to the FDA for denosumab for the treatment and prevention of PMO in women and bone loss in patients undergoing hormone ablation for either prostate or breast cancer. On February 18, 2009, the FDA accepted our BLA and informed us that it will target an FDA action within ten months of the BLA's submission date. Additionally, in January 2009, we submitted an application to the EMEA for the approval of denosumab for treatment of PMO in women and treatment of bone loss associated with hormone ablation therapy in patients with breast and prostate cancer. In addition, 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.

### *Other charges*

As discussed in Note 2, *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

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to make significant R&D investments and build the framework for our future growth. As a result of this restructuring plan, we recorded in *Other charges* in 2008 and 2007 expenses for staff separation costs of \$7 million and \$209 million, respectively, asset impairments of \$36 million and \$366 million, respectively, and charges of \$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 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.

### *Income taxes*

Our effective tax rate was 20.1%, 20.1% and 26.6% for 2008, 2007 and 2006, respectively. 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.

Our effective tax rate for 2007 decreased over 2006 primarily due to the lesser amount of the write-off of nondeductible acquired IPR&D costs in 2007 than in 2006 and the greater tax benefit from the favorable resolutions of our prior years' income tax examinations in 2007 than in 2006.

As permitted in Accounting Principles Board Opinion (APB) No. 23, *Accounting for Income Taxes - Special Areas*, 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 Note 5, *Income taxes* to the Consolidated Financial Statements for further discussion.)

### *Recent accounting pronouncements*

In May 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1) that changes the method of accounting for convertible debt securities that require or permit settlement in cash either in whole or in part upon conversion, including our convertible debt securities (see Note 6, *Financing arrangements* to the Consolidated Financial Statements). We will adopt FSP APB 14-1, effective January 1, 2009, and retrospectively apply this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new standard. Under this new method of accounting, the debt and equity components of our convertible debt securities will be bifurcated and accounted for separately in a manner that will result in recognizing interest expense on these securities at effective rates reflective of what we would have incurred had we issued nonconvertible debt with otherwise similar terms. The equity component of our convertible debt securities will be included in Stockholders' equity on our Consolidated Balance Sheets and, accordingly, the initial carrying values of these debt securities will be reduced. Our net income for financial reporting purposes will be reduced by recognizing the accretion of the reduced carrying values of our convertible debt securities to their face amounts as additional non-cash interest expense. The adoption of FSP APB 14-1 will result in a reduction in the carrying value of our convertible debt by approximately \$824 million as of December 31, 2008 and will increase interest expense, net by approximately \$234 million, \$168 million and \$197 million, for the years ended December 31, 2008, 2007 and 2006, respectively. This new standard will also materially increase interest expense in future periods that our convertible debt is outstanding, but will have no impact on past or future cash flows.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS 141(R)) and SFAS No. 160, *Accounting and Reporting of Noncontrolling Interests in Consolidated Financial Statements - an amendment of ARB No. 51* (SFAS 160). These standards will significantly change the accounting and reporting for business combination transactions and noncontrolling (minority) interests in consolidated financial statements, including capitalizing the fair value of acquired IPR&D at the acquisition date and subsequently testing these assets for impairment. These new standards will be applied prospectively for business combinations.

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that occur on or after January 1, 2009, except that presentation and disclosure requirements of SFAS 160 regarding noncontrolling interests will be applied retrospectively.

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* (EITF 07-5). Equity-linked instruments (or embedded features) that otherwise meet the definition of a derivative as outlined in SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, are not accounted for as derivatives if certain criteria are met, one of which is that the instrument (or embedded feature) must be indexed to the entity's own stock. EITF 07-5 provides guidance on how to determine if equity-linked instruments (or embedded features) such as warrants to purchase our stock, our convertible notes and convertible note hedges are considered indexed to our stock. We will adopt EITF 07-5, effective January 1, 2009, and apply its provisions to outstanding instruments as of that date. The adoption of EITF 07-5 will not have a material impact on our consolidated results of operations, financial position or cash flows.

In December 2007, the FASB ratified EITF No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which includes certain arrangements the Company has entered into regarding development and commercialization of products and product candidates. EITF 07-1 is effective for the Company as of January 1, 2009, and its adoption will not have a material impact on our consolidated results of operations, financial position or cash flows.

## Financial Condition, Liquidity and Capital Resources

The following table summarizes selected financial data (in millions):

|                                                  | December 31, |          |
|--------------------------------------------------|--------------|----------|
|                                                  | 2008         | 2007     |
| Cash, cash equivalents and marketable securities | \$ 9,552     | \$ 7,151 |
| Total assets                                     | 36,443       | 34,639   |
| Current debt                                     | 1,000        | 2,000    |
| Non-current debt                                 | 9,176        | 9,177    |
| Stockholders' equity                             | 20,386       | 17,869   |

We believe that existing funds, including those generated from our \$2.0 billion debt offering in January 2009, 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 programs and other business initiatives, including acquisitions and licensing activities. 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 other debt markets and equity markets. (See *Item 1A. Risk Factors* *Current levels of market volatility are unprecedented and adverse capital and credit market conditions may affect our ability to access cost-effective sources of funding and our investment in marketable securities may be subject to market, interest and credit risk that could reduce their value.* )

### *Cash, cash equivalents and marketable securities*

Of the total cash, cash equivalents and marketable securities at December 31, 2008, approximately \$8.8 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 the United States, we would be required to pay additional U.S. 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.

**Table of Contents***Financing arrangements*

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements as of December 31, 2008 and 2007 (in millions):

|                                                                                              | 2008     | 2007     |
|----------------------------------------------------------------------------------------------|----------|----------|
| 0.125% convertible notes due 2011 (2011 Convertible Notes)                                   | \$ 2,500 | \$ 2,500 |
| 0.375% convertible notes due 2013 (2013 Convertible Notes)                                   | 2,500    | 2,500    |
| Floating rate notes due 2008 (2008 Floating Rate Notes)                                      |          | 2,000    |
| 5.85% notes due 2017 (2017 Notes)                                                            | 1,099    | 1,099    |
| 4.85% notes due 2014 (2014 Notes)                                                            | 1,000    | 1,000    |
| 4.00% notes due 2009 (2009 Notes)                                                            | 1,000    | 999      |
| 6.375% notes due 2037 (2037 Notes)                                                           | 899      | 899      |
| 6.15% notes due 2018 (2018 Notes)                                                            | 499      |          |
| 6.90% notes due 2038 (2038 Notes)                                                            | 498      |          |
| Zero coupon 30 year modified convertible notes due in 2032 (2032 Modified Convertible Notes) | 81       | 80       |
| Other                                                                                        | 100      | 100      |
| Total borrowings                                                                             | 10,176   | 11,177   |
| Less current portion                                                                         | 1,000    | 2,000    |
| Total non-current debt                                                                       | \$ 9,176 | \$ 9,177 |

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.

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 ASR entered into in May 2007. 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 retired \$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 retired in November 2008.

In February 2006, we issued \$2.5 billion principal amount of convertible notes due in 2011 (the 2011 Convertible Notes) and \$2.5 billion principal amount of convertible notes due in 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 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 price of approximately \$79.84 and \$79.48 per share, respectively). The 2011 Convertible Notes and 2013 Convertible Notes may only be converted (i) during any

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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 (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"). 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. See *Recent accounting pronouncements* above.

In connection with the issuance of the 2011 Convertible Notes and 2013 Convertible 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 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, which aggregated approximately \$1.5 billion, was recorded as a reduction of equity. The net proceeds from the issuance of the 2011 Convertible Notes and 2013 Convertible Notes, the repurchase of our common stock and the purchase of the convertible note hedges was \$439 million.

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.

As of December 31, 2008, we had \$2.2 billion of additional notes outstanding. The notes consisted of (i) \$1.0 billion of notes that bear interest at a fixed rate of 4.00% and mature in November of 2009 ("2009 Notes"), (ii) \$1.0 billion of notes that bear interest at a fixed rate of 4.85% and mature in 2014 ("2014 Notes"), (iii) \$100 million of long-term debt securities that bear interest at a fixed rate of 8.125% and mature in 2097 ("Century Notes") and (iv) zero coupon convertible notes due in 2032 with an accreted value of \$81 million and having an aggregate face amount of \$105 million and yield to maturity of 1.125%. See *Recent accounting pronouncements* above.

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, 2008, we had interest rate swap agreements for our 2009 Notes, 2014 Notes, 2018 Notes and Century Notes, with an aggregate face value of \$2.6 billion. As of December 31, 2007, we had interest rate swap agreements for our 2009 Notes, 2014 Notes and Century Notes, with an aggregate face value of \$2.1 billion.

In addition to the outstanding debt noted above, 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 2039 Notes pay interest at fixed annual rates of 5.70% and 6.40%, respectively. The 2019 Notes and 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 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 2019 Notes and 2039 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. Debt issuance costs totaled approximately \$12 million and are being amortized over the life of the notes.

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On April 17, 2008, we filed a shelf registration statement with the SEC, which replaced our previous \$1.0 billion shelf registration statement and 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.

In May 2008, we increased our commercial paper program by \$1.3 billion, which provides for unsecured, short-term borrowings of up to an aggregate of \$2.5 billion. We also have a \$2.5 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; however, \$178 million of such commitment was provided by a subsidiary of Lehman. Lehman declared bankruptcy on September 15, 2008, and the subsidiary participant in our credit facility subsequently declared bankruptcy on October 5, 2008. As a result, we would not anticipate the ability to access this specific commitment provided by Lehman in the future. No amounts were outstanding under the commercial paper program or credit facility as of December 31, 2008.

As of December 31, 2008, 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, 2008, 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, 2008. 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 for the years ended December 31, 2008, 2007 and 2006 (in millions):

|                                           | <b>2008</b> | <b>2007</b> | <b>2006</b> |
|-------------------------------------------|-------------|-------------|-------------|
| Net cash provided by operating activities | \$ 5,988    | \$ 5,401    | \$ 5,389    |
| Net cash used in investing activities     | (3,165)     | (1,992)     | (5,131)     |
| Net cash used in financing activities     | (3,073)     | (2,668)     | (815)       |

### *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 2008 primarily as a result of improvement in operating income.

Cash provided by operating activities remained relatively unchanged in 2007 as higher cash receipts from customers were substantially offset by the timing of payments in the ordinary course of business.

### *Investing*

Net purchases of marketable securities were \$2.6 billion for the year ended December 31, 2008 compared to net purchases of \$52 million for the year ended December 31, 2007 and net purchases of \$1.5 billion for the year ended December 31, 2006.

Capital expenditures totaled \$672 million in 2008 and were significantly lower compared to \$1.3 billion in 2007 and \$1.2 billion in 2006 as we reassessed our capital spending needs. Capital expenditures in 2008 were primarily associated with manufacturing capacity expansions in Puerto Rico, Fremont and other site developments and

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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. Capital expenditures in 2006 were primarily associated with manufacturing capacity and site expansions in Ireland, Puerto Rico and other locations and costs associated with implementing our ERP system. We currently estimate 2009 spending on capital projects and equipment to be approximately \$700 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.

On October 24, 2006, we completed our acquisition of Avidia and paid \$275 million in cash, net of cash acquired and our existing equity stake in Avidia. In addition, we may be subject to pay additional amounts upon the achievement of certain future events. On April 1, 2006, we completed our acquisition of Abgenix and paid \$2.1 billion in cash to the shareholders of Abgenix to acquire all outstanding shares. In addition, we acquired \$252 million in cash, and subsequent to the completion of the acquisition, we paid off \$653 million of debt assumed in this transaction.

*Financing*

In July 2007, the Board of Directors authorized us to repurchase up to \$5.0 billion of common stock. As of December 31, 2008, we had \$4.2 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 for the years ended December 31, 2008, 2007 and 2006 is as follows (in millions):

|                | 2008   |                      | 2007                |          | 2006   |          |
|----------------|--------|----------------------|---------------------|----------|--------|----------|
|                | Shares | Dollars              | Shares              | Dollars  | Shares | Dollars  |
| First quarter  |        | \$                   | 8.8                 | \$ 537   | 46.6   | \$ 3,374 |
| Second quarter | 32.7   | 1,549 <sup>(1)</sup> | 73.9 <sup>(2)</sup> | 4,463    | 13.0   | 876      |
| Third quarter  |        | 19 <sup>(1)</sup>    | 2.5 <sup>(2)</sup>  |          | 7.3    | 505      |
| Fourth quarter | 12.6   | 700                  | 1.8                 | 100      | 3.3    | 245      |
| Total          | 45.3   | \$ 2,268             | 87.0                | \$ 5,100 | 70.2   | \$ 5,000 |

<sup>(1)</sup> 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.

<sup>(2)</sup> 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 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 million. In June 2008, upon receipt of the proceeds from the issuance of these notes, we exercised our right to call and retired \$1.0 billion of floating rate notes scheduled to mature in November 2008 and in November 2008, we retired the remaining \$1.0 billion of floating rate notes that matured.

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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.

In February 2006, we issued \$5.0 billion of convertible notes, of which \$2.5 billion pay interest at 0.125% and are due in 2011 and \$2.5 billion pay interest at 0.375% and are due in 2013. In connection with the issuance of these convertible 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 convertible notes, we purchased convertible note hedges at a cost of approximately \$1.5 billion. The net proceeds received from the issuance of the 2011 and 2013 Convertible Notes, the repurchase of common stock and the purchase of the convertible note hedges was \$439 million. Also, concurrent with the issuance of the convertible notes, we sold 62.8 million warrants to acquire shares of our common stock for proceeds of \$774 million, 31.3 million of which may be settled in May 2011 and 31.5 million of which may be settled in May 2013.

We receive cash from the exercise of employee stock options. Employee stock option exercises provided \$155 million, \$277 million and \$528 million of cash during the years ended December 31, 2008, 2007 and 2006, 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, 2008, aggregated by type (in millions):

| Contractual Obligations                   | Total            | Payments Due by Period |                 |                 |                      |
|-------------------------------------------|------------------|------------------------|-----------------|-----------------|----------------------|
|                                           |                  | Less than<br>1 Year    | 2-3<br>Years    | 4-5<br>Years    | More than<br>5 Years |
| Long-term debt obligations <sup>(1)</sup> | \$ 14,277        | \$ 1,236               | \$ 2,914        | \$ 3,022        | \$ 7,105             |
| Operating lease obligations               | 1,064            | 126                    | 222             | 186             | 530                  |
| Purchase obligations <sup>(2)</sup>       | 2,959            | 850                    | 1,012           | 409             | 688                  |
| Unrecognized tax benefits <sup>(3)</sup>  | 120              | 120                    |                 |                 |                      |
| <b>Total contractual obligations</b>      | <b>\$ 18,420</b> | <b>\$ 2,332</b>        | <b>\$ 4,148</b> | <b>\$ 3,617</b> | <b>\$ 8,323</b>      |

<sup>(1)</sup> The long-term debt obligation amounts include future interest payments. Future interest payments are included on the 2009 Notes at a fixed rate of 4.00%, the 2011 Convertible Notes at a fixed rate of 0.125%, the 2013 Convertible Notes at a fixed rate of 0.375%, the 2014 Notes at a fixed rate of 4.85%, the 2017 Notes at a fixed rate of 5.85%, the 2018 Notes at a fixed rate of 6.15%, the 2037 Notes at a fixed rate of 6.375%, the



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2038 Notes at a fixed rate of 6.90% and the Century 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, 2008 to compute the net amounts to be included in the table above for future interest payments on our variable rate interest rate swaps.

- (2) Purchase obligations primarily relate to (i) our long-term supply agreement with BI Pharma for the manufacture of commercial quantities of ENBREL, which are based on firm commitments for the purchase of production capacity for ENBREL and reflect certain estimates such as production run success rates and bulk drug yields achieved; (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, included in the table above, is estimated to be \$505 million. The estimated aggregate additional cost of the three one-year renewal options not included in the table above is approximately \$254 million. Our obligation to pay certain of these amounts may be reduced based on certain future events.
- (3) In addition to the current liabilities for unrecognized tax benefits ( UTBs ) included in the table above, long-term liabilities for UTBs (net of federal tax benefits on state taxes) and related accrued interest totaling approximately \$915 million at December 31, 2008 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.

On February 4, 2009, we entered into an agreement for certain integrated facilities management services. The contract has an initial term of five years and automatically renews annually thereafter at the Company's option. The cost to the Company for the initial five-year term is estimated to be approximately \$500 million. The contractual obligations under this contract are not included in the table above given the timing of entering into the agreement.

In addition to the above table, we have committed to make potential future milestone payments to third-parties as part of in-licensing and product development programs all of which are contingent upon the occurrence of certain future events. Such events could include, but are not limited to, development milestones, regulatory approvals and product sales. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingencies have not been included in the table above or recorded on our Consolidated Balance Sheets. Individually, these arrangements are not material in any one reporting period. However, if the achievement of the milestones covered by these arrangements would happen to be reached in the same reporting period, the resulting payment obligation would be approximately \$1.3 billion.

## **Summary of Critical Accounting Policies**

The preparation of our consolidated 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 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 incentives and returns*

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 incentives (collectively sales incentives ) and returns.

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In the United States, we utilize wholesalers as the principal means of distributing our products to healthcare providers, such as physicians or their clinics, dialysis centers, hospitals and pharmacies. Products we sell outside the United States are principally distributed to hospitals and/or wholesalers depending upon the distribution practice in each country for which the product has been launched. We monitor the inventory levels of our products at our wholesale distributors using third-party data 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 incentives and returns.

Accruals for sales incentives are recorded in the same period that the related sales are recorded and are recognized as a reduction in product sales. Sales incentive accruals are 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 incentives are product-specific and, therefore, for any given year, can be impacted by the mix of products sold.

For the years ended December 31, 2008, 2007 and 2006, reductions in product sales relating to sales incentives were comprised of the following (dollar amounts in millions):

|                                | 2008     | 2007     | 2006     |
|--------------------------------|----------|----------|----------|
| Rebates                        | \$ 1,813 | \$ 2,156 | \$ 2,164 |
| Wholesaler chargebacks         | 1,635    | 1,649    | 1,636    |
| Discounts and other incentives | 790      | 694      | 653      |
| Total sales incentives         | \$ 4,238 | \$ 4,499 | \$ 4,453 |
| Percent of gross product sales | 22%      | 24%      | 24%      |

Rebates earned by healthcare providers, such as physicians or their clinics, dialysis centers and hospitals 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 \$1.8 billion in 2008, \$2.2 billion in 2007 and \$2.2 billion in 2006. 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 2008 would have had an impact of approximately \$63 million on our 2008 product sales and a corresponding impact on our financial condition and liquidity.

Wholesaler chargebacks are another type of arrangement included in sales incentives that 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. These chargebacks from wholesalers totaled \$1.6 billion for each of the three years ended December 31, 2008. 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.

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Amounts accrued for sales incentives are adjusted when trends or significant events indicate that adjustment is appropriate. Accruals are also adjusted to reflect actual results. However, such adjustments to date have not been material to our results of operations or financial position. The following table summarizes amounts recorded in accrued liabilities regarding sales incentives (in millions):

| Year ended:       | Balance at<br>Beginning of<br>Period | Amounts Charged<br>Against Product<br>Sales <sup>(1)</sup> | Payments | Balance at<br>End of<br>Period |
|-------------------|--------------------------------------|------------------------------------------------------------|----------|--------------------------------|
| December 31, 2008 | \$ 1,064                             | \$ 4,238                                                   | \$ 4,426 | \$ 876                         |
| December 31, 2007 | \$ 1,079                             | \$ 4,499                                                   | \$ 4,514 | \$ 1,064                       |

<sup>(1)</sup> Includes immaterial amounts related to prior year product sales based on changes in estimates. Such amounts represented less than 2% of incentive amounts charged against product sales for 2008 and 2007.

Accruals for estimated sales returns are recorded in the same period that the related product sales are recorded and are recognized as reductions in product sales. 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.

*Deferred income taxes*

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.

*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 10, *Contingencies* 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.

In addition, our income tax returns are routinely audited by the Internal Revenue Service ( IRS ) and various state and foreign tax authorities. Significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions because of differing interpretations of tax laws and regulations.

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.

*Valuation of acquired intangible assets*

We have acquired and continue to acquire intangible assets primarily by acquiring biotechnology companies. These intangible assets primarily consist of technology associated with human therapeutic products and in-process product candidates as well as goodwill arising in business combinations. Discounted cash flow

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models are typically used in these valuations, and these models require the use of significant estimates and assumptions including but not limited to:

determining the timing and expected costs to complete the in-process projects,

projecting regulatory approvals,

estimating future cash flows from product sales resulting from completed products and in-process projects and

developing appropriate discount rates and probability rates by project.

We believe the fair values assigned to the intangible assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition dates.

### *Fair value measurement of financial instruments*

The Company adopted the provisions of the FASB's Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* (SFAS 157), effective January 1, 2008, for its financial assets and liabilities. Under this standard, fair value is 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.

In determining the fair value of its financial assets and liabilities, the Company uses various valuation approaches. SFAS 157 establishes a hierarchy for inputs used in measuring fair value 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 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.

Whenever the estimated fair value of any of our available-for-sale securities is less than their related cost, we perform an impairment analysis in accordance with the FASB's SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and related guidance issued by the FASB and the SEC, in order to determine the classification of the impairment as temporary or other-than-temporary. A temporary impairment results in an unrealized loss being recorded in the other comprehensive income component of stockholders' equity. Such an unrealized loss does not affect net income for the applicable accounting period. However, an other-than-temporary impairment charge is recorded as a realized loss in the consolidated statement of income and reduces net income for the applicable accounting period. The primary factors we consider to differentiate our impairments between temporary and other-than-temporary impairments include the length of the time and the extent to which the market value has been less than cost, the financial condition and near-term prospects of the issuer and our intent and ability to retain our investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

As of December 31, 2008, the Company's available-for-sale securities were comprised of U.S. Treasury securities, obligations of U.S. government agencies, FDIC guaranteed bank debt, corporate debt securities, mortgage and asset backed securities, other short-term interest bearing securities, including money market funds, and publicly traded equity investments. U.S. Treasury securities, money market funds and publicly traded equity investments are valued using quoted market prices with no valuation adjustments applied. Obligations of U.S. government agencies, FDIC guaranteed bank debt, corporate debt securities, mortgage and asset backed securities and other short-term interest bearing securities are valued using quoted market prices of recent transactions or are benchmarked to transactions of very similar securities.

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Our derivatives assets and liabilities include interest rate swaps and foreign currency forward and option contracts. The fair values of these derivatives are determined using models based on market observable inputs, including interest rate curves and both forward and spot prices for foreign currencies.

We believe that the values assigned to our available-for-sale securities and derivative instruments as of December 31, 2008 and 2007 are fairly stated in accordance with GAAP and are based upon reasonable estimates and assumptions. In addition, we believe that the cost basis for our available-for-sale securities as of December 31, 2008 and 2007 was recoverable in all material respects. In 2008, the U.S. economy continued to be adversely affected by tightening in the credit markets and volatility in capital markets. Interest rates on U.S. treasury instruments declined considerably during this crisis while other interest rates fluctuated in excess of historical norms. In addition, the U.S. dollar strengthened dramatically over the second half of the year against most other currencies during a period of extremely high levels of currency volatility. Continuing distress in the economic environment could ultimately result in other-than-temporary impairments of the carrying values of our available-for-sale securities and/or a material adverse impact on the carrying values of our financial instruments.

**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, 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, 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.

In 2008, the U.S. economy continued to be adversely affected by a tightening in the credit markets and volatility in the capital markets. In an attempt to increase liquidity and stabilize the global financial markets, the U.S. federal government acted in concert with other foreign governments through various forms of direct market intervention. Short-term interest rates on U.S. treasury instruments have declined considerably during this crisis 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 or 20%, as applicable, from those at December 31, 2008. As this crisis deepened, it spread to the economies of many countries worldwide. This resulted in increased demand for the U.S. dollar due to the financial market's perception of its relatively higher quality and liquidity. Consequently, the U.S. dollar strengthened dramatically over the second half of the year against most other currencies but also experienced unprecedented levels of volatility. Our analysis which follows assumes 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, 2008.

*Interest rate sensitive financial instruments*

Our investment portfolio of available-for-sale securities at December 31, 2008 and 2007 was comprised primarily of U.S. treasury securities and obligations of U.S. government agencies, money market funds whose underlying securities were U.S. treasury and agency obligations, corporate debt instruments, commercial paper and mortgage backed securities that are guaranteed by U.S. government agencies. The fair value of our investment portfolio was \$9.4 billion and \$6.7 billion at December 31, 2008 and 2007, 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, 2008 and December 31, 2007 would not have a material effect on the fair values of these securities. In addition a hypothetical 100 basis point decrease in interest rates at December 31, 2008 and December 31, 2007 would not have a material effect on the income or cash flows.

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On December 31, 2008, we had outstanding debt with a carrying value and a fair value of \$10.2 billion, including \$5.1 billion of convertible debt with a fair value of \$4.8 billion. Our outstanding debt at December 31, 2008 was comprised entirely of debt with fixed interest rates. On December 31, 2007, we had \$11.2 billion of outstanding debt with a fair value of \$10.6 billion, including \$5.1 billion of convertible debt with a fair value of \$4.5 billion. Our outstanding debt at December 31, 2007 was comprised of \$9.2 billion of debt with fixed interest rates and \$2.0 billion of debt with variable interest rates. Changes in interest rates do not affect interest expense or cash flows on our fixed rate debt but would impact our variable rate debt outstanding at December 31, 2007. A hypothetical 20% increase in interest rates relative to interest rates at December 31, 2007 would not have a material impact on income or cash flows with respect to our \$2.0 billion of variable rate debt that was outstanding at December 31, 2007.

Changes in interest rates would, however, affect the fair values of all of the outstanding debt at December 31, 2008 and 2007, including, to a lesser extent, our variable rate debt outstanding at December 31, 2007 for which the interest rate reset quarterly. A hypothetical 20% decrease in interest rates relative to interest rates at December 31, 2008 would result in an increase of approximately \$550 million in the aggregate fair value of our outstanding debt. A hypothetical 20% decrease in interest rates relative to the interest rates at December 31, 2007 would result in an increase of approximately \$460 million in the aggregate fair value of our outstanding debt.

To achieve a desired mix of fixed and floating interest rate debt, we enter into interest rate swap agreements, which qualify and are designated as fair value hedges, for certain of our fixed rate debt with carrying values totaling \$2.6 billion and \$2.1 billion at December 31, 2008 and 2007, 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 20% increase in interest rates relative to interest rates at December 31, 2008 and 2007 would not have a material effect on the fair value, cash flows or income of our interest rate swap agreements.

*Market price sensitive instruments*

As noted above, a portion of our outstanding debt may be converted into our common stock in certain circumstances. Accordingly, the price of our common stock may affect the fair value of our convertible debt. A hypothetical 20% increase in the price of Amgen stock from the price at December 31, 2008 would have increased the fair value of our then outstanding convertible debt by approximately \$325 million. A hypothetical 10% increase in the price of Amgen stock from the price at December 31, 2007 would have increased the fair value of our then outstanding convertible debt by approximately \$78 million.

On December 31, 2008 and 2007, 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 on December 31, 2008 and 2007 was not material.

*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 sales 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 have entered into foreign currency forward and option contracts.

On December 31, 2008, we had outstanding forward and options contracts, primarily Euro based, with notional amounts of \$2.5 billion and \$386 million, respectively. On December 31, 2007, we had outstanding forward and options contracts, primarily Euro based, with notional amounts of \$1.4 billion and \$788 million, respectively. These contracts are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2008 the net unrealized gains and as of December 31, 2007

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the net unrealized losses on these contracts were not material. With regard to these contracts, a hypothetical 20% adverse movement in foreign exchange rates compared with the U.S. dollar relative to exchange rates on December 31, 2008 would result in a reduction in fair value of approximately \$550 million, a reduction in income of \$270 million in the ensuing year and no material impact on cash flows. A hypothetical 10% adverse movement in foreign exchange rates compared with the U.S. dollar relative to exchange rates on December 31, 2007 would result in a reduction in fair value of approximately \$160 million and no material reductions in income or cash flows.

Also on December 31, 2008 and 2007, we had outstanding forward contracts with notional amounts totaling \$472 million and \$622 million, respectively, that hedge fluctuations of certain assets and liabilities denominated in foreign currencies but have not been designated as hedges for accounting purposes. These contracts had no material net unrealized gains or losses as of December 31, 2008 and 2007. With regard to these contracts, a hypothetical 20% adverse movement in foreign exchange rates compared with the U.S. dollar relative to exchange rates on December 31, 2008 would not have a material impact on fair value, income or cash flows. A hypothetical 10% adverse movement in foreign exchange rates compared with the U.S. dollar relative to exchange rates on 2007 would not have a material impact on fair value, income or cash flows.

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

*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, 2008.

Management determined that, as of December 31, 2008, 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, 2008. 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, 2008, 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, 2008.

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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, 2008, 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, 2008, 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 of Amgen Inc. as of December 31, 2008 and 2007, and the related Consolidated Statements of Income, Stockholders' Equity, and Cash Flows for each of the three years in the period ended December 31, 2008 of Amgen Inc. and our report dated February 23, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California

February 23, 2009

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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 **ELECTION OF DIRECTORS** in our Proxy Statement for the 2009 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2008 (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*.

#### **Changes to Procedures for Recommending Director Nominees**

On December 9, 2008, our Board approved an amendment (the **Amendment**) to our Amended and Restated Bylaws (the **Bylaws**), which became effective upon the Amendment's adoption by the Board on December 9, 2009. Among other things, the Amendment modifies the advance notice provisions in our Amended and Restated Bylaws by requiring that additional information be furnished in connection with nominations and other business proposals, clarifying that the advance notice provisions apply to all stockholder nominations and other business proposals and effecting other technical changes to the requirements applicable to stockholder nominations and other business proposals.

Section 15(a)(2) of the Amendment requires, among other things, that the following disclosure be provided with respect to nominations and business proposals that stockholders seek to present at any meeting of stockholders:

information regarding nominees for election to the Board, including information regarding the nominee's eligibility to serve as a director, whether the proponent received payment for making the nomination and required disclosure under federal securities laws;

information regarding business proposals, including a description of why the proposal was made and whether the proponent received payment relating to the proposal; and

information regarding the proponent, including disclosure regarding the class or series and number of shares beneficially owned by the proponent, a description of any agreement among any group of persons making the proposal and disclosure regarding hedging and derivative transactions entered into by such group.

In addition, Section 15(c)(3) of the Amendment clarifies that the advance notice provisions apply to all stockholder nominations and other business proposals, whether or not they are to be included in our annual proxy statement, and provides that such provisions are the exclusive means of making nominations or other business proposals. However, the Amendment continues to treat business proposals that are submitted in compliance with Rule 14a-8 (or any successor thereof) promulgated under the Securities Exchange Act of 1934, as amended, and included in our proxy statement as having been made in compliance with the advance notice bylaw.

The preceding disclosure is qualified in its entirety by reference to the Amendment, a copy of which is attached as Exhibit 3.1 to the Form 8-K we filed on December 10, 2008, and is incorporated herein by reference.

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**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](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 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.

**Table of Contents****Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS****Securities Authorized for Issuance Under Equity Compensation Plans**

The following table sets forth certain information as of December 31, 2008 concerning our common stock that may be issued upon the exercise of options or pursuant to purchases of stock under all of our equity compensation plans approved by stockholders and equity compensation plans not approved by stockholders in effect as of December 31, 2008:

| <b>Plan Category</b>                                                               | <b>(a)<br/>Number of<br/>Securities to be<br/>Issued Upon<br/>Exercise of<br/>Outstanding<br/>Options and Rights</b> | <b>(b)<br/>Weighted<br/>Average<br/>Exercise Price<br/>Outstanding<br/>Options and<br/>Rights</b> | <b>(c)<br/>Number of<br/>Securities Remaining<br/>Available for Future<br/>Issuance Under<br/>Equity Compensation<br/>Plans (Excluding<br/>Securities Reflected<br/>in Column (a))</b> |
|------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Equity compensation plans approved by Amgen security holders:                      |                                                                                                                      |                                                                                                   |                                                                                                                                                                                        |
| Amended and Restated 1991 Equity Incentive Plan                                    | 27,991,005                                                                                                           | \$ 36.54                                                                                          | 15,461,792                                                                                                                                                                             |
| Amended and Restated Employee Stock Purchase Plan <sup>(1)</sup>                   |                                                                                                                      | \$                                                                                                | 7,037,126                                                                                                                                                                              |
| <b>Total Approved Plans</b>                                                        | <b>27,991,005</b>                                                                                                    | <b>\$ 36.54</b>                                                                                   | <b>22,498,918</b>                                                                                                                                                                      |
| Equity compensation plans not approved by Amgen security holders:                  |                                                                                                                      |                                                                                                   |                                                                                                                                                                                        |
| Amended and Restated 1993 Equity Incentive Plan <sup>(2)</sup>                     | 948,840                                                                                                              | \$ 39.66                                                                                          |                                                                                                                                                                                        |
| Amended and Restated 1999 Equity Incentive Plan <sup>(2)</sup>                     | 13,350,798                                                                                                           | \$ 61.12                                                                                          | 915,364                                                                                                                                                                                |
| Amended and Restated 1997 Equity Incentive Plan <sup>(3)</sup>                     | 1,597,099                                                                                                            | \$ 51.64                                                                                          |                                                                                                                                                                                        |
| Amended and Restated 1997 Special Non-Officer Equity Incentive Plan <sup>(4)</sup> | 15,568,320                                                                                                           | \$ 58.80                                                                                          |                                                                                                                                                                                        |
| Amended and Restated 1996 Stock Incentive Plan <sup>(5)</sup>                      | 364,238                                                                                                              | \$ 66.84                                                                                          |                                                                                                                                                                                        |
| Amended and Restated 1999 Stock Incentive Plan <sup>(5)</sup>                      | 2,425,145                                                                                                            | \$ 48.20                                                                                          | 98,390                                                                                                                                                                                 |
| Amended and Restated Assumed Avidia Equity Plan <sup>(6)</sup>                     | 24,222                                                                                                               | \$ 1.98                                                                                           |                                                                                                                                                                                        |
| <b>Foreign Affiliate Plans:</b>                                                    |                                                                                                                      |                                                                                                   |                                                                                                                                                                                        |
| Amgen Limited Sharesave Plan <sup>(7)</sup>                                        |                                                                                                                      | \$                                                                                                | 372,839                                                                                                                                                                                |
| The Amgen Limited 2000 U.K. Company Employee Share Option Plan <sup>(8)</sup>      |                                                                                                                      | \$                                                                                                | 300,000                                                                                                                                                                                |
| The Amgen Technology Ireland Irish Tax Approved Share Plan <sup>(9)</sup>          |                                                                                                                      | \$                                                                                                | 592,168                                                                                                                                                                                |
| <b>Total Unapproved Plans</b>                                                      | <b>34,278,662</b>                                                                                                    | <b>\$ 58.14</b>                                                                                   | <b>2,278,761</b>                                                                                                                                                                       |
| <b>Total All Plans</b>                                                             | <b>62,269,667</b>                                                                                                    | <b>\$ 48.43</b>                                                                                   | <b>24,777,679</b>                                                                                                                                                                      |

<sup>(1)</sup> The purchases occurred on September 30, 2008 (the Purchase Date) with a purchase of an aggregate 217,612 shares of Common Stock at a purchase price of \$56.31 per share on September 30, 2008. Such purchase price reflects 95% of the closing price of the Common Stock on the Purchase Date.

<sup>(2)</sup> These plans were 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 Amended and Restated 1993 Equity Incentive Plan terminated on March 11, 2003 and no shares are available for issuance under the 1993 Plan for future grants.

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- (3) This plan was 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. This plan terminated on March 2, 2007 and no shares are available for issuance under this plan for future grants.
- (4) This plan terminated on December 9, 2007 and no shares are available for issuance under this plan for future grants.
- (5) These plans were 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 Stock Incentive Plan (the 1996 Plan) was previously approved by Abgenix's shareholders. The 1996 Plan terminated on July 16, 2006 and no shares are available for issuance for future grants.
- (6) This plan was assumed by Amgen in connection with the merger of Avidia with and into Amgen Mountain View Inc., a wholly owned subsidiary of Amgen, on October 24, 2006. This plan was terminated on November 23, 2006 and no shares are available for issuance for future grants.
- (7) As of December 31, 2003, there were no further offerings under the Amgen Limited Sharesave Plan and the last share purchase under this plan was March 31, 2003.
- (8) Although 300,000 shares of Common Stock are authorized for issuance under the Amgen Limited 2000 U.K. Company Employee Share Option Plan, no shares have been issued under this plan.
- (9) The Amgen Technology Ireland Irish Tax Approved Share Plan was approved by the Board of Directors on March 6, 2007 and 7,832 shares were purchased on March 27, 2007.

### **Summary of Equity Compensation Plans Not Approved by Stockholders**

The following is a summary of the equity compensation plans, which have shares available for issuance for future grants as of December 31, 2008 and were adopted or assumed by the Board of Directors without the approval of our stockholders:

#### *Amended and Restated 1999 Equity Incentive Plan*

The Amended and Restated 1999 Equity Incentive Plan (formerly known as the Immunex Corporation 1999 Stock Option Plan) (the 1999 Plan) was assumed pursuant to the terms of the merger agreement between the Company and Immunex which was approved by the Company's stockholders in May 2002. The plan was previously approved by Immunex's shareholders. The 1999 Plan consists of two articles—Article I which governs awards granted prior to July 15, 2002 (the Restatement Date) and Article II which governs awards granted on or after the Restatement Date. As the terms of Stock Awards (as defined below) made pursuant to the 1999 Plan going forward are governed exclusively by Article II of the plan, the following is a description of the material provisions of Article II of the 1999 Plan. This description is qualified in its entirety by reference to the 1999 Plan itself, which was filed as an exhibit to the Company's Form S-8 dated July 16, 2002.

*Stock Subject to the 1999 Plan.* Subject to adjustments upon certain changes in the common stock, the shares available for issuance under the 1999 Plan upon exercise of the outstanding grants made pursuant to the 1999 Plan are Amgen's common stock. The number of shares authorized for issuance under the 1999 Plan is 19,273,852. Awards of (i) incentive stock options, (ii) nonqualified stock options, (iii) stock bonuses and (iv) rights to purchase restricted stock (Stock Award) may be granted under the 1999 Plan. Pursuant to the 1999 Plan, no incentive stock options may be granted under the 1999 Plan after February 22, 2009.

*Administration.* The 1999 Plan is administered by the Board of Directors. The Board of Directors has delegated administration of the 1999 Plan to the committees of the Board of Directors.



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*Eligibility.* Incentive stock options may be granted under the 1999 Plan to all employees (including officers) of Amgen or its affiliates. All employees (including officers) and directors of Amgen or its affiliates and consultants to Amgen or its affiliates, or trusts for the benefit of such an employee, director or consultant or his or her spouse or members of their immediate family ( permitted trusts ) designated by any such employee, director or consultant, are eligible to receive Stock Awards other than incentive stock options under the 1999 Plan. For incentive stock options granted under the 1999 Plan, the aggregate fair market value, determined at the time of grant, of the shares of common stock with respect to which such options are exercisable for the first time by an optionee during any calendar year (under all such plans of Amgen or any affiliate of Amgen) may not exceed \$100,000. No person may receive Stock Awards for more than 649,455 shares of common stock in any calendar year.

*Terms of Discretionary Options.* The following is a description of the permissible terms of options granted under the 1999 Plan, other than options awarded to non-employee directors which are described below under the heading *Terms of Non-Discretionary Options Awarded to Non-Employee Directors* - (the options described in this section are referred to as Discretionary Options ). Individual Discretionary Option grants may be more restrictive as to any or all of the permissible terms described below. The exercise price of Discretionary Options must be equal to at least 100% of the fair market value of the underlying stock on the date of the option grant. The exercise price of Discretionary Options must be paid either: (i) in cash at the time the option is exercised or (ii) at the discretion of the Board of Directors, (a) by delivery of common stock of Amgen that has been held for the period required to avoid a charge to Amgen's earnings, (b) pursuant to a deferred payment or other arrangement or (c) in any other form of legal consideration acceptable to the Board of Directors. Generally, optionees may designate certain specified trusts as beneficiaries with respect to Discretionary Options. In the absence of such a designation, after the death of the optionee, Discretionary Options shall be exercisable by the person(s) to whom the optionee's rights pass by will or by the laws of descent and distribution. Generally, during the lifetime of an optionee who is a natural person, only the optionee may exercise the Discretionary Option.

The maximum term of Discretionary Options is ten years. Absent death, disability or voluntary retirement in certain circumstances, Discretionary Options generally terminate three months after termination of the optionee's employment or relationship as a consultant or director of Amgen or any affiliate of Amgen. Individual options by their terms may provide for exercise within a longer period of time following termination of employment or the relationship as a director or consultant. Discretionary Options either become exercisable in cumulative increments or are exercisable in full immediately. The Board of Directors has the power to accelerate the beginning of the period during which an option may be exercised (the vesting date ). Options granted from the Restatement Date under the 1999 Plan typically vest at the rate of 25% per year during the optionee's employment or service as a consultant and expire seven years from the date of grant. The grants typically provide for the continuation of the vesting of options if the optionee voluntarily retires at or after age 65 or after age 55, after having been an employee of Amgen or its affiliate for at least ten consecutive years, and such retirement is not the result of permanent and total disability ( Voluntary Retirement ). Generally, if any optionee shall terminate his or her employment or relationship as a director or consultant with Amgen or an affiliate due to death or disability, then, in such event, the Discretionary Options granted to such employee, director or consultant or to the permitted trust of such employee, director or consultant which have not vested as of the date of such employee's, director's or consultant's termination for reasons of death or disability shall automatically be accelerated in full. In the case of Voluntary Retirement death or disability, Discretionary Options terminate the earlier of the termination date set forth in the applicable grant agreement or five years.

The Board of Directors also has the power to accelerate the time during which a Discretionary Option may be exercised. To the extent provided by the terms of a Discretionary Option, an optionee may satisfy any federal, state or local tax withholding obligations relating to the exercise of such option by (i) a cash payment upon exercise, (ii) by authorizing Amgen to withhold a portion of the stock otherwise issuable to the optionee, (iii) by delivering already-owned stock of Amgen or (iv) by a combination of these means.

*Terms of Non-Discretionary Options Awarded to Non-Employee Directors.* The Board of Directors may from time to time adopt award programs under the 1999 Plan providing for the grant of formula or

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non-discretionary Stock Awards to directors of Amgen who are not employees of Amgen or any affiliate. The terms and conditions of any such program shall be established by the Board of Directors in its sole discretion, subject to the terms and conditions of the 1999 Plan.

*Terms of Stock Bonuses and Purchases of Restricted Stock.* Stock bonuses and purchases of restricted stock shall be in such form and contain such terms and conditions as the Board of Directors shall deem appropriate. The following is a description of some of the permissible terms of stock bonuses and purchases of restricted stock under the 1999 Plan. Individual stock bonuses or purchases of restricted stock may be more restrictive as to any or all of the permissible terms described below or on different terms and conditions.

The purchase price under each stock purchase agreement shall be determined by the Board of Directors and may provide for a nominal purchase price or a purchase price that is less than fair market value of the underlying common stock on the award date. The Board of Directors may determine that eligible participants may be awarded stock pursuant to a stock bonus agreement in consideration for past services actually rendered to Amgen or for its benefit. The purchase price of stock acquired pursuant to a stock purchase agreement must be paid in accordance with the same terms as Discretionary Options. See *Terms of Discretionary Options*. Shares of common stock sold or awarded under the 1999 Plan may, but need not, be subject to a repurchase option in favor of the Company in accordance with a vesting schedule determined by the Board of Directors. To the extent provided by the terms of a stock bonus or restricted stock purchase agreement, a participant may satisfy any federal, state or local tax withholding obligations relating to the lapsing of a repurchase option or vesting of a stock bonus or a restricted stock award in the same manner as that of Discretionary Options. See *Terms of Discretionary Options*. Generally, rights under a stock bonus or restricted stock purchase agreement shall not be assignable by any participant under the 1999 Plan.

*Adjustment Provisions.* If there is any change in the stock subject to the 1999 Plan or subject to any Stock Award granted under the 1999 Plan (through merger, consolidation, reorganization, recapitalization, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other transaction not involving the receipt of consideration by the Company), the 1999 Plan and outstanding Stock Awards thereunder will be appropriately adjusted as to the class and the maximum number of shares subject to such plan, the maximum number of shares which may be granted to a participant in a calendar year, the class, number of shares and price per share of stock subject to such outstanding Stock Awards.

*Change in Control.* For purposes of the 1999 Plan, a Change in Control occurs at the following times: (i) upon the acquisition of beneficial ownership of 50% or more of either the then outstanding shares of common stock or the combined voting power of the Company's then outstanding voting securities entitled to vote generally in the election of directors; (ii) at the time individuals making up the Incumbent Board (as defined in the 1999 Plan) cease for any reason to constitute at least a majority of the Board; (iii) immediately prior to the consummation by the Company of a reorganization, merger or consolidation with respect to which persons who were the stockholders of the Company immediately prior to such transaction do not, immediately thereafter, own more than 50% of the combined voting power of the reorganized, merged or consolidated company's voting securities entitled to vote generally in the election of directors, or a liquidation or dissolution of the Company or the sale of all or substantially all of the assets of the Company or (iv) the occurrence of any other event which the Incumbent Board determines is a Change of Control. Upon the occurrence of a Change in Control, to the extent permitted by applicable law, the vesting and exercisability of any outstanding Stock Awards under the 1999 Plan will accelerate. Upon and following such acceleration, at the election of the holder of the Stock Award, the Stock Award may be (i) exercised with respect to stock options or, if the surviving or acquiring corporation agrees to assume the Stock Awards or substitute similar awards, (ii) assumed or (iii) replaced with substitute Stock Awards. Options not exercised, substituted or assumed prior to or upon the Change in Control shall be terminated.

*Duration, Amendment and Termination.* The Board of Directors may suspend or terminate the 1999 Plan without stockholder approval or ratification at any time or from time to time. No amendment, suspension or termination may impair the rights or obligations under any Stock Award except with the consent of the person to whom the Stock Award was granted.

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### *Amgen Inc. Amended and Restated 1999 Stock Incentive Plan*

The Amgen Inc. Amended and Restated 1999 Stock Incentive Plan (formerly known as the Abgenix, Inc. 1999 Nonstatutory Stock Option Plan, as amended) (the "Acquired 1999 Plan") was 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 Acquired 1999 Plan consists of two articles: Article I which governs awards granted prior to April 1, 2006 (the "Restatement Date") and Article II which governs awards granted on or after the Restatement Date. As the terms of option grants made pursuant to the Acquired 1999 Plan going forward are governed exclusively by Article II of the plan, the following is a description of the material provisions of Article II of the Acquired 1999 Plan. This description is qualified in its entirety by reference to the Acquired 1999 Plan itself, which was filed as an exhibit to the Company's Form S-8 dated April 3, 2006. Except as described below, the material provisions of Article II of the Acquired 1999 Plan are substantially similar to those of Article II of the 1999 Plan described above (reference to the 1999 Plan are deemed to be replaced with references to the Acquired 1999 Plan, as applicable):

The Acquired 1999 Plan will terminate on October 4, 2009;

Subject to adjustments upon certain changes in the common stock, the number of shares authorized for issuance under Article II of the Acquired 1999 Plan is 1,950,597;

No Stock Award may be granted to any person under Article II of the Acquired 1999 Plan who is an employee or director of or consultant to the Company or its affiliates (other than Abgenix) on the Restatement Date;

Under Article II of the Acquired 1999 Plan, no person may receive Stock Awards for more than 2,000,000 shares of common stock in any calendar year;

The purchase price under each stock purchase agreement shall be not less than fifty (50%) of the fair market value of the Company's Common Stock on the date such award is made; and

The Board of Directors shall have the power to condition the grant or vesting of stock bonuses and rights to purchase restricted stock under Article II of the Acquired 1999 Plan upon attainment of performance goals with respect to any one or more of the following business criteria with respect to the Company, any affiliate, any division, any operating unit or any product line: (i) return on capital, assets or equity, (ii) sales or revenue, (iii) net income, (iv) cash flow, (v) earnings per share, (vi) adjusted earnings or adjusted net income (as defined by the plan), (vii) working capital, (viii) total shareholder return, (ix) economic value or (x) product development, research, in-licensing, out-licensing, litigation, human resources, information services, manufacturing, manufacturing capacity, production, inventory, site development, plant, building or facility development, government relations, product market share, mergers, acquisitions or sales of assets or subsidiaries.

### *The Amgen Limited Sharesave Plan*

The Amgen Limited Sharesave Plan (the "Sharesave Plan") was adopted by the Board of Directors of Amgen Limited, the Company's indirectly wholly-owned U.K. subsidiary, and approved by the Board of Directors of the Company in October 1998. In general, the Sharesave Plan authorizes Amgen Limited to grant options to certain employees of Amgen Limited to buy shares of the Company's common stock during three-year offering periods through savings contributions and guaranteed company bonuses. The principal purposes of the Sharesave Plan are to provide the Company's eligible Amgen Limited employees with benefits comparable to those received by U.S. employees under the Company's Amended and Restated Employee Stock Purchase Plan through the granting of options. Under the Sharesave Plan, not more than 400,000 shares of Common Stock are authorized for issuance upon exercise of options subject to adjustment upon certain changes in the Company's Common Stock. The Sharesave Plan is administered by the Board of Directors of Amgen Limited. Options are generally exercisable during the six months following the three-year offering period at an exercise price determined by the Board of Directors, which

cannot be less than 80% of the market value of the Company's Common Stock determined in accordance with sections 272 and 273 of the U.K. Taxation of Chargeable Gains Act of 1992 (the "Act of 1992") and agreed for the



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purpose of the Sharesave Plan with the Shares Valuation Division (the Division ) of the Inland Revenue for the business day last preceding the date of invitation (the Exercise Price Determination Process ) at the commencement of the offering. Amounts in the Sharesave Plan are paid to the participants to the extent that options are not exercised.

### *Amgen Limited 2000 U.K. Company Employee Share Option Plan*

The Amgen Limited 2000 U.K. Company Employee Share Option Plan ( CSOP ) was adopted by the Board of Directors of Amgen Limited and approved by the Board of Directors of the Company in June 1999. The CSOP was established to provide stock option grants to employees of Amgen Limited in accordance with certain U.K. tax laws. The terms of the CSOP are, to the extent permitted under U.K. laws, consistent with the Company s 1999 Plan, as described above, with the exception of the following variations: (i) options cannot be granted to consultants, (ii) options cannot be transferred, (iii) options outstanding after an employee s death must be exercised within 12 months of the date of such death and (iv) the change in control provision is eliminated. No termination date has been specified for the CSOP. Although 300,000 shares of common stock are authorized for issuance under the CSOP, no shares have been issued under the CSOP.

### *The Amgen Technology Ireland Irish Tax Approved Share Plan*

The Amgen Technology Ireland Irish Tax Approved Share Plan (the Ireland Share Plan ) was adopted by the Board of Directors of Amgen Technology (Ireland) Limited ( ATI ), the Company s indirectly wholly-owned Ireland subsidiary, and approved by the Board of Directors of the Company in March 2007. In general, the Ireland Share Plan permits certain employees of Amgen Limited to buy shares of the Company s common stock during annual offering periods. The principal purpose of the Share Plan is to enable the Company s eligible ATI employees to use their bonus or salary to acquire shares of the Company s stock in a tax efficient manner, subject to certain terms and holding requirements under the plan. Under the Ireland Share Plan, not more than 600,000 shares of common stock are authorized for issuance subject to adjustment upon certain changes in the Company s common stock. The Ireland Share Plan is administered by the Board of Directors of ATI.

## **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 CERTAIN BENEFICIAL OWNERS AND MANAGEMENT in our Proxy Statement.

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

Information about security ownership of certain beneficial owners and management is incorporated by reference from the sections entitled CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS and CORPORATE GOVERNANCE Board Independence in our Proxy Statement.

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

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

**Table of Contents****PART IV****Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES***(a)1. Index to Financial Statements*

The following Consolidated Financial Statements are included herein:

|                                                                                                                          | <b>Page<br/>number</b> |
|--------------------------------------------------------------------------------------------------------------------------|------------------------|
| <u>Report of Independent Registered Public Accounting Firm</u>                                                           | F-1                    |
| <u>Consolidated Statements of Income for each of the three years in the period ended December 31, 2008</u>               | F-2                    |
| <u>Consolidated Balance Sheets at December 31, 2008 and 2007</u>                                                         | F-3                    |
| <u>Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2008</u> | F-4                    |
| <u>Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2008</u>           | F-5                    |
| <u>Notes to Consolidated Financial Statements</u>                                                                        | F-6 - F-52             |

*(a)2. Index to Financial Statement Schedules*

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

|                               | <b>Page<br/>number</b> |
|-------------------------------|------------------------|
| <u>II. Valuation Accounts</u> | F-53                   |

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*

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                 |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.1                | Restated Certificate of Incorporation (As Restated December 6, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)                              |
| 3.2                | Certificate of Amendment of the Restated Certificate of Incorporation (As Amended May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)    |
| 3.3                | Certificate of Correction of the Restated Certificate of Incorporation (As Corrected May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.) |
| 3.4*               | Certificate of Elimination of the Certificate of Designations of the Series A Junior Participating Preferred Stock (As Eliminated December 10, 2008).                                                                              |
| 3.5                | Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 14, 2007). (Filed as an exhibit to Form 8-K filed on February 20, 2007 and incorporated herein by reference.)                                          |
| 3.6                | Amendment to Amended and Restated Bylaws of Amgen Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)                                              |
| 3.7                | Second Amendment to Amended and Restated Bylaws of Amgen Inc. (Filed as an exhibit to Form 8-K on December 10, 2008 and incorporated herein by reference.)                                                                         |
| 4.1                |                                                                                                                                                                                                                                    |

## Edgar Filing: AMGEN INC - Form 10-K

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.)

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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 4.8 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% 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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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. Amended and Restated 1991 Equity Incentive Plan (As Amended and Restated October 1, 2008). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                                                                       |
| 10.2+*             | Amgen Inc. Amended and Restated Director Equity Incentive Program (As Amended and Restated December 10, 2007) (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.), forms of Stock Option Grant Agreement and Restricted Stock Unit Agreement (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.) and Forms of Stock Option Grant Agreement and Restricted Stock Unit Agreement for Ex-U.S. Grants (filed herewith). |
| 10.3+              | Amgen Inc. Amended and Restated 1999 Equity Incentive Plan (As Amended and Restated of October 1, 2008). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                                                                    |
| 10.4+              | Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (As Amended and Restated October 1, 2008). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                                                                        |
| 10.5+              | Forms of Stock Option Grant Agreement and Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 1991 Equity Incentive Plan, the Amgen Inc. Amended and Restated 1999 Equity Incentive Plan and the Amgen Inc. Amended and Restated 1999 Incentive Stock Plan. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)                                                                                                                                                             |
| 10.6+              | Amgen Inc. Amended and Restated Employee Stock Purchase Plan. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                                                                                                                      |
| 10.7+              | First Amendment to the Amgen Inc. Amended and Restated Employee Stock Purchase Plan, effective July 12, 2005. (Filed as an exhibit to Form 8-K on July 14, 2005 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                                                                                                            |
| 10.8+              | Second Amendment to the Amgen Inc. Amended and Restated Employee Stock Purchase Plan, effective January 1, 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.)                                                                                                                                                                                                                                                                                                                               |

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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                   |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.9+              | Amgen Supplemental Retirement Plan (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)                        |
| 10.10+             | Amgen Inc. Change of Control Severance Plan. (Filed as an exhibit to Form 10-K for the year ended December 31, 1998 on March 16, 1999 and incorporated herein by reference.)                                                                         |
| 10.11+             | First Amendment to Amgen Inc. Change of Control Severance Plan (As Amended May 10, 2000). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)                             |
| 10.12+             | Second Amendment to the Amgen Inc. Change in Control Severance Plan (As Amended October 16, 2001). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2001 on October 26, 2001 and incorporated herein by reference.)             |
| 10.13+             | Third Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended January 1, 2004). (Filed as an exhibit to Form 10-K for the year ended December 31, 2004 on March 9, 2005 and incorporated herein by reference.)                      |
| 10.14+             | Fourth Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended June 1, 2004). (Filed as an exhibit to Form 10-K for the year ended December 31, 2004 on March 9, 2005 and incorporated herein by reference.)                        |
| 10.15+             | Fifth Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended December 6, 2004). (Filed as an exhibit to Form 8-K on December 9, 2004 and incorporated herein by reference.)                                                        |
| 10.16+             | Sixth Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended May 10, 2006). (Filed as an exhibit to Form 8-K on May 16, 2006 and incorporated herein by reference.)                                                                |
| 10.17+             | Seventh Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended October 4, 2006). (Filed as exhibit to Form 8-K on October 6, 2006 and incorporated herein by reference.)                                                           |
| 10.18+             | Eighth Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended December 15, 2006). (Filed as an exhibit to Form 10-K for the year ended December 31, 2006 on February 28, 2007 and incorporated herein by reference.)               |
| 10.19+*            | Amendment and Restatement of the Amgen Change of Control Severance Plan (As Amended December 9, 2008).                                                                                                                                               |
| 10.20+             | 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.)                      |
| 10.21+             | 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.)        |
| 10.22+             | Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)             |
| 10.23+             | Amended and Restated Amgen Inc. Performance Award Program (As Amended and Restated effective October 1, 2008.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.) |
| 10.24+             | Form of Performance Unit Agreement. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)                                                                                    |

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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.25+             | 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.)                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 10.26+             | Restricted Stock Purchase Agreement, dated March 3, 2003, between Amgen Inc. and Brian M. McNamee. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2003 on July 30, 2003 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 10.27+             | Agreement, dated February 11, 2004, between Amgen Inc. and David J. Scott. (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              | 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.)                                                                                                                                                                                                                                                                                                                                              |
| 10.29              | 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.)                                                                                                                                                                                                                                                                                                                                                                                                     |
| 10.30              | 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.)                                                                                                                                                                                                                                                                                                               |
| 10.31              | 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.) |
| 10.32              | 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.)                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 10.33              | 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.)                                                                                                                                                                                                                                                                                                                                                                                    |
| 10.34              | 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.)                                                                                                                                                                                                                                                                                                                                  |
| 10.35              | 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.)                                                                                                                                                                                                                                                                                                                                                        |
| 10.36              | 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.)                                                                                                                                                                                                                                                                      |

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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.37              | 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.)                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 10.38              | G-CSF United States License Agreement, dated June 1, 1987 (effective July 1, 1986), Amendment No. 1, dated October 20, 1988, and Amendment No. 2, dated October 17, 1991 (effective November 13, 1990), between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                                      |
| 10.39              | 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.) |
| 10.40              | Enbrel® Supply Agreement among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, dated as of November 5, 1998 (with certain confidential information deleted therefrom). (Filed as an exhibit to the Immunex Corporation Annual Report on Form 10-K for the year ended December 31, 1998 on March 23, 1998 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                        |
| 10.41              | Amendment No. 1 to the Enbrel® Supply Agreement, dated June 27, 2000, among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, (with certain confidential information deleted therefrom). (Filed as an exhibit to the Immunex Corporation Form 10-Q for the quarter ended June 30, 2000 on August 11, 2000 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                         |
| 10.42              | Amendment No. 2 to the Enbrel® Supply Agreement, dated June 3, 2002, among Immunex Corporation, Wyeth (formerly known as American Home Products Corporation) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2002 on August 13, 2002 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                         |
| 10.43              | Amendment No. 1 to Amendment No. 2 to the Enbrel® Supply Agreement, dated June 23, 2008, among Immunex Corporation, Wyeth (formerly American Home Products Corporation ) and Boehringer Ingelheim Pharma KG (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2008 on August 8, 2008 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                                                                         |
| 10.44              | Amendment No. 3 to the Enbrel® Supply Agreement, dated December 18, 2002, among Immunex Corporation, Wyeth (formerly, American Home Products Corporation ) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2002 on March 10, 2003 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                           |
| 10.45              | Amendment No. 4 to the Enbrel® Supply Agreement, dated May 21, 2004, among Immunex Corporation, Wyeth (formerly, American Home Products Corporation ) and Boehringer Ingelheim Pharma KG. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2005 on August 8, 2005 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                                                                                           |
| 10.46              | Amendment No. 5 to the Enbrel® Supply Agreement, dated August 30, 2005, among Immunex Corporation, Wyeth (formerly, American Home Products Corporation ) and Boehringer Ingelheim Pharma KG. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2005 on November 9, 2005 and incorporated herein by reference.)                                                                                                                                                                                                                                                                                                                                                 |

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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                        |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.47              | Amendment No. 6 to the Enbrel® Supply Agreement, dated November 27, 2007, among Immunex Corporation, Wyeth (formerly, American Home Products Corporation ) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom) (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)                                                |
| 10.48              | Amendment No. 2 to Amendment No. 6, dated August 26, 2008, to the Enbrel® Supply Agreement, dated November 27, 2007, among Immunex Corporation, Wyeth (formerly, American Home Products Corporation ) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.) |
| 10.49              | 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.)                                                                  |
| 10.50              | 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.)                                                                               |
| 10.51              | 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.)                                                                                     |
| 10.52              | 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.)                                                                                                                                                                            |
| 10.53              | 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.)                                                                                              |
| 10.54              | 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.)                                                                                                        |
| 10.55              | 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.)                                                                                                            |
| 10.56              | 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.)                                                                                   |
| 10.57              | 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.)                                                                                                                                                           |

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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                               |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.58              | Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International for warrants expiring in 2013. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)                                                                                                                  |
| 10.59              | 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.)                                                                                                   |
| 10.60              | 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.)                                                           |
| 10.61              | 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.)                                                                                                                                                                       |
| 10.62              | 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.)                                                                                                     |
| 10.63              | 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.) |
| 10.64              | 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.)                                                               |
| 10.65              | 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.)                                                                         |
| 10.66              | 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.)                                                                                                    |
| 10.67              | 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.)                                                                                         |
| 10.68              | 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.)                                                                |
| 10.69              | 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.)                                                                                                               |

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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                     |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.70              | 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.) |
| 10.71*             | Master Services Agreement, dated October 22, 2008, between Amgen Inc. and International Business Machines Corporation (with certain confidential information deleted therefrom).                                                                                                                                                                       |
| 10.72*             | Integrated Facilities Management Services Agreement, dated February 4, 2009 between Amgen Inc. and Jones Lang LaSalle Americas, Inc (with certain confidential information deleted therefrom).                                                                                                                                                         |
| 21*                | Subsidiaries of the Company.                                                                                                                                                                                                                                                                                                                           |
| 23                 | Consent of Independent Registered Public Accounting Firm. The consent is set forth on pages 118 and 119 of this Annual Report on Form 10-K.                                                                                                                                                                                                            |
| 24                 | Power of Attorney. The Power of Attorney is set forth on pages 116 and 117 of this Annual Report on Form 10-K.                                                                                                                                                                                                                                         |
| 31*                | Rule 13a-14(a) Certifications.                                                                                                                                                                                                                                                                                                                         |
| 32**               | Section 1350 Certifications.                                                                                                                                                                                                                                                                                                                           |

(\* = filed herewith)

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

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

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**SIGNATURES**

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

AMGEN INC.  
(Registrant)

Date: 02/27/09

By:

/s/ ROBERT A. BRADWAY  
**Robert A. Bradway**  
**Executive Vice President**  
**and Chief Financial Officer**

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**Table of Contents****EXHIBIT 24****POWER OF ATTORNEY**

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints 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:

| <b>Signature</b>                                              | <b>Title</b>                                                                                             | <b>Date</b> |
|---------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|-------------|
| /s/ KEVIN W. SHARER<br><br><b>Kevin W. Sharer</b>             | Chairman of the Board, Chief Executive Officer and President, and Director (Principal Executive Officer) | 02/27/09    |
| /s/ ROBERT A. BRADWAY<br><br><b>Robert A. Bradway</b>         | Executive Vice President and Chief Financial Officer (Principal Financial Officer)                       | 02/27/09    |
| /s/ MICHAEL A. KELLY<br><br><b>Michael A. Kelly</b>           | Vice President Finance and Chief Accounting Officer (Principal Accounting Officer)                       | 02/27/09    |
| /s/ DAVID BALTIMORE<br><br><b>David Baltimore</b>             | Director                                                                                                 | 02/27/09    |
| /s/ FRANK J. BIONDI, JR.<br><br><b>Frank J. Biondi, Jr.</b>   | Director                                                                                                 | 02/27/09    |
| /s/ JERRY D. CHOATE<br><br><b>Jerry D. Choate</b>             | Director                                                                                                 | 02/27/09    |
| /s/ VANCE D. COFFMAN<br><br><b>Vance D. Coffman</b>           | Director                                                                                                 | 02/27/09    |
| /s/ FRANÇOIS DE CARBONNEL<br><br><b>François de Carbonnel</b> | Director                                                                                                 | 02/27/09    |
| /s/ FREDERICK W. GLUCK<br><br><b>Frederick W. Gluck</b>       | Director                                                                                                 | 02/24/09    |
| /s/ FRANK C. HERRINGER                                        | Director                                                                                                 | 02/27/09    |

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**Frank C. Herringer**

/s/ GILBERT S. OMENN

Director

02/27/09

**Gilbert S. Omenn**

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| <b>Signature</b>                                            | <b>Title</b> | <b>Date</b> |
|-------------------------------------------------------------|--------------|-------------|
| /s/ JUDITH C. PELHAM<br><br><b>Judith C. Pelham</b>         | Director     | 02/27/09    |
| /s/ J. PAUL REASON<br><br><b>J. Paul Reason</b>             | Director     | 02/27/09    |
| /s/ LEONARD D. SCHAEFFER<br><br><b>Leonard D. Schaeffer</b> | Director     | 02/27/09    |

**Table of Contents****EXHIBIT 23****CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 33-5111) pertaining to the 1984 Stock Option Plan, 1981 Incentive Stock Option Plan and Nonqualified Stock Option Plan of Amgen Inc., in the Registration Statement (Form S-8 No. 33-24013) pertaining to the Amended and Restated 1988 Stock Option Plan of Amgen Inc., in the Registration Statement (Form S-8 No. 33-39183) pertaining to the Amended and Restated Employee Stock Purchase Plan, in the Registration Statement (Form S-8 No. 33-39104) pertaining to the Amended and Restated Amgen Retirement and Savings Plan, in the Registration Statements (Form S-3/S-8 No. 33-29791 and Form S-8 No. 33-42501) pertaining to the Amended and Restated 1987 Directors' Stock Option Plan, in the Registration Statement (Form S-8 No. 33-42072) pertaining to the Amgen Inc. Amended and Restated 1991 Equity Incentive Plan, in the Registration Statement (Form S-8 No. 33-47605) pertaining to the Retirement and Savings Plan for Amgen Puerto Rico, Inc., in the Registration Statement (Form S-8 No. 333-44727) pertaining to the Amgen Inc. 1997 Special Non-Officer Equity Incentive Plan, in the Registration Statement (Form S-3 No. 333-19931) of Amgen Inc., in the Registration Statement (Form S-3 No. 333-40405) of Amgen Inc., in the Registration Statement (Form S-8 No. 333-62735) pertaining to the Amgen Inc. Amended and Restated 1997 Special Non-Officer Equity Incentive Plan, in the 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, in the Registration Statement (Form S-8 No. 333-74585) pertaining to the Amgen Limited Sharesave Plan, in the Registration Statement (Form S-8 No. 333-81284) pertaining to the Amgen Nonqualified Deferred Compensation Plan, in the Registration Statement (Form S-8 No. 333-56672) pertaining to the Amended and Restated 1997 Special Non-Officer Equity Incentive Plan, in the Registration Statement (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, the Amended and Restated 1988 Stock Option Plan of Amgen Inc., and the Amended and Restated 1987 Directors' Stock Option Plan, in the Registration Statement (Form S-8 No. 333-83824) pertaining to the Amgen Inc. Amended and Restated 1997 Special Non-Officer Equity Incentive Plan, in the Registration Statement (Form S-3 No. 333-88834) pertaining to Amgen Inc.'s Liquid Yield Option Notes, in the Registration Statement (Form S-3 No. 333-92450 and Amendment No. 1 thereto) pertaining to Amgen Inc.'s Common Stock, in the 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), the Amgen Inc. Amended and Restated 1999 Employee Stock Purchase Plan (formerly known as the Immunex Corporation 1999 Employee Stock Purchase Plan), the Immunex Corporation Stock Option Plan for Nonemployee Directors, and the Amgen Inc. Profit Sharing 401(k) Plan and Trust (formerly known as the Immunex Corporation Profit Sharing 401(k) Plan and Trust), in the Registration Statement (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, in the 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), the Tularik Inc. 1991 Stock Plan, as amended, the Tularik Inc. Amended and Restated 1997 Non-Employee Directors' Stock Option Plan, as amended, the Amgen Salary Savings Plan (formerly known as Tularik Salary Savings Plan), a Nonstatutory Stock Option Agreement, in the 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, in the 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) Abgenix, Inc. 1998 Director Option Plan, as amended and restated Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (formerly known as Abgenix, Inc. 1999 Nonstatutory Stock Option Plan, as amended and restated), in the Registration Statement (Form S-8 No. 333-133002) pertaining to the Amgen Inc.

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Amended and Restated 1996 Incentive Stock Plan (formerly known as Abgenix, Inc. 1996 Incentive Stock Plan, as amended and restated) Abgenix, Inc. 1998 Director Option Plan, as amended and restated Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (formerly known as Abgenix, Inc. 1999 Nonstatutory Stock Option Plan, as amended and restated), in the 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), in the Registration Statement (Form S-8 No. 333-141304) pertaining to the Amgen Technology Ireland Irish Tax Approved Share Plan, in the Registration Statement (Form S-8 No. 333-144579) pertaining to the Amgen Inc. Amended and Restated 1991 Equity Incentive Plan, in the Registration Statement (Form S-8 No. 333-144580) pertaining to the Retirement and Savings Plan for Amgen Manufacturing, Limited, in the Registration Statement (Form S-8 No. 333-144581) pertaining to the Amgen Retirement and Savings Plan, in the Registration Statement (Form S-8 No. 333-144678 ) pertaining to the Amgen Inc. Assumed Ilypsa, Inc. Stock Plan (formerly known as the Ilypsa Inc. 2003 Stock Plan), in the Registration Statement (Form S-8, Registration No. 33-39104) pertaining to the Amgen Retirement and Savings Plan, in the Registration Statement (Form S-8 No. 033-47605) pertaining to the Retirement and Savings Plan for Amgen Manufacturing, Limited, in the 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 in the Registration Statement (Form S-3 No. 333-150290) relating to debt securities, common stock, preferred stock, warrants to purchase debt securities, common stock, preferred stock or depositary shares, rights to purchase common stock or preferred stock, securities purchase contracts, securities purchase units and depositary shares of Amgen Inc. and in the related Prospectuses, of our reports dated February 23, 2009, with respect to the consolidated financial statements and schedule of Amgen Inc., and the effectiveness of internal control over financial reporting of Amgen Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2008.

/s/ Ernst & Young LLP

Los Angeles, California

February 24, 2009

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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, 2008 and 2007, and the related Consolidated Statements of Income, Stockholders' Equity, and Cash Flows for each of the three years in the period ended December 31, 2008. 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, 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, 2008, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 23, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California

February 23, 2009

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**Table of Contents****AMGEN INC.****CONSOLIDATED STATEMENTS OF INCOME****Years ended December 31, 2008, 2007 and 2006****(In millions, except per share data)**

|                                                                                     | <b>2008</b>     | <b>2007</b>     | <b>2006</b>     |
|-------------------------------------------------------------------------------------|-----------------|-----------------|-----------------|
| <b>Revenues:</b>                                                                    |                 |                 |                 |
| Product sales                                                                       | \$ 14,687       | \$ 14,311       | \$ 13,858       |
| Other revenues                                                                      | 316             | 460             | 410             |
| <b>Total revenues</b>                                                               | <b>15,003</b>   | <b>14,771</b>   | <b>14,268</b>   |
| <b>Operating expenses:</b>                                                          |                 |                 |                 |
| Cost of sales (excludes amortization of acquired intangible assets presented below) | 2,296           | 2,548           | 2,095           |
| Research and development                                                            | 3,030           | 3,266           | 3,366           |
| Selling, general and administrative                                                 | 3,789           | 3,361           | 3,366           |
| Amortization of acquired intangible assets                                          | 294             | 298             | 370             |
| Write-off of acquired in-process research and development                           |                 | 590             | 1,231           |
| Other charges                                                                       | 380             | 728             |                 |
| <b>Total operating expenses</b>                                                     | <b>9,789</b>    | <b>10,791</b>   | <b>10,428</b>   |
| <b>Operating income</b>                                                             | <b>5,214</b>    | <b>3,980</b>    | <b>3,840</b>    |
| <b>Other income (expense):</b>                                                      |                 |                 |                 |
| Interest and other income, net                                                      | 352             | 309             | 309             |
| Interest expense, net                                                               | (316)           | (328)           | (129)           |
| <b>Total other income (expense)</b>                                                 | <b>36</b>       | <b>(19)</b>     | <b>180</b>      |
| <b>Income before income taxes</b>                                                   | <b>5,250</b>    | <b>3,961</b>    | <b>4,020</b>    |
| <b>Provision for income taxes</b>                                                   | <b>1,054</b>    | <b>795</b>      | <b>1,070</b>    |
| <b>Net income</b>                                                                   | <b>\$ 4,196</b> | <b>\$ 3,166</b> | <b>\$ 2,950</b> |
| <b>Earnings per share:</b>                                                          |                 |                 |                 |
| Basic                                                                               | \$ 3.92         | \$ 2.83         | \$ 2.51         |
| Diluted                                                                             | \$ 3.90         | \$ 2.82         | \$ 2.48         |
| <b>Shares used in calculation of earnings per share:</b>                            |                 |                 |                 |
| Basic                                                                               | 1,070           | 1,117           | 1,176           |
| Diluted                                                                             | 1,075           | 1,123           | 1,190           |

See accompanying notes.

**Table of Contents****AMGEN INC.****CONSOLIDATED BALANCE SHEETS****December 31, 2008 and 2007****(In millions, except per share data)**

|                                                                                                                                                     | <b>2008</b>      | <b>2007</b>      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------|------------------|
| <b>ASSETS</b>                                                                                                                                       |                  |                  |
| Current assets:                                                                                                                                     |                  |                  |
| Cash and cash equivalents                                                                                                                           | \$ 1,774         | \$ 2,024         |
| Marketable securities                                                                                                                               | 7,778            | 5,127            |
| Trade receivables, net                                                                                                                              | 2,073            | 2,101            |
| Inventories                                                                                                                                         | 2,075            | 2,091            |
| Other current assets                                                                                                                                | 1,521            | 1,698            |
| Total current assets                                                                                                                                | 15,221           | 13,041           |
| Property, plant and equipment, net                                                                                                                  | 5,879            | 5,941            |
| Intangible assets, net                                                                                                                              | 2,988            | 3,332            |
| Goodwill                                                                                                                                            | 11,339           | 11,240           |
| Other assets                                                                                                                                        | 1,016            | 1,085            |
|                                                                                                                                                     | <b>\$ 36,443</b> | <b>\$ 34,639</b> |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>                                                                                                         |                  |                  |
| Current liabilities:                                                                                                                                |                  |                  |
| Accounts payable                                                                                                                                    | \$ 504           | \$ 378           |
| Accrued liabilities                                                                                                                                 | 3,382            | 3,801            |
| Current portion of other long-term debt                                                                                                             | 1,000            | 2,000            |
| Total current liabilities                                                                                                                           | 4,886            | 6,179            |
| Convertible notes                                                                                                                                   | 5,081            | 5,080            |
| Other long-term debt                                                                                                                                | 4,095            | 4,097            |
| Other non-current liabilities                                                                                                                       | 1,995            | 1,414            |
| Commitments and contingencies                                                                                                                       |                  |                  |
| Stockholders' equity:                                                                                                                               |                  |                  |
| Common stock and additional paid-in capital; \$0.0001 par value; 2,750 shares authorized; outstanding 1,047 shares in 2008 and 1,087 shares in 2007 | 25,527           | 24,976           |
| Accumulated deficit                                                                                                                                 | (5,258)          | (7,160)          |
| Accumulated other comprehensive income                                                                                                              | 117              | 53               |
| Total stockholders' equity                                                                                                                          | 20,386           | 17,869           |
|                                                                                                                                                     | <b>\$ 36,443</b> | <b>\$ 34,639</b> |

See accompanying notes.

**Table of Contents****AMGEN INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY****Years ended December 31, 2008, 2007 and 2006****(In millions)**

|                                                                                 | <b>Number<br/>of shares<br/>of common<br/>stock</b> | <b>Common<br/>stock and<br/>additional<br/>paid-in capital</b> | <b>Accumulated<br/>deficit</b> | <b>Accumulated<br/>other<br/>comprehensive<br/>income</b> | <b>Total</b> |
|---------------------------------------------------------------------------------|-----------------------------------------------------|----------------------------------------------------------------|--------------------------------|-----------------------------------------------------------|--------------|
| Balance at December 31, 2005                                                    | 1,224                                               | \$ 23,561                                                      | \$ (3,132)                     | \$ 22                                                     | \$ 20,451    |
| Comprehensive income:                                                           |                                                     |                                                                |                                |                                                           |              |
| Net income                                                                      |                                                     |                                                                | 2,950                          |                                                           | 2,950        |
| Other comprehensive loss, net of tax:                                           |                                                     |                                                                |                                |                                                           |              |
| Unrealized losses on securities and hedges, net of reclassification adjustments |                                                     |                                                                |                                | (49)                                                      | (49)         |
| Foreign currency translation adjustments                                        |                                                     |                                                                |                                | 39                                                        | 39           |
| Total other comprehensive loss                                                  |                                                     |                                                                |                                |                                                           | (10)         |
| Comprehensive income                                                            |                                                     |                                                                |                                |                                                           | 2,940        |
| Issuance of common stock in connection with the Company's equity award programs | 12                                                  | 528                                                            |                                |                                                           | 528          |
| Fair value of options assumed from acquisitions                                 |                                                     | 61                                                             |                                |                                                           | 61           |
| Stock-based awards                                                              |                                                     | 335                                                            |                                |                                                           | 335          |
| Tax benefits related to employee stock options                                  |                                                     | 58                                                             |                                |                                                           | 58           |
| Convertible note hedge and warrants                                             |                                                     | (284)                                                          |                                |                                                           | (284)        |
| Reclassification of performance award program to liabilities                    |                                                     | (104)                                                          |                                |                                                           | (104)        |
| Repurchases of common stock                                                     | (70)                                                |                                                                | (5,021)                        |                                                           | (5,021)      |
| Balance at December 31, 2006                                                    | 1,166                                               | 24,155                                                         | (5,203)                        | 12                                                        | 18,964       |
| Comprehensive income:                                                           |                                                     |                                                                |                                |                                                           |              |
| Net income                                                                      |                                                     |                                                                | 3,166                          |                                                           | 3,166        |
| Other comprehensive income, net of tax:                                         |                                                     |                                                                |                                |                                                           |              |
| Unrealized gains on securities and hedges, net of reclassification adjustments  |                                                     |                                                                |                                | 27                                                        | 27           |
| Foreign currency translation adjustments                                        |                                                     |                                                                |                                | 14                                                        | 14           |
| Total other comprehensive income                                                |                                                     |                                                                |                                |                                                           | 41           |
| Comprehensive income                                                            |                                                     |                                                                |                                |                                                           | 3,207        |
| Issuance of common stock in connection with the Company's equity award programs | 8                                                   | 333                                                            |                                |                                                           | 333          |
| Stock-based awards                                                              |                                                     | 462                                                            |                                |                                                           | 462          |
| Tax benefits related to employee stock options                                  |                                                     | 26                                                             |                                |                                                           | 26           |
| Repurchases of common stock                                                     | (87)                                                |                                                                | (5,123)                        |                                                           | (5,123)      |
| Balance at December 31, 2007                                                    | 1,087                                               | 24,976                                                         | (7,160)                        | 53                                                        | 17,869       |
| Comprehensive income:                                                           |                                                     |                                                                |                                |                                                           |              |
| Net income                                                                      |                                                     |                                                                | 4,196                          |                                                           | 4,196        |
| Other comprehensive income, net of tax:                                         |                                                     |                                                                |                                |                                                           |              |

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|                                                                                 |       |           |            |        |           |
|---------------------------------------------------------------------------------|-------|-----------|------------|--------|-----------|
| Unrealized gains on securities and hedges, net of reclassification adjustments  |       |           |            | 105    | 105       |
| Foreign currency translation adjustments                                        |       |           |            | (34)   | (34)      |
| Other                                                                           |       |           |            | (7)    | (7)       |
| Total other comprehensive income                                                |       |           |            |        | 64        |
| Comprehensive income                                                            |       |           |            |        | 4,260     |
| Issuance of common stock in connection with the Company's equity award programs | 5     | 198       |            |        | 198       |
| Stock-based awards                                                              |       | 267       |            |        | 267       |
| Tax benefits related to employee stock options                                  |       | 86        |            |        | 86        |
| Repurchases of common stock                                                     | (45)  |           | (2,294)    |        | (2,294)   |
| Balance at December 31, 2008                                                    | 1,047 | \$ 25,527 | \$ (5,258) | \$ 117 | \$ 20,386 |

See accompanying notes.

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**Table of Contents****AMGEN INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****Years ended December 31, 2008, 2007 and 2006****(In millions)**

|                                                                                                   | <b>2008</b> | <b>2007</b> | <b>2006</b> |
|---------------------------------------------------------------------------------------------------|-------------|-------------|-------------|
| Cash flows from operating activities:                                                             |             |             |             |
| Net income                                                                                        | \$ 4,196    | \$ 3,166    | \$ 2,950    |
| Depreciation and amortization                                                                     | 1,073       | 1,202       | 963         |
| Write-off of acquired in-process research and development                                         |             | 590         | 1,231       |
| Stock-based compensation expense                                                                  | 262         | 263         | 403         |
| Deferred income taxes                                                                             | (46)        | 136         | (540)       |
| Property, plant and equipment impairments                                                         | 59          | 404         |             |
| Other items, net                                                                                  | 17          | 81          | (81)        |
| Changes in operating assets and liabilities, net of acquisitions:                                 |             |             |             |
| Trade receivables, net                                                                            | 65          | 38          | (355)       |
| Inventories                                                                                       | (59)        | (109)       | (561)       |
| Other current assets                                                                              | 15          | (119)       | (6)         |
| Accounts payable                                                                                  | 95          | (181)       | (24)        |
| Accrued income taxes                                                                              | 14          | (810)       | 581         |
| Other accrued liabilities                                                                         | (30)        | 688         | 790         |
| Deferred revenue                                                                                  | 327         | 52          | 38          |
| Net cash provided by operating activities                                                         | 5,988       | 5,401       | 5,389       |
| Cash flows from investing activities:                                                             |             |             |             |
| Purchases of property, plant and equipment                                                        | (672)       | (1,267)     | (1,218)     |
| Cash paid for acquisitions, net of cash acquired                                                  | (56)        | (697)       | (2,167)     |
| Purchases of marketable securities                                                                | (10,345)    | (5,579)     | (5,386)     |
| Proceeds from sales of marketable securities                                                      | 6,762       | 5,073       | 3,065       |
| Proceeds from maturities of marketable securities                                                 | 1,018       | 454         | 785         |
| Other                                                                                             | 128         | 24          | (210)       |
| Net cash used in investing activities                                                             | (3,165)     | (1,992)     | (5,131)     |
| Cash flows from financing activities:                                                             |             |             |             |
| Repurchases of common stock                                                                       | (2,268)     | (5,100)     | (2,000)     |
| Repayment of debt                                                                                 | (2,000)     | (1,840)     | (653)       |
| Proceeds from issuance of debt                                                                    | 991         | 3,982       |             |
| Proceeds from issuance of convertible notes and related transactions, net                         |             |             | 439         |
| Proceeds from issuance of warrants                                                                |             |             | 774         |
| Net proceeds from issuance of common stock in connection with the Company's equity award programs | 155         | 277         | 528         |
| Other                                                                                             | 49          | 13          | 97          |
| Net cash used in financing activities                                                             | (3,073)     | (2,668)     | (815)       |
| (Decrease) increase in cash and cash equivalents                                                  | (250)       | 741         | (557)       |
| Cash and cash equivalents at beginning of year                                                    | 2,024       | 1,283       | 1,840       |

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|                                          |          |          |          |
|------------------------------------------|----------|----------|----------|
| Cash and cash equivalents at end of year | \$ 1,774 | \$ 2,024 | \$ 1,283 |
|------------------------------------------|----------|----------|----------|

See accompanying notes.

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**AMGEN INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2008**

**1. Summary of significant accounting policies**

*Business*

Amgen Inc., including its subsidiaries, ( Amgen ) is a global biotechnology company that discovers, develops, manufactures and markets human therapeutics based on advances in cellular and molecular biology.

*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.

*Fair value measurement*

The Company adopted the provisions of the Financial Accounting Standards Board's ( FASB's ) Statement of Financial Accounting Standards ( SFAS ) No. 157, *Fair Value Measurements* ( SFAS 157 ), effective January 1, 2008, for its financial assets and liabilities. The FASB delayed the effective date of SFAS 157 until January 1, 2009, with respect to the fair value measurement requirements for non-financial assets and liabilities that are not remeasured on a recurring basis. Under this standard, fair value is 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 (see Note 13, *Fair values* ).

*Cash equivalents*

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

*Available-for-sale securities*

We consider our investment portfolio and marketable equity investments available-for-sale as defined in SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Accordingly, these investments are recorded at fair value, as discussed above. For the years ended December 31, 2008, 2007 and 2006, realized gains totaled \$124 million, \$17 million and \$23 million, respectively, and realized losses totaled \$49 million, \$20 million and \$25 million, respectively. The cost of securities sold is based on the specific identification method.

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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):

|                                                                       | <b>Amortized<br/>cost</b> | <b>Gross<br/>unrealized<br/>gains</b> | <b>Gross<br/>unrealized<br/>losses</b> | <b>Estimated<br/>fair value</b> |
|-----------------------------------------------------------------------|---------------------------|---------------------------------------|----------------------------------------|---------------------------------|
| <b>December 31, 2008</b>                                              |                           |                                       |                                        |                                 |
| 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                             |
| Other short-term interest backed securities <sup>(1)</sup>            | 2,126                     |                                       |                                        | 2,126                           |
| <b>Total debt securities</b>                                          | <b>9,358</b>              | <b>170</b>                            | <b>(83)</b>                            | <b>9,445</b>                    |
| Equity securities                                                     | 65                        |                                       | (8)                                    | 57                              |
|                                                                       | \$ 9,423                  | \$ 170                                | \$ (91)                                | \$ 9,502                        |

<sup>(1)</sup> Primarily comprised of money market funds whose underlying securities were U.S. treasury and agency obligations.

|                                              | <b>Amortized<br/>cost</b> | <b>Gross<br/>unrealized<br/>gains</b> | <b>Gross<br/>unrealized<br/>losses</b> | <b>Estimated<br/>fair value</b> |
|----------------------------------------------|---------------------------|---------------------------------------|----------------------------------------|---------------------------------|
| <b>December 31, 2007</b>                     |                           |                                       |                                        |                                 |
| Type of security:                            |                           |                                       |                                        |                                 |
| U.S. Treasury securities                     | \$ 1,257                  | \$ 33                                 | \$                                     | \$ 1,290                        |
| Obligations of U.S. government agencies      | 1,520                     | 31                                    |                                        | 1,551                           |
| Corporate debt securities                    | 1,789                     | 15                                    | (16)                                   | 1,788                           |
| Mortgage and asset backed securities         | 375                       | 1                                     | (1)                                    | 375                             |
| Other short-term interest bearing securities | 1,709                     |                                       |                                        | 1,709                           |
| <b>Total debt securities</b>                 | <b>6,650</b>              | <b>80</b>                             | <b>(17)</b>                            | <b>6,713</b>                    |
| Equity securities                            | 80                        |                                       | (1)                                    | 79                              |
|                                              | \$ 6,730                  | \$ 80                                 | \$ (18)                                | \$ 6,792                        |

| <b>Contractual maturity</b>                 | <b>December 31,</b> |              |
|---------------------------------------------|---------------------|--------------|
|                                             | <b>2008</b>         | <b>2007</b>  |
| Maturing in one year or less                | \$ 3,179            | \$ 2,269     |
| Maturing after one year through three years | 3,724               | 2,611        |
| Maturing after three years                  | 2,542               | 1,833        |
| <b>Total debt securities</b>                | <b>9,445</b>        | <b>6,713</b> |

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|                                                      |                     |             |
|------------------------------------------------------|---------------------|-------------|
| Equity securities                                    | 57                  | 79          |
|                                                      | \$ 9,502            | \$ 6,792    |
|                                                      |                     |             |
| <b>Classification in Consolidated Balance Sheets</b> | <b>December 31,</b> | <b>2007</b> |
|                                                      | <b>2008</b>         |             |
| Cash and cash equivalents                            | \$ 1,774            | \$ 2,024    |
| Marketable securities                                | 7,778               | 5,127       |
| Other assets    noncurrent                           | 30                  | 30          |
|                                                      | 9,582               | 7,181       |
| Less cash                                            | (80)                | (389)       |
|                                                      | \$ 9,502            | \$ 6,792    |

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**AMGEN INC.**

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

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.

We review periodically our available-for-sale securities for other than temporary declines in fair value below the cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. As of December 31, 2008 and 2007, the Company believes that the cost basis for our available-for-sale securities was recoverable in all material respects.

*Derivative instruments*

We use financial instruments, including foreign currency forward, foreign currency option and interest rate swap contracts to manage our exposures to movements in foreign exchange rates and interest rates. The use of these financial instruments modifies the exposure of these risks with the intent to reduce the risk or cost to us. We do not use derivatives for speculative trading purposes and are not a party to leveraged derivatives.

We recognize all of our derivative instruments as either assets or liabilities at fair value in our Consolidated Balance Sheets. Fair value is determined in accordance with SFAS No. 157 (see Note 13, *Fair values* ). The accounting for changes in the fair value of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and further, on the type of hedging relationship. For derivatives designated as hedges, we formally assess, both at inception and periodically 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 enter into foreign currency forward and option contracts to protect against possible changes in values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with sales denominated in Euros. These contracts are designated as cash flow hedges and accordingly, the gains and losses on these forward and option contracts are reported in accumulated other comprehensive income and reclassified to earnings, specifically product sales, in the same periods during which the hedged transactions affect earnings. During the years ended December 31, 2008, 2007 and 2006, unrealized and realized gains and losses on these foreign currency forward and option contracts were not material. No portions of these contracts are excluded from the assessment of hedge effectiveness, and there are no material ineffective portions of these hedging instruments. At December 31, 2008 and 2007, amounts in accumulated other comprehensive income related to cash flow hedges were not material.

We also enter into foreign currency forward contracts to reduce exposures to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies. These forward contracts have not been designated as hedges and accordingly, changes in the fair value of these foreign currency forward contracts are recognized in interest and other income, net in the current period. During the years ended December 31, 2008, 2007 and 2006, gains and losses on these foreign currency forward contracts were not material.

We also have interest rate swap agreements, which qualify and are designated as fair value hedges, to achieve a desired mix of fixed and floating interest rate debt. The terms of the interest rate swap agreements correspond to the related hedged debt instruments. As a result, there is no material hedge ineffectiveness. During the years ended December 31, 2008, 2007 and 2006, gains and losses on these interest rate swap agreements were not material and were fully offset by the losses and gains on the hedged debt instruments through current earnings.

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***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. During 2008, we wrote-off \$84 million of inventory resulting from a strategic decision to change manufacturing processes. During 2007, we wrote-off \$90 million of excess inventory principally due to changing regulatory and reimbursement environments. Such charges are included in Cost of sales (excludes amortization of acquired intangible assets) in our Consolidated Statements of Income. Inventories consisted of the following (in millions):

|                 | <b>December 31,</b> |             |
|-----------------|---------------------|-------------|
|                 | <b>2008</b>         | <b>2007</b> |
| Raw materials   | \$ 112              | \$ 173      |
| Work in process | 1,519               | 1,246       |
| Finished goods  | 444                 | 672         |
|                 | \$ 2,075            | \$ 2,091    |

*Depreciation*

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:

| <b>Asset Category</b>                | <b>Years</b> |
|--------------------------------------|--------------|
| Buildings and improvements           | 10-40        |
| Manufacturing equipment              | 5-12         |
| Laboratory equipment                 | 5-12         |
| Furniture, fixtures and other assets | 3-15         |

*Property, plant and equipment*

As of December 31, 2008 and 2007, property, plant and equipment are recorded at cost and consisted of the following (in millions):

|                                                | <b>December 31,</b> |             |
|------------------------------------------------|---------------------|-------------|
|                                                | <b>2008</b>         | <b>2007</b> |
| Land                                           | \$ 456              | \$ 451      |
| Buildings and improvements                     | 3,205               | 3,102       |
| Manufacturing equipment                        | 1,431               | 1,221       |
| Laboratory equipment                           | 923                 | 831         |
| Furniture, fixtures and other assets           | 3,154               | 3,003       |
| Construction in progress                       | 826                 | 893         |
|                                                | 9,995               | 9,501       |
| Less accumulated depreciation and amortization | (4,116)             | (3,560)     |

|          |          |
|----------|----------|
| \$ 5,879 | \$ 5,941 |
|----------|----------|

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.

During the years ended December 31, 2008, 2007 and 2006, we recognized depreciation and amortization charges associated with our property, plant and equipment of \$648 million, \$786 million and \$547 million, respectively.

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**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Intangible assets and goodwill*

Intangible assets are recorded at cost, less accumulated amortization. Amortization of intangible assets is provided over their estimated useful lives ranging from 5 to 15 years on a straight-line basis (weighted average remaining amortization period of 8 years at December 31, 2008). As of December 31, 2008 and 2007, intangible assets consisted of the following (in millions):

| Intangible assets subject to amortization     | Weighted average<br>amortization period | December 31, |          |
|-----------------------------------------------|-----------------------------------------|--------------|----------|
|                                               |                                         | 2008         | 2007     |
| Acquired product technology rights:           |                                         |              |          |
| Developed product technology <sup>(1)</sup>   | 15 years                                | \$ 2,872     | \$ 2,872 |
| Core technology <sup>(1)</sup>                | 15 years                                | 1,348        | 1,348    |
| Trade name <sup>(1)</sup>                     | 15 years                                | 190          | 190      |
| Acquired R&D technology rights <sup>(2)</sup> | 5 years                                 | 350          | 350      |
| Other intangible assets <sup>(3)</sup>        | 10 years                                | 537          | 456      |
|                                               |                                         | 5,297        | 5,216    |
| Less accumulated amortization                 |                                         | (2,309)      | (1,884)  |
|                                               |                                         | \$ 2,988     | \$ 3,332 |

<sup>(1)</sup> Amortization is included in Amortization of acquired intangible assets in the Consolidated Statements of Income.

<sup>(2)</sup> Amortization is included in Research and development expense in the Consolidated Statements of Income.

<sup>(3)</sup> Amortization is principally included in Cost of sales and Selling, general and administrative expense in the Consolidated Statements of Income.

Acquired product technology rights relate to the identifiable intangible assets acquired in connection with the Immunex Corporation ( Immunex ) acquisition in July 2002. Intangible assets also include acquired research and development ( R&D ) technology rights consisting of technology used in R&D with alternative future uses. Acquired R&D technology rights principally include certain technology acquired in the Abgenix, Inc. ( Abgenix ) acquisition (see Note 8, *Acquisitions* ). During the years ended December 31, 2008, 2007 and 2006, we recognized amortization charges associated with our intangible assets of \$425 million, \$416 million and \$416 million, respectively. The total estimated amortization for each of the next five years for our intangible assets is \$425 million, \$418 million, \$367 million, \$344 million and \$335 million in 2009, 2010, 2011, 2012 and 2013, respectively.

We review our intangible assets for impairment periodically and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. During the years ended December 31, 2007 and 2006, we recognized \$3 million and \$49 million, respectively, of impairment charges related to a non-ENBREL related intangible asset previously acquired in the Immunex acquisition, which is included in Amortization of acquired intangible assets in the Consolidated Statements of Income.

We had \$11.3 billion and \$11.2 billion of goodwill at December 31, 2008 and 2007, respectively, which primarily relates to the acquisition of Immunex. The increase in 2008 is principally related to the goodwill associated with our acquisition of the remaining 51% ownership interest of Dompé Biotec, S.p.A ( Dompé ) on January 4, 2008 (see Note 8, *Acquisitions* ). We perform an impairment test annually and whenever events or changes in circumstances indicate that the carrying amount of goodwill may not be recoverable.

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**AMGEN INC.**

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

*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 incentives (collectively sales incentives ) and returns. Taxes assessed by government authorities on 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 Ortho Biotech Products, L.P. ( Ortho Biotech )), 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 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. Corporate partner revenues are primarily comprised of amounts earned from Kirin-Amgen, Inc. ( KA ) for certain R&D activities and are generally earned as the R&D activities are performed and the amounts become due (see Note 4, *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 performance milestones is recognized based upon the achievement of the milestones, 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 that have no alternative future use. Net payment or reimbursement of R&D costs for R&D collaborations are recognized as the obligation has been incurred or as we become entitled to the cost recovery.

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**AMGEN INC.**

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

*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.

We have a co-promotion agreement with Wyeth. Under the terms of this agreement, Amgen and Wyeth market and sell ENBREL in the United States and Canada and develop certain future indications of ENBREL for use in these geographic territories. Wyeth is paid a share of the resulting profits on our sales of ENBREL, after deducting the applicable costs of sales, including manufacturing costs and royalties paid to third parties, and certain expenses associated with R&D and sales and marketing. The profit share paid to Wyeth is included in Selling, general and administrative in the Consolidated Statements of Income. The rights to market ENBREL outside of the United States and Canada are reserved to Wyeth. We also have a global supply agreement with Wyeth related to the manufacture, supply and allocation of bulk supply of ENBREL. For the years ended December 31, 2008, 2007 and 2006, the Wyeth profit share expense, excluding recoveries recorded as part of our restructuring, was \$1,195 million, \$984 million and \$837 million, respectively (see Note 2, *Restructuring* ).

Advertising costs are expensed as incurred. For the years ended December 31, 2008, 2007 and 2006, advertising costs were \$81 million, \$93 million and \$134 million, respectively.

*Acquired in-process research and development*

For acquisitions prior to January 1, 2009, the estimated fair value of acquired in-process R&D ( IPR&D ) projects, which have not reached technological feasibility at the date of acquisition and which do not have an alternative future use, are immediately expensed. In 2007, we wrote-off \$270 million and \$320 million of acquired IPR&D related to the Alantos Pharmaceuticals Holding, Inc. ( Alantos ) and Ilypsa, Inc. ( Ilypsa ) acquisitions, respectively. In 2006, we wrote-off \$1.1 billion and \$130 million of acquired IPR&D related to the Abgenix and Avidia, Inc. ( Avidia ) acquisitions, respectively. Acquired IPR&D is considered part of total R&D expense (see Note 8, *Acquisitions* ). See *Recent accounting pronouncements* below.

*Share based payments*

We have employee compensation plans under which various types of stock-based instruments are granted. We account for our share-based payments in accordance with SFAS No. 123(R), *Share-Based Payment* ( SFAS 123(R) ). This statement requires all share-based payments to employees, including grants of employee stock options, to be 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 3, *Employee stock-based payments* ).

*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, 2008, 2007 and 2006 was \$316 million, \$328 million and \$129 million, respectively. Interest costs capitalized for the years ended December 31, 2008, 2007 and 2006 were \$22 million, \$28 million and \$43 million, respectively. Interest paid, net of interest rate swap settlement activity, during the years ended December 31, 2008, 2007 and 2006, totaled \$303 million, \$258 million and \$122 million, respectively. Included in interest expense, net, for the year ended December 31, 2007, is a pro rata portion, \$51 million, of deferred financing and related costs, which were immediately charged to interest expense upon the repurchase of the 2032 Modified Convertible Notes. (See *Recent accounting pronouncements* below and Note 6, *Financing arrangements* ).

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Earnings per share*

Basic earnings per share ( EPS ) is based upon the weighted-average number of common shares outstanding. Diluted EPS is based upon the weighted-average number of common shares and dilutive potential common shares outstanding. Potential common shares outstanding principally include stock options, restricted stock (including 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 6, *Financing arrangements*.

Our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified Convertible Notes are considered Instrument C securities as defined by Emerging Issues Task Force Issue ( EITF ) No. 90-19 *Convertible Bonds with Issuer Option to Settle for Cash upon Conversion*. Therefore, only the shares of common stock potentially issuable with respect to the excess of the notes' conversion value over their principal amount, if any, are considered as dilutive potential common shares for purposes of calculating diluted EPS. For the years ended December 31, 2008, 2007 and 2006, the conversion values for our convertible notes were less than the related principal amounts and, accordingly, no shares were assumed to be issued for purposes of computing diluted EPS. For further information regarding our convertible notes, see Note 6, *Financing arrangements*.

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

|                                                        | <b>Years ended December 31,</b> |             |             |
|--------------------------------------------------------|---------------------------------|-------------|-------------|
|                                                        | <b>2008</b>                     | <b>2007</b> | <b>2006</b> |
| Income (Numerator):                                    |                                 |             |             |
| Net income for basic and diluted EPS                   | \$ 4,196                        | \$ 3,166    | \$ 2,950    |
| Shares (Denominator):                                  |                                 |             |             |
| Weighted-average shares for basic EPS                  | 1,070                           | 1,117       | 1,176       |
| Effect of Dilutive Securities, primarily stock options | 5                               | 6           | 14          |
| Weighted-average shares for diluted EPS                | 1,075                           | 1,123       | 1,190       |
| Basic EPS                                              | \$ 3.92                         | \$ 2.83     | \$ 2.51     |
| Diluted EPS                                            | \$ 3.90                         | \$ 2.82     | \$ 2.48     |

For the years ended December 31, 2008, 2007 and 2006, there were employee stock options, calculated on a weighted average basis, to purchase 45 million, 48 million and 13 million shares, respectively, with exercise prices greater than the average market prices of common stock that are not included in the computation of diluted EPS as their impact would have been anti-dilutive. In addition, shares which may be issued upon conversion of our convertible debt or upon exercise of our warrants are not included above as their impact on diluted EPS would have been anti-dilutive. Shares which may be issued under our 2007 performance award programs were also excluded because conditions under the programs were not met as of December 31, 2008.

*Recent accounting pronouncements*

In May 2008, the FASB issued FASB Staff Position ( FSP ) No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP APB 14-1 ) that changes the method of accounting for convertible debt securities that require or permit settlement in cash either in whole or in part upon conversion, including our convertible debt securities (see Note 6,



**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Financing arrangements* ). We will adopt FSP APB 14-1, effective January 1, 2009, and retrospectively apply this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new standard. Under this new method of accounting, the debt and equity components of our convertible debt securities will be bifurcated and accounted for separately in a manner that will result in recognizing interest expense on these securities at effective rates reflective of what we would have incurred had we issued nonconvertible debt with otherwise similar terms. The equity component of our convertible debt securities will be included in Stockholders equity on our Consolidated Balance Sheets and, accordingly, the initial carrying values of these debt securities will be reduced. Our net income for financial reporting purposes will be reduced by recognizing the accretion of the reduced carrying values of our convertible debt securities to their face amounts as additional non-cash interest expense. The adoption of FSP APB 14-1 will result in a reduction in the carrying value of our convertible debt by approximately \$824 million as of December 31, 2008 and will increase interest expense, net by approximately \$234 million, \$168 million and \$197 million, for the years ended December 31, 2008, 2007 and 2006, respectively. This new standard will also materially increase interest expense in future periods that our convertible debt is outstanding, but will have no impact on past or future cash flows.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* ( SFAS 141(R) ) and SFAS No. 160, *Accounting and Reporting of Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* ( SFAS 160 ). These standards will significantly change the accounting and reporting for business combination transactions and noncontrolling (minority) interests in consolidated financial statements, including capitalizing the fair value of acquired IPR&D at the acquisition date and subsequently testing these assets for impairment. These new standards will be applied prospectively for business combinations that occur on or after January 1, 2009, except that presentation and disclosure requirements of SFAS 160 regarding noncontrolling interests will be applied retrospectively.

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* ( EITF 07-5 ). Equity-linked instruments (or embedded features) that otherwise meet the definition of a derivative as outlined in SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* ( SFAS 133 ), are not accounted for as derivatives if certain criteria are met, one of which is that the instrument (or embedded feature) must be indexed to the entity's own stock. EITF 07-5 provides guidance on how to determine if equity-linked instruments (or embedded features) such as warrants to purchase our stock, our convertible notes and convertible note hedges are considered indexed to our stock. We will adopt EITF 07-5, effective January 1, 2009, and apply its provisions to outstanding instruments as of that date. The adoption of EITF 07-5 will not have a material impact on our consolidated results of operations, financial position or cash flows.

In December 2007, the FASB ratified EITF No. 07-1, *Accounting for Collaborative Agreements* ( EITF 07-1 ). EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which includes certain arrangements the Company has entered into regarding development and commercialization of products and product candidates. EITF 07-1 is effective for the Company as of January 1, 2009, and its adoption will not have a material impact on our consolidated results of operations, financial position or cash flows.

**2. Restructuring**

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. 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.

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Through December 31, 2008, we have completed substantially all of the actions initially included in our restructuring plan. Key components of our restructuring plan initially included: (i) worldwide staff reductions aggregating approximately 2,500 positions, (ii) rationalization of our worldwide network of manufacturing facilities in order to gain cost efficiencies while continuing to meet future commercial and clinical demand for our products and product candidates 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. During 2008, 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. The estimated cost of these additional initiatives is \$95 million to \$135 million. As a result of these additional initiatives and certain minor changes in the expected costs for the actions initially included in our restructuring plan, the total charges currently expected to be incurred in connection with our restructuring plan, including related implementation costs, has been increased to \$950 million to \$985 million, as compared to our prior estimate of \$775 million to \$825 million as of December 31, 2007. Through December 31, 2008, we have incurred \$887 million of these costs and estimate that all remaining costs will be incurred through 2009. Such cost estimates and amounts incurred are net of amounts recovered from our ENBREL co-promotion partner, Wyeth.

The following tables summarize the charges (credits) recorded during the years ended December 31, 2008 and 2007 related to the restructuring plan by type of activity (in millions):

| <b>Year ended December 31, 2008</b>                         | <b>Separation costs</b> | <b>Asset impairments</b> | <b>Accelerated depreciation</b> | <b>Other</b> | <b>Total</b> |
|-------------------------------------------------------------|-------------------------|--------------------------|---------------------------------|--------------|--------------|
| Cost of sales (excluding amortization of intangible assets) | \$                      | \$ 6                     | \$                              | \$           | \$ 6         |
| Research and development                                    | 3                       |                          |                                 |              | 3            |
| Selling, general and administrative                         |                         | 17                       |                                 | 20           | 37           |
| Other charges                                               | 7                       | 36                       |                                 | 49           | 92           |
| Interest and other income, net                              |                         |                          |                                 | 10           | 10           |
|                                                             | \$ 10                   | \$ 59                    | \$                              | \$ 79        | \$ 148       |
| <b>Year ended December 31, 2007</b>                         | <b>Separation costs</b> | <b>Asset impairments</b> | <b>Accelerated depreciation</b> | <b>Other</b> | <b>Total</b> |
| Cost of sales (excluding amortization of intangible assets) | \$ (1)                  | \$ 4                     | \$ 147                          | \$           | \$ 150       |
| Research and development                                    | (19)                    | 38                       |                                 |              | 19           |
| Selling, general and administrative                         | (11)                    |                          | 1                               | (114)        | (124)        |
| Other charges                                               | 209                     | 366                      |                                 | 119          | 694          |
|                                                             | \$ 178                  | \$ 408                   | \$ 148                          | \$ 5         | \$ 739       |

As noted above, since the inception of our restructuring plan, we have incurred \$887 million of the estimated \$950 million to \$985 million of charges expected to be incurred. The charges incurred through December 31, 2008 include \$188 million of separation costs, \$467 million of asset impairments, \$148 million of accelerated depreciation and \$84 million of other charges, which primarily include \$161 million of loss accruals for leases, \$10 million loss on the disposal of certain less significant marketed products, \$9 million for implementation costs associated with certain restructuring initiatives and \$19 million of other charges, offset by \$115 million of cost recoveries from Wyeth.

During the years ended December 31, 2008 and 2007, we recorded staff separation costs of \$10 million and \$209 million, respectively, principally consisting of severance. Partially offsetting these amounts in Cost of



**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

sales (excluding amortization of intangible assets), Research and development and Selling, general and administrative expenses for the year ended December 31, 2007 are the reversal of previously accrued expenses for bonuses and stock-based compensation awards totaling \$31 million, which were forfeited as a result of the employees' termination.

We also recorded asset impairment charges of \$59 million and \$408 million during the years ended December 31, 2008 and 2007, respectively. The charges for both periods 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 certain revisions to and 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.

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. 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 no longer had 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 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.

During the years ended December 31, 2008 and 2007, we also recorded cost recoveries of \$1 million and \$114 million, respectively, for certain restructuring charges, principally with respect to accelerated depreciation, in connection with our co-promotion agreement with Wyeth. Such amounts are recorded as a reduction of the Wyeth profit share expense included in Selling, general and administrative expenses. Also included in Selling, general and administrative expenses in 2008 are \$12 million of loss accruals for leases principally related to certain facilities that will not be used in our operations and \$9 million for implementation costs associated with certain restructuring initiatives. In addition during the years ended December 31, 2008 and 2007, we accrued \$49 million and \$119 million, respectively, included in Other charges, primarily related to loss accruals for leases for certain facilities that will not be used in our operations. For 2007, these charges primarily related to loss accruals for leases for certain R&D facilities. 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.

The following table summarizes the charges and spending relating to the restructuring plan (in millions):

|                                                | Separation<br>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 |



**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company records restructuring activities in accordance with SFAS 88, *Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits*, SFAS 144, *Accounting for the Impairment and Disposal of Long-Lived Assets* and SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*.

**3. Employee stock-based payments**

We have employee compensation plans under which various types of stock-based instruments are granted. These instruments, as more fully described below, principally include stock options, restricted stock (including restricted stock units) and performance units. As of December 31, 2008, these plans provide for future grants and/or issuances of up to approximately 25 million shares of common stock to our employees. 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, 2008, 2007 and 2006 (in millions):

|                                                    | 2008   | 2007   | 2006   |
|----------------------------------------------------|--------|--------|--------|
| Stock options                                      | \$ 103 | \$ 181 | \$ 233 |
| Restricted stock                                   | 105    | 76     | 58     |
| Performance units                                  | 54     | 6      | 112    |
| Total stock-based compensation expense, pre-tax    | 262    | 263    | 403    |
| Tax benefit from stock-based compensation expense  | (89)   | (81)   | (117)  |
| Total stock-based compensation expense, net of tax | \$ 173 | \$ 182 | \$ 286 |

During the year ended December 31, 2007, based on revised estimates of our operating performance, we reduced the expense associated with our performance units recorded in prior years by approximately \$60 million.

*Employee stock option and restricted stock grants*

Our equity-based compensation plans provide 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. These plans also provide for grants of restricted stock and restricted stock units. Grants of these equity instruments generally vest/have restrictions which lapse 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. These stock-based plans provide for accelerated or continued vesting/lapse of restrictions in certain circumstances, including upon death, disability, a change in control as defined in the plans, or retirement of employees who meet certain service and/or age requirements.

We use the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options. The expected volatility reflects the consideration of the implied volatility in publicly traded instruments associated with Amgen's common stock during the period the options were granted. We believe implied volatility in these instruments is more indicative of expected future volatility than the historical volatility in the price of our common stock. As permitted by the Securities and Exchange Commission (SEC) Staff Accounting Bulletin No. 107, we estimated the expected life of stock options using the simplified method during the years ended December 31, 2007 and 2006. 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. The



**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

weighted-average assumptions used to estimate the fair value of the stock options using the Black-Scholes option valuation model were as follows for the years ended December 31, 2008, 2007 and 2006:

|                                     | 2008     | 2007     | 2006     |
|-------------------------------------|----------|----------|----------|
| Fair value of common stock          | \$ 43.60 | \$ 62.92 | \$ 71.16 |
| Fair value of stock options granted | \$ 14.50 | \$ 19.06 | \$ 21.70 |
| Risk-free interest rate             | 2.9%     | 4.5%     | 4.8%     |
| Expected life (in years)            | 4.6      | 4.7      | 4.8      |
| Expected volatility                 | 31.6%    | 24.9%    | 24.1%    |
| Expected dividend yield             | 0%       | 0%       | 0%       |

Stock option information with respect to our stock-based compensation plans during the three years ended December 31, 2008 is as follows:

|                                                  | Options<br>(in millions) | Weighted-average<br>exercise price | Weighted-average<br>remaining<br>contractual<br>life (years) | Aggregate<br>intrinsic<br>value<br>(in millions) |
|--------------------------------------------------|--------------------------|------------------------------------|--------------------------------------------------------------|--------------------------------------------------|
| Balance unexercised at December 31, 2005         | 67.6                     | \$ 56.03                           |                                                              |                                                  |
| Granted                                          | 11.8                     | \$ 71.17                           |                                                              |                                                  |
| Assumed from acquisitions (including 1.5 vested) | 2.2                      | \$ 29.94                           |                                                              |                                                  |
| Exercised                                        | (10.7)                   | \$ 40.94                           |                                                              |                                                  |
| Forfeited/expired                                | (2.7)                    | \$ 58.10                           |                                                              |                                                  |
| 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                           | 3.5                                                          | \$ 196                                           |
| Vested or expected to vest at December 31, 2008  | 50.1                     | \$ 59.41                           | 3.4                                                          | \$ 190                                           |
| Exercisable at December 31, 2008                 | 34.6                     | \$ 60.09                           | 2.6                                                          | \$ 106                                           |

The total intrinsic value of options exercised during the year ended December 31, 2008 was \$68 million.

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The fair values of shares of restricted stock are determined based on the closing price of Amgen common stock on the grant dates. Information regarding our restricted stock during the three years ended December 31, 2008 is as follows:

|                                | Shares<br>(in millions) | Weighted-average<br>grant date<br>fair value |
|--------------------------------|-------------------------|----------------------------------------------|
| <b>Nonvested shares</b>        |                         |                                              |
| Nonvested at December 31, 2005 | 2.8                     | \$ 58.90                                     |
| Granted                        | 2.3                     | \$ 71.57                                     |
| Vested                         | (0.7)                   | \$ 59.29                                     |
| Forfeited                      | (0.3)                   | \$ 62.89                                     |
| 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                                     |

The total fair value of shares of restricted stock that vested during the year ended December 31, 2008 was \$77 million.

As of December 31, 2008, there was \$518 million of total unrecognized compensation cost related to nonvested awards of both stock options and shares of restricted stock. That cost is expected to be recognized over a weighted-average period of 1.7 years. For stock option and restricted stock awards subject to graded vesting that were issued after January 1, 2006, we recognize compensation cost on a straight-line basis over the service period for the entire award.

*Performance award program*

Certain management-level employees 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 are based upon one or more of the following, in each case with respect to compound annual growth rates as defined in the program: (i) Amgen's standalone financial performance, (ii) Amgen's financial performance compared to other benchmark companies and (iii) the Company's annual stockholder return. 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, including upon death, disability, a change in control as defined, or retirement of employees who meet certain service and/or age requirements.

The performance period for those units granted in 2006, totaling approximately 1.1 million units, ended on December 31, 2008. These performance units were accounted for as liability awards and the expense recognized was based on the assigned value per unit, \$71.88, multiplied by the estimated or actual number of units earned. The number of units earned was based on the Company's standalone and comparative financial performance. The aggregate dollar value of units earned is divided by the average closing price of our common stock during a specified period following the performance period to determine the number of shares of common stock payable to the recipient.

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The performance units granted in 2007 and 2008, totaling approximately 1.3 million and 0.9 million, respectively, are accounted for as equity awards and include total stockholder return performance measures. The

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awards granted in 2007 also include performance measures based on the Company's standalone financial performance. The expense recognized for the awards granted in 2007 is 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 measures for the Company's standalone financial performance. 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. The impact of the Company's stockholder returns for the awards granted in 2007 and 2008 is reflected in the grant date fair values of the units, as discussed below. The number of shares of Amgen's common stock payable to the recipient for performance units granted in 2007 and 2008 will equal the number of performance units earned. With respect to those performance units granted in 2007 and 2008, there are approximately 2.0 million units which continue to be subject to performance conditions.

The grant date fair value of performance units granted in 2007 and 2008 was calculated using a lattice model with the following assumptions:

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

The lattice model uses 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. The assumptions with respect to the risk-free interest rate and expected volatility are computed in a similar manner as discussed above for stock options.

The performance period for those instruments granted in 2005 ended on December 31, 2007 and the related liability was paid by the issuance of approximately one million shares of our common stock to the participants in May 2008, net of shares withheld for taxes. The performance period for those instruments granted in 2004 ended on December 31, 2006 and the related liability was paid by the issuance of approximately one million shares of our common stock to the participants in May 2007, net of shares withheld for taxes.

As of December 31, 2008, there was approximately \$50 million of total estimated unrecognized compensation cost related to the 2007 and 2008 performance unit grants that is expected to be recognized over a weighted-average period of approximately 1 year.

Under Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), the estimated amounts owed for performance units granted in 2004 and 2005 were classified in stockholders' equity, but upon adoption of SFAS 123(R), these amounts were required to be classified as liabilities based upon the terms of these plans. Accordingly, on January 1, 2006, a reclassification was made from stockholders' equity to liabilities (current and non-current) totaling \$104 million.

**4. 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 in the Consolidated Statements of Income. For the years ended December 31, 2008, 2007 and 2006, our share of KA's profits were \$72 million, \$51 million and \$61 million, respectively. At December 31, 2008 and 2007, the carrying value of our equity method investment in KA, net of dividends paid, was \$356 million and \$292 million, respectively, and is included in non-current Other assets in the Consolidated Balance Sheets. KA's revenues consist of royalty income related to its licensed technology.

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rights. All of our rights to manufacture and market certain products including darbepoetin alfa, pegfilgrastim, granulocyte colony-stimulating factor ( G-CSF ) and recombinant human erythropoietin are pursuant to exclusive licenses from KA, which we currently market under the brand names Aranesp®, Neulasta®, NEUPOGEN® and EPOGEN®, 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, 2008, 2007 and 2006, KA earned royalties from us of \$321 million, \$336 million and \$324 million, respectively. These amounts are included in Cost of sales (excludes amortization of acquired intangible assets) in the Consolidated Statements of Income. At December 31, 2008 and 2007, we owed KA \$82 million and \$91 million, respectively, which was 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, 2008, 2007 and 2006, we earned revenues from KA of \$124 million, \$180 million and \$131 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.

**5. Income taxes**

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

|                                    | Years ended December 31, |        |          |
|------------------------------------|--------------------------|--------|----------|
|                                    | 2008                     | 2007   | 2006     |
| Current provision:                 |                          |        |          |
| Federal                            | \$ 866                   | \$ 467 | \$ 1,392 |
| State                              | 82                       | 40     | 73       |
| Foreign                            | 151                      | 176    | 138      |
| Total current provision            | 1,099                    | 683    | 1,603    |
| Deferred (benefit) provision:      |                          |        |          |
| Federal                            | (3)                      | 135    | (481)    |
| State                              | (36)                     | (24)   | (49)     |
| Foreign                            | (7)                      | 1      | (3)      |
| Total deferred (benefit) provision | (46)                     | 112    | (533)    |
| Total provision                    | \$ 1,053                 | \$ 795 | \$ 1,070 |

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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 and the net tax effects of net operating loss and credit carryforwards. Significant components of our deferred tax assets and liabilities are as follows (in millions):

|                                                      | <b>December 31,</b> |             |
|------------------------------------------------------|---------------------|-------------|
|                                                      | <b>2008</b>         | <b>2007</b> |
| Deferred tax assets:                                 |                     |             |
| Intercompany inventory related items                 | \$ 359              | \$ 581      |
| Expense accruals                                     | 576                 | 535         |
| Acquired net operating loss and credit carryforwards | 243                 | 399         |
| Expenses capitalized for tax                         | 175                 | 134         |
| Convertible debt                                     | 315                 | 407         |
| Stock-based compensation                             | 220                 | 128         |
| Deferred revenue                                     | 153                 |             |
| Other                                                | 106                 | 172         |
| <br>Total deferred tax assets                        | <br>2,147           | <br>2,356   |
| Valuation allowance                                  | (106)               | (166)       |
| <br>Net deferred tax assets                          | <br>2,041           | <br>2,190   |
| Deferred tax liabilities:                            |                     |             |
| Acquired intangibles                                 | (1,025)             | (1,167)     |
| Fixed assets                                         | (184)               | (158)       |
| Other                                                | (154)               | (185)       |
| <br>Total deferred tax liabilities                   | <br>(1,363)         | <br>(1,510) |
| <br>Total deferred taxes                             | <br>\$ 678          | <br>\$ 680  |

At December 31, 2008, we had net current deferred tax assets of \$859 million, primarily composed of temporary differences related to inventory, accrued liabilities and acquired net operating losses and credits. At December 31, 2007, our net current deferred tax assets were \$1.2 billion.

The valuation allowance for deferred tax assets decreased by \$60 million in 2008. The decrease was primarily due to the deferred tax expense relating to certain foreign subsidiaries' expenses capitalized for tax and expiration of certain acquired credit 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, 2008, we had operating loss carryforwards of \$73 million available to reduce future federal taxable income, which will begin expiring in 2020. In addition, we had operating loss carryforwards of \$765 million available to reduce future taxable income in various state taxing jurisdictions. We have provided a valuation allowance against \$495 million of the state operating loss carryforwards. The state operating loss carryforwards will begin expiring in 2009.

At December 31, 2008, we had tax credit carryforwards of \$32 million available to reduce future federal income taxes, which will begin expiring in 2009. We also had \$124 million of tax credit carryforwards available to reduce future state income taxes which have no expiration date, and \$79 million of state tax credit carryforwards for which a full valuation allowance has been provided.

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Effective January 1, 2007, we adopted FASB Interpretation No. ( FIN ) 48, *Accounting for Uncertainty in Income Taxes* an interpretation of *FASB Statement No. 109* ( FIN 48 ). FIN 48 clarifies the accounting for

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uncertainty in income taxes by prescribing rules for recognition, measurement and classification in our consolidated financial statements of tax positions taken or expected to be taken in a tax return. For tax benefits to be recognized under FIN 48, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50% likely of being realized upon settlement. There was no cumulative effect of applying the recognition and measurement provisions upon adoption of FIN 48.

FIN 48 also provides guidance on the balance sheet classification of liabilities for unrecognized tax benefits ( UTBs ) as either current or non-current depending on the expected timing of payments. Upon adoption of FIN 48, we reclassified approximately \$240 million of UTBs and related accrued interest from current income taxes payable to other non-current liabilities.

The reconciliation of the total gross amounts of UTBs for the years ended December 31, 2008 and 2007 is as follows (in millions):

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

The majority of the UTBs as of December 31, 2008 and 2007, 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 this examination primarily related to transfer pricing tax positions. Our closing agreement with the IRS also covers 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. However, these years have not been effectively settled for all other issues.

As of December 31, 2008, we believe that it was reasonably possible that our liabilities for UTBs may de-crease by \$100 million within the succeeding twelve months due to potential resolution of the tax examination process.

Interest and penalties related to UTBs are included in our provision for income taxes. During 2008, we recognized approximately \$71 million of interest and penalty expense through the income tax provision in the Consolidated Statement of Income. At December 31, 2008, there was approximately \$119 million of accrued interest and penalties associated with UTBs.

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

|                                                                    | <b>Years ended December 31,</b> |             |             |
|--------------------------------------------------------------------|---------------------------------|-------------|-------------|
|                                                                    | <b>2008</b>                     | <b>2007</b> | <b>2006</b> |
| Federal statutory rate applied to income before income taxes       | 35.0%                           | 35.0%       | 35.0%       |
| Foreign earnings, including earnings invested indefinitely         | (15.9)%                         | (16.1)%     | (18.3)%     |
| State taxes                                                        | 1.4%                            | 1.1%        | 1.6%        |
| Acquired IPR&D                                                     | 0.0%                            | 5.2%        | 10.7%       |
| Audit settlements                                                  | 0.0%                            | (3.6)%      | (2.2)%      |
| Utilization of tax credits, primarily research and experimentation | (1.0)%                          | (1.6)%      | (1.0)%      |
| Other, net                                                         | 0.6%                            | 0.1%        | 0.8%        |
| Effective tax rate                                                 | 20.1%                           | 20.1%       | 26.6%       |

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, 2008, these earnings amounted to approximately \$10.8 billion. If these earnings were repatriated to the United States, we would be required to accrue and pay approximately \$3.8 billion of additional taxes based on the current tax rates in effect. For the years ended December 31, 2008, 2007 and 2006, our total foreign income before income taxes was approximately \$2.6 billion, \$2.4 billion, and \$2.3 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 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, 2008, 2007 and 2006, totaled \$673 million, \$895 million, and \$987 million, respectively.

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. Financing arrangements**

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements as of December 31, 2008 and 2007 (in millions):

|                                                                                              | 2008     | 2007     |
|----------------------------------------------------------------------------------------------|----------|----------|
| 0.125% convertible notes due 2011 (2011 Convertible Notes)                                   | \$ 2,500 | \$ 2,500 |
| 0.375% convertible notes due 2013 (2013 Convertible Notes)                                   | 2,500    | 2,500    |
| Floating rate notes due 2008 (2008 Floating Rate Notes)                                      |          | 2,000    |
| 5.85% notes due 2017 (2017 Notes)                                                            | 1,099    | 1,099    |
| 4.85% notes due 2014 (2014 Notes)                                                            | 1,000    | 1,000    |
| 4.00% notes due 2009 (2009 Notes)                                                            | 1,000    | 999      |
| 6.375% notes due 2037 (2037 Notes)                                                           | 899      | 899      |
| 6.15% notes due 2018 (2018 Notes)                                                            | 499      |          |
| 6.90% notes due 2038 (2038 Notes)                                                            | 498      |          |
| Zero coupon 30 year modified convertible notes due in 2032 (2032 Modified Convertible Notes) | 81       | 80       |
| Other                                                                                        | 100      | 100      |
| Total borrowings                                                                             | 10,176   | 11,177   |
| Less current portion                                                                         | 1,000    | 2,000    |
| Total non-current debt                                                                       | \$ 9,176 | \$ 9,177 |

*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. Concurrent with the issuance of the 2018 Notes, we entered into interest rate swap agreements that effectively convert the payment of our fixed rate interest payments to variable rate interest payments over the life of the 2018 Notes. 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.

*2008 Floating Rate Notes, 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 above, in June 2008 we



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

exercised our right to call and retired \$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 retired in November 2008.

*2011 and 2013 Convertible Notes*

In February 2006, we issued \$2.5 billion principal amount of convertible notes due in 2011 (the 2011 Convertible Notes) and \$2.5 billion principal amount of convertible notes due in 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 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 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 in 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). 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. See Note 1, *Summary of significant accounting policies* *Recent accounting pronouncements*.

In connection with the issuance of these convertible notes, a total of \$3.0 billion of our common stock was repurchased under our stock repurchase program. Also, 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, which aggregated approximately \$1.5 billion. The net proceeds from the issuance of the 2011 Convertible Notes and 2013 Convertible Notes, the repurchase of our common stock and the purchase of the convertible note hedges was \$439 million.

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 stock, and these contracts meet all of the applicable criteria for equity classification as outlined in EITF No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, the cost of the convertible note hedges and net proceeds from the sale of the warrants are classified

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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 own common stock, they are not accounted for as derivatives under SFAS 133.

*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 (\$1,000 face amount per note) and yield to maturity of 1.125%. The original issue discount of \$1.1 billion or \$285.77 per note (prior to repurchase of a portion of the 2032 Convertible Notes discussed below) is being accreted and recognized as interest expense over the life of the 2032 Convertible Notes (or the 2032 Modified Convertible Notes, as discussed below) using the effective interest method.

The holders of the 2032 Convertible Notes had the right to require us to repurchase all or a portion of their notes on March 1, 2005. As a result of certain holders of the Convertible Notes exercising this March 1, 2005 put option, we repurchased \$1.6 billion aggregate principal amount of 2032 Convertible Notes for their then-accreted value of \$1.2 billion in cash. Upon the repurchase of such 2032 Convertible Notes, a pro rata portion, \$20 million, of the related debt issuance costs was immediately charged to interest expense. We then made an aggregate cash payment of \$22 million to the remaining holders of the 2032 Convertible Notes. Concurrently, we amended the terms of the 2032 Convertible Notes to add an additional put date in order to permit the remaining holders, at their option, to cause us to repurchase the remaining 2032 Convertible Notes on March 1, 2006 at the then-accreted value. Subsequently, substantially all of the convertible note holders did not require us to repurchase such notes on the March 1, 2006 put date.

On May 6, 2005, we exchanged new zero-coupon senior convertible notes (the 2032 Modified Convertible Notes ) and a cash payment of approximately \$6 million for approximately 95% of the remaining 2032 Convertible Notes then outstanding. Subsequently, we exchanged substantially all of the remaining outstanding 2032 Convertible Notes. The changes to the 2032 Convertible Notes outstanding as a result of these exchanges combined with those made in March 2005 were accounted for as a debt modification. Accordingly, all cash paid to the holders of the 2032 Modified Convertible Notes is being amortized to interest expense over the life of the convertible notes using the effective interest method, and the costs incurred to modify the terms of the convertible notes were expensed as incurred.

On March 2, 2007, as a result of holders of substantially all of our 2032 Modified Convertible Notes exercising their March 1, 2007 put option, we repurchased \$2.3 billion aggregate principal amount of these convertible notes for their then accreted value of \$1.7 billion in cash, representing the majority of the then outstanding balance of these notes. Upon the repurchase of these notes, a pro rata portion, \$51 million, of deferred financing and related costs were immediately charged to interest expense.

Holders of 2032 Modified Convertible Notes may convert each of their notes based on a conversion rate of 8.8601 shares of common stock. The conversion price per share of the convertible notes as of any day will equal the original issuance price plus the accrued original issue discount to that day, divided by the conversion rate or \$87.02 as of December 31, 2008. The 2032 Modified Convertible Notes can only be converted in certain circumstances. If converted, the 2032 Modified Convertible Notes will be settled for a conversion value equal to the product of the conversion rate (8.8601 shares of Amgen common stock per note as of December 31, 2008) multiplied by the average closing price of our common stock during a specified period following the conversion date. The conversion value is paid in: (i) cash equal to the lesser of the accreted value of the 2032 Modified Convertible Notes at the conversion date or the conversion value and (ii) shares of common stock, if any, to the extent the conversion value exceeds the accreted value. See Note 1, *Summary of significant accounting policies - Recent accounting pronouncements*.

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

*2009 Notes and 2014 Notes*

At December 31, 2008 and 2007, we had \$1.0 billion aggregate principal amount of notes with a fixed interest rate of 4.00% due in November of 2009 (the 2009 Notes ) and \$1.0 billion aggregate principal amount of notes with a fixed interest rate of 4.85% due 2014 (the 2014 Notes ) outstanding.

*Other*

We had \$100 million of debt securities outstanding at December 31, 2008 and 2007 with a fixed interest rate of 8.125% due in 2097 (the Century Notes ).

During the year ended December 31, 2007, we repaid \$135 million of other debt securities.

*Shelf registration statements and other facilities*

In 2008, we filed a shelf registration statement with the SEC, which replaced our previous \$1.0 billion shelf registration statement and 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.

In 2008, we increased our commercial paper program by \$1.3 billion, which provides for unsecured, short-term borrowings of up to an aggregate of \$2.5 billion. We also have a \$2.5 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; however, \$178 million of such commitment was provided by a subsidiary of Lehman Brothers Holdings Inc. ( Lehman ). Lehman declared bankruptcy on September 15, 2008, and the subsidiary participant in our credit facility subsequently declared bankruptcy on October 5, 2008. As a result, we would not anticipate the ability to access this specific commitment provided by Lehman in the future. No amounts were outstanding under the commercial paper program or credit facility as of December 31, 2008.

As of December 31, 2008, 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, 2008, 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, 2008, we had interest rate swap agreements for our 2009 Notes, 2014 Notes, 2018 Notes and Century Notes, with an aggregate face value of \$2.6 billion. As of December 31, 2007, we had interest rate swap agreements for our 2009 Notes, 2014 Notes and Century Notes, with an aggregate face value of \$2.1 billion.

Certain of our financing arrangements contain non-financial covenants and we were in compliance with all applicable covenants as of December 31, 2008. None of our financing arrangements contain any financial covenants.

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The aggregate contractual maturities of all long-term debt obligations due subsequent to December 31, 2008 are as follows (in millions):

| <b>Maturity date</b> | <b>Amount</b>    |
|----------------------|------------------|
| 2009                 | \$ 1,000         |
| 2010                 |                  |
| 2011                 | 2,500            |
| 2012 <sup>(1)</sup>  | 84               |
| 2013                 | 2,500            |
| Thereafter           | 4,100            |
| <b>Total</b>         | <b>\$ 10,184</b> |

- <sup>(1)</sup> 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.

**7. Stockholders' equity***Stock repurchase program*

A summary of the activity under our stock repurchase program for the years ended December 31, 2008, 2007 and 2006 is as follows (in millions):

|                | <b>2008</b>   |                      | <b>2007</b>         |                 | <b>2006</b>   |                 |
|----------------|---------------|----------------------|---------------------|-----------------|---------------|-----------------|
|                | <b>Shares</b> | <b>Dollars</b>       | <b>Shares</b>       | <b>Dollars</b>  | <b>Shares</b> | <b>Dollars</b>  |
| First quarter  |               | \$                   | 8.8                 | \$ 537          | 46.6          | \$ 3,374        |
| Second quarter | 32.7          | 1,549 <sup>(1)</sup> | 73.9 <sup>(2)</sup> | 4,463           | 13.0          | 876             |
| Third quarter  |               | 19 <sup>(1)</sup>    | 2.5 <sup>(2)</sup>  |                 | 7.3           | 505             |
| Fourth quarter | 12.6          | 700                  | 1.8                 | 100             | 3.3           | 245             |
| <b>Total</b>   | <b>45.3</b>   | <b>\$ 2,268</b>      | <b>87.0</b>         | <b>\$ 5,100</b> | <b>70.2</b>   | <b>\$ 5,000</b> |

- <sup>(1)</sup> 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.

- <sup>(2)</sup> 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.

In July 2007, the Board of Directors authorized us to repurchase up to \$5.0 billion of common stock. As of December 31, 2008, we had \$4.2 billion available for stock repurchases as authorized by our Board of Directors. The manner of purchases, the amount we spend and the number

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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. In addition to the shares repurchased under our publicly announced stock repurchase program, for the years ended December 31, 2008, 2007 and 2006, we withheld shares for the payment of taxes upon vesting of certain employees restricted stock aggregating \$26 million, \$23 million and \$21 million, respectively.

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**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Accumulated other comprehensive income*

The components of accumulated other comprehensive income as of December 31, 2008 are as follows (in millions):

|                                                   | <b>Before-tax</b> | <b>Tax impact</b> | <b>After-tax</b> |
|---------------------------------------------------|-------------------|-------------------|------------------|
| Unrealized gains on foreign currency hedges       | \$ 82             | \$ (32)           | \$ 50            |
| Unrealized gains on available-for-sale securities | 79                | (30)              | 49               |
| Cumulative foreign currency translation gain      | 46                | (21)              | 25               |
| Other                                             | (11)              | 4                 | (7)              |
| <b>Balance as of December 31, 2008</b>            | <b>\$ 196</b>     | <b>\$ (79)</b>    | <b>\$ 117</b>    |

The components of accumulated other comprehensive income as of December 31, 2007 are as follows (in millions):

|                                                   | <b>Before-tax</b> | <b>Tax impact</b> | <b>After-tax</b> |
|---------------------------------------------------|-------------------|-------------------|------------------|
| Unrealized losses on foreign currency hedges      | \$ (73)           | \$ 28             | \$ (45)          |
| Unrealized gains on available-for-sale securities | 62                | (23)              | 39               |
| Cumulative foreign currency translation gain      | 89                | (30)              | 59               |
| <b>Balance as of December 31, 2007</b>            | <b>\$ 78</b>      | <b>\$ (25)</b>    | <b>\$ 53</b>     |

*Other*

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, \$0.0001 par value. At December 31, 2008 and 2007, no shares of preferred stock were issued or outstanding.

At December 31, 2008, we had reserved 236 million shares of our common stock, which may be issued through our employee compensation and stock purchase plans, through conversion of our convertible notes and through our warrants.

**8. Acquisitions***Dompé Biotec, S.p.A*

On January 4, 2008, we completed the acquisition of 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 net assets acquired of approximately \$63 million based on their estimated fair values at the acquisition date and the excess of the purchase price over the fair values of net assets acquired of approximately \$105 million was assigned to goodwill. There was no material gain or loss related to the reacquisition of marketing rights previously granted to Dompé as a result of this business combination. The results of Dompé's operations have been included in the consolidated financial statements commencing January 4, 2008. Pro forma results of operations for the year ended December 31, 2008 assuming the acquisition of Dompé had taken place at the beginning of 2008 would not differ significantly from the actual reported results.

*Ilypsa, Inc.*

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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

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**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

*Avidia, Inc.*

On October 24, 2006, we completed the acquisition of Avidia, which was accounted for as a business combination. Avidia was a privately held company focused on the discovery and development of a new class of human therapeutic known as Avimer proteins. Pursuant to the merger agreement, we paid cash of approximately \$275 million, net of cash acquired and our existing equity stake in Avidia, and may be subject to pay additional amounts upon the achievement of certain future events, as discussed further below. The purchase price, including cash paid to the former shareholders, the fair value of stock options assumed and transaction costs was allocated to acquired IPR&D of \$130 million and other net assets acquired of \$29 million, primarily intangible assets associated with R&D technology rights, 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 \$126 million was assigned to goodwill. The estimated fair values of the acquired IPR&D and the identifiable intangible asset were 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 Avidia's operations have been included in the consolidated financial statements commencing October 24, 2006. Pro forma results of operations for the year ended December 31, 2006 assuming the acquisition of Avidia had taken place at the beginning of 2006 would not differ significantly from actual reported results.

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

We may be required to pay an additional \$30 million to the former Avidia shareholders if on or before October 24, 2009 we complete the first dosing in humans of a once per week subcutaneous formulation of a specified interleukin 6 ( IL-6 ) inhibitor molecule developed using Avidia's proprietary methodology. We also may be required to make an additional payment to the former Avidia shareholders if on or before December 31, 2010 we complete the first dosing of a registration-enabling clinical trial with any IL-6 inhibitor molecule developed using Avidia's proprietary methodology. If the first such dosing is completed on or before December 31, 2009, the amount of the payment owed would be \$30 million; if the first dosing is completed after December 31, 2009 but on or before December 31, 2010, the amount of the payment owed would be reduced to \$5 million.

*Abgenix, Inc.*

On April 1, 2006, we acquired all of the outstanding common stock of Abgenix, a company with expertise in the discovery and development of monoclonal antibodies. We paid cash consideration of \$22.50 per share in this transaction that was accounted for as a business combination. Additionally, we issued 1.9 million stock options in exchange for Abgenix stock options assumed in the acquisition, 1.4 million of which were vested at the date of acquisition. The purchase price was as follows (in millions):

|                                                         |                 |
|---------------------------------------------------------|-----------------|
| Cash paid for shares                                    | \$ 2,103        |
| Other, principally fair value of vested options assumed | 96              |
| <b>Total</b>                                            | <b>\$ 2,199</b> |

The purchase price was allocated to all of the tangible and amortizable intangible assets acquired, including acquired IPR&D, and liabilities assumed 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 was assigned to goodwill. The following table summarizes the allocation of the purchase price (in millions):

|                               |                 |
|-------------------------------|-----------------|
| Acquired IPR&D                | \$ 1,101        |
| Identifiable intangible asset | 320             |
| Cash                          | 252             |
| Deferred tax assets, net      | 290             |
| Property, plant and equipment | 220             |
| Other assets                  | 75              |
| Liabilities, principally debt | (743)           |
| Goodwill                      | 684             |
| <b>Net assets acquired</b>    | <b>\$ 2,199</b> |

The estimated fair values of the acquired IPR&D and the identifiable intangible asset were determined based upon discounted after-tax cash flows adjusted for the probabilities of successful development and commercialization. The identifiable intangible asset consists of certain technology that has alternative future uses in our R&D activities and will be amortized over its five-year estimated useful life. 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 Abgenix's operations have been included in the consolidated financial statements commencing April 1, 2006. Pro forma results of operations for the year ended December 31, 2006 assuming the acquisition of Abgenix had taken place at the beginning of 2006 would not differ significantly from actual reported results.

In addition, proforma results of operations for the year ended December 31, 2006, assuming both the acquisitions of Avidia and Abgenix had taken place at the beginning of 2006, would not differ significantly from the actual reported results.



**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. Commitments**

We lease certain administrative, R&D, sales and marketing and manufacturing facilities and equipment under non-cancelable operating leases that expire through December 2023. The following table summarizes the minimum future rental commitments under non-cancelable operating leases at December 31, 2008 (in millions):

| <b>Year ending December 31,</b>             | <b>Lease commitments</b> |
|---------------------------------------------|--------------------------|
| 2009                                        | \$ 126                   |
| 2010                                        | 117                      |
| 2011                                        | 105                      |
| 2012                                        | 95                       |
| 2013                                        | 91                       |
| Thereafter                                  | 530                      |
| <b>Total</b>                                | <b>1,064</b>             |
| Less income from subleases                  | 140                      |
| <b>Net minimum operating lease payments</b> | <b>\$ 924</b>            |

Included in the table above are future rental commitments for abandoned leases in the amount of \$337 million less assumed sublease income of \$139 million. Rental expense on operating leases, net of sublease rental income, for the years ended December 31, 2008, 2007 and 2006 was \$120 million, \$104 million and \$69 million, respectively. Sublease income for the years ended December 31, 2008, 2007 and 2006 was not material.

The following table summarizes the minimum contractual commitments to all third-party contract manufacturers at December 31, 2008 (in millions):

| <b>Year ending December 31,</b>    | <b>Commitments</b> |
|------------------------------------|--------------------|
| 2009                               | \$ 165             |
| 2010                               | 141                |
| 2011                               | 114                |
| 2012                               | 59                 |
| 2013                               |                    |
| Thereafter                         |                    |
| <b>Total contractual purchases</b> | <b>\$ 479</b>      |

The amounts above primarily relate to our long-term supply agreement with Boehringer Ingelheim Pharma KG ( BI Pharma ) for the manufacture of commercial quantities of ENBREL. Under the terms of this agreement, we are required to purchase certain minimum quantities of ENBREL each year through 2012. Amounts owed to BI Pharma are based on firm commitments for the purchase of ENBREL and reflect certain estimates such as production run success rates and bulk drug yields achieved.

Amounts purchased under contractual inventory commitments from third-party contract manufacturers for the years ended December 31, 2008, 2007 and 2006 were \$196 million, \$153 million and \$333 million, respectively.

## 10. 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. In accordance with SFAS No. 5, *Accounting for Contingencies*, 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.

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**AMGEN INC.**

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

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

*Transkaryotic Therapies ( TKT ) and Aventis Litigation*

On April 15, 1997, Amgen filed a lawsuit in the U.S. District Court for the District of Massachusetts (the Massachusetts District Court ) against TKT and Hoechst Marion Roussel, Inc. ( HMR now Aventis Pharmaceuticals Inc., together with TKT, the TKT Defendants ) alleging, after subsequent amendment, infringement of five U.S. patents owned by Amgen that included claims to erythropoietin products and processes for making erythropoietin products. Amgen sought an injunction preventing the TKT Defendants from making, importing, using or selling erythropoietin in the United States. The TKT Defendants amended answer asserted that all five of the patents-in-suit were not infringed, were invalid and were unenforceable due to inequitable conduct.

As a result of multiple proceedings before the Massachusetts District Court and the United States Court of Appeals for the Federal Circuit (the Federal Circuit ), it has been finally determined that claim 1 of U.S. Patent No. 5,955,422 ( the 422 Patent ), claims 1, 3, 4, 6 and 7 of U.S. Patent No. 5,756,349 ( the 349 Patent ) and claims 4 through 9 of U.S. Patent No. 5,618,698 ( the 698 Patent ), are valid, enforceable and would be infringed by the TKT Defendant s erythropoietin product and the cells and processes used to produce it. Likewise, it was also determined that claims 2 through 4 of U.S. Patent No. 5,621,080 ( the 080 Patent ) are valid and enforceable but not infringed, and that claims 1 and 2 of U.S. Patent No. 5,547,933 ( the 933 Patent ) are invalid.

On October 2, 2008, the Massachusetts District Court entered a Memorandum and Order enjoining the TKT Defendants from infringing the 422 Patent, the 698 Patent and 349 Patent for the life of the patents, the last of which expires in 2015. No appeal from this judgment has been taken.

*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 v. Abbott Laboratories, Inc., et al.; County of Erie v. Abbott Laboratories, Inc., et al.; County of*

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*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 Dutchess 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. The class certification hearing for the Track I group was held on February 10, 2004. On January 30, 2006, the Massachusetts District Court certified three classes (one nationwide class and two Massachusetts only classes) with respect to the Track I 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 November 6, 2006, the Massachusetts District Court commenced the Track I trial as to the two Massachusetts only classes certified. Closing arguments in that case were held on January 26, 2007. 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.), Sicom, Inc., Gensia, Inc., Gensia Sicom 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 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.

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 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

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**AMGEN INC.**

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

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.

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

*Robert J. Swanston v. TAP Pharmaceutical Products, Inc., et al.* This Arizona state class action was filed against Amgen and Immunex on December 20, 2002 in the Maricopa County, Arizona Superior Court. The Maricopa County, Arizona Superior Court set a hearing on plaintiffs motion to certify a statewide class for May 13, 2005; however, the state court stayed the entire case on March 10, 2005. The case remains stayed and another status conference was held on March 17, 2008. On August 6, 2008, Defendants filed a motion for summary judgment. The hearing on defendants' motion for summary judgment was postponed due to need for assignment of a new judge. On October 20, 2008, the Track II defendants filed a motion to stay all proceedings.

*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. Amgen and Immunex filed answers to the complaint on January 5, 2006. Immunex filed an answer to the Commonwealth of Pennsylvania's amended complaint on April 6, 2006. 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.

*State of Wisconsin v. Amgen Inc., et al.* An amended complaint was filed against Amgen and Immunex on November 1, 2004 in the Circuit Court for Dane County, Wisconsin. Defendants filed their motions to dismiss the complaint on January 20, 2005. On July 13, 2005, defendants filed a notice of removal from the Circuit Court to the U.S. District Court for the Western District of Wisconsin (the Wisconsin District Court). This case was remanded to state court by order dated September 29, 2005. On October 11, 2006, this case was removed to the Wisconsin District Court. Plaintiffs filed a motion to remand and on January 16, 2007, the Wisconsin District Court remanded the case back to state court. On July 16, 2007, defendants filed a motion to sever, which was denied on September 28, 2007. Amgen and Immunex reached a settlement with the State, and both companies were dismissed with prejudice from the case on December 22, 2008. Amgen and Immunex admitted to no wrongdoing as part of the settlement agreement.

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*Commonwealth of Kentucky v. Alpharma, Inc., et al.* This case was filed against Amgen and Immunex on November 4, 2004 in the Franklin County Circuit Court, Franklin County, Kentucky. Defendants filed their motions to dismiss the complaint on February 1, 2005. On July 13, 2005, defendants filed a notice of removal from County Circuit Court to the U.S. District Court for the Eastern District of Kentucky. A hearing on plaintiffs' opposition to the proposed transfer of this case to the MDL Proceeding in Boston was considered by the Joint Panel on Multidistrict Litigation on November 17, 2005. This case was remanded to state court by order dated March 16, 2006. A hearing on defendants' motion to dismiss was held on June 6, 2006. Defendants filed a motion to sever the case on July 9, 2007, and a decision on that motion is pending. A case management conference was held on February 27, 2008, and a trial date of May 16, 2009 has been set for the first defendant, which did not include Amgen. On June 20, 2008, Immunex was dismissed with prejudice from the matter after reaching a settlement with the Commonwealth of Kentucky. Amgen subsequently reached a settlement with the Commonwealth and was dismissed with prejudice from the case on January 12, 2009. Amgen and Immunex admitted to no wrongdoing as part of the settlement agreements.

*State of Alabama v. Abbott Laboratories, Inc., et al.* This case was filed against Amgen and Immunex on January 26, 2005, in the Circuit Court of Montgomery County, Alabama. On July 13, 2005, defendants filed a notice of removal from the Circuit Court to the U.S. District Court for the Middle District of Alabama (the Alabama District Court). This case was remanded to state court by order dated August 11, 2005. Defendants' motions to dismiss were denied on October 13, 2005. Amgen and Immunex filed their answer to plaintiff's second amended complaint on January 30, 2006. On October 11, 2006, this case was removed to the Alabama District Court. On November 3, 2006, this case was remanded to state court. On January 22, 2007, the state court issued an order assigning defendants into four tracks for trial. Amgen and Immunex were assigned to Track 4. The Track 1 trial commenced on February 11, 2008. Two additional trials of non-Track 4 defendants (which did not include Amgen and Immunex) were held in June 2008. Following these trials, plaintiff Alabama filed a motion to set a trial date for four additional companies, including Amgen and Immunex. The state court granted the motion and set trial for Amgen and Immunex for February 2009. The plaintiff also filed a motion to consolidate the four defendants into one trial and the motion to consolidate was granted as to two of the four defendants, which did not include Amgen or Immunex. Amgen and Immunex reached a settlement with the State, and both companies were dismissed with prejudice from the case on December 19, 2008. Amgen and Immunex admitted to no wrongdoing as part of the settlement agreement.

*People of State of Illinois v. Abbott Laboratories, Inc., et al.* This case was filed against Amgen and Immunex on February 7, 2005 in the Circuit Court for Cook County, Illinois. Defendants filed their motions to dismiss the complaint on June 7, 2005. A hearing on plaintiffs' opposition to the proposed transfer of this case to the MDL Proceeding in Boston was considered by the Joint Panel on Multidistrict Litigation on November 17, 2005. This case was remanded to state court by order dated March 16, 2006. On October 11, 2006, this case was removed to the U.S. District Court for the Northern District of Illinois. On December 14, 2006, the case was transferred to the MDL Proceeding. A hearing before the Massachusetts District Court on plaintiff's motion to remand was held on February 1, 2007. On September 1, 2007, the case was remanded to the state court. Defendants have filed a joint motion to dismiss and a hearing on the motions to dismiss was held on March 13, 2008. An amended complaint was filed on June 10, 2008 in the state court. A status hearing was held on July 22, 2008 and on October 29, 2008.

*State of Mississippi v. Abbott Laboratories, Inc., et al.* This case was filed against Amgen and Immunex, along with several other pharmaceutical manufacturers, on October 20, 2005 in the Chancery Court of Hinds County, Mississippi, First Judicial District. The complaint alleges that defendants reported prices for certain products in a manner that allegedly inflated reimbursement under the Mississippi state Medicaid program. On October 11, 2006, this case was removed to the U.S. District Court for the Northern District of Mississippi. On October 25, 2006, the case was transferred to the MDL Proceeding. A hearing before the Massachusetts District Court on plaintiff's motion to remand was held on February 1, 2007. On September 1, 2007, the case was

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remanded to the state court. On December 13, 2007, defendants' motion to dismiss for subject matter jurisdiction was denied. On September 3, 2008, order to sever defendants and transfer the case was granted. Defendants are awaiting the assignment of a new judge in a new county.

*State of Arizona, etc., et al. v. Abbott Laboratories, Inc., et al.* This case was filed against Amgen and Immunex, along with several other pharmaceutical manufacturers, on December 7, 2005 in Maricopa County, Arizona. The complaint alleges that Amgen and Immunex, together with many other pharmaceutical manufacturers, reported prices for certain products in a manner that allegedly inflated reimbursement under the Arizona state Medicaid program. On October 10, 2006, this case removed to the Massachusetts District Court and was transferred to the MDL Proceeding. Plaintiff's motion to remand was denied on October 25, 2006.

*State of Alaska v. Abbott Laboratories, Inc., et al.* This case was filed against Amgen and Immunex, along with several other pharmaceutical manufacturers, on October 6, 2006 in the Alaska Superior Court in Anchorage, Alaska. The complaint alleges that Amgen and Immunex, together with many other pharmaceutical manufacturers, reported prices for certain products in a manner that allegedly inflated reimbursement under the Alaska state Medicaid program. Amgen and Immunex were served with the complaint on October 19, 2006. Amgen and Immunex filed motions to dismiss on January 5, 2007. A hearing on defendants', which includes Amgen and Immunex together with other pharmaceutical manufacturers, motions to dismiss was held on May 9, 2007. At this hearing, the court orally denied the joint motion to dismiss. A tentative trial date of April 2010 has been set. On February 4, 2008, Immunex was dismissed from the case without prejudice. Amgen subsequently reached a settlement with the State and was dismissed with prejudice from the case on January 2, 2009. Amgen admitted to no wrongdoing as part of the settlement agreement.

*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. A hearing on defendants' motion to dismiss was held on May 2, 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 U.S. District Court for the Northern District of New York. Plaintiffs filed a motion to remand on November 6, 2006. 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

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Court for the Northern District of New York. Plaintiffs filed a motion to remand on November 6, 2006. 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.

*Roche Matters*

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

On November 8, 2005, Amgen filed a lawsuit in the U.S. District Court for the District of Massachusetts (the "Massachusetts District Court") against F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively, "Roche Defendants") seeking a declaration by the 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"). Amgen 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.

On August 27, 2007, the Massachusetts District Court granted Amgen's motions for summary judgment that the "349 Patent", the "422 Patent" and the "933 Patent" are not invalid for obviousness-type double patenting over Amgen's now expired U.S. Patent 4,703,008 (the "008 Patent") and that certain of the asserted patent claims are not invalid for indefiniteness, lack of written description or lack of enablement. On August 28, 2007, the Massachusetts District Court granted Amgen's motion for summary judgment of infringement of claim 1 of the "422 Patent".

During the period starting September 4, 2007 and ending October 18, 2007, Amgen's remaining patent infringement claims were tried before a jury along with certain of the Roche Defendants' defenses and counterclaims of non-infringement and patent invalidity. On September 25, 2007, the Massachusetts District Court granted judgment as a matter of law that the Roche Defendants had not satisfied its burden of proving that "422 Patent" claim 1 is anticipated. On October 16, 2007, the Massachusetts District Court granted judgment as a matter of law that Amgen had not satisfied its burden to prove that the production of Roche Defendants' peg-EPO product infringes claim 7 of the "349 Patent". On October 17, 2007, the Massachusetts District Court granted judgment as a matter of law that Amgen had not satisfied its burden to prove that the Roche Defendants' peg-EPO product infringes claim 9 of the "933 Patent". On October 23, 2007, the jury rendered a verdict 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" were valid and that claims 3, 7, 8 and 12 of the "933 Patent", claims 1 and 2 of the "868 Patent" and claims 6 through 9 of the "698 Patent" will be infringed by the Roche Defendants.

Roche's defenses and counterclaims of invalidity based on obviousness-type double patenting and unenforceability based on alleged inequitable conduct were tried to the Massachusetts District Court in separate

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proceedings. On October 23, 2007, the Massachusetts District Court ruled that Roche did not meet its burden to prove the patents-in-suit are unenforceable. On October 30, 2007, the Massachusetts District Court granted Roche's post-trial motion overturning the jury's verdict of infringement of claim 12 of the '933 Patent.

Evidentiary hearings were held on November 15, 2007 and December 5-7, 2007 before the Massachusetts District Court concerning Amgen's request for a permanent injunction. On February 29, 2008, the Massachusetts District Court preliminarily enjoined the Roche Defendants from infringing the claims of the patents-in-suit found to have been infringed. Roche appealed this grant of a preliminary injunction but the Federal Circuit affirmed the District Court's actions on October 10, 2008.

On October 2, 2008, the Massachusetts District Court entered an Order denying the parties' post-trial motions and upholding the jury's verdict in all respects except infringement of claim 12 of the '933 Patent under the Doctrine of Equivalents, finding that the '868 Patent and the '698 Patent were not invalid for obviousness-type double patenting in view of the '008 Patent, that the '933 Patent, the '422 Patent and the '349 Patent were not invalid for obviousness-type double patenting in view of the '868 Patent or the '698 Patent, and that the Roche Defendants' antitrust counterclaims were moot. On October 17, 2008, the Massachusetts District Court entered judgment that the patents-in-suit are valid, enforceable and 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.

On December 15, 2008, the Roche Defendants filed their opening brief with the Federal Circuit in support of their appeal of the Massachusetts District Court's final judgment and permanent injunction. On January 27, 2009, Amgen filed its brief in response to the Roche Defendants' appeal and in support of Amgen's cross-appeal of the Massachusetts District Court's judgment of non-infringement of '349 claim 7 and '933 claims 9, 11-12 and 14. The Roche Defendant's brief in opposition to Amgen's cross appeal and in reply to Amgen's opposition to the Roche appeal is due by March 9, 2009.

*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 July 14, 2006, Amgen filed a petition requesting that the ALJ's summary determination be reviewed by the full ITC and 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. On March 19, 2008, the Federal Circuit issued a ruling on Amgen's appeal reversing the ITC's dismissal of the investigation on jurisdictional grounds and remanding the case for further proceeding to determine if infringement has occurred or will occur and to provide a remedy, if appropriate. In May 2008, Roche and the ITC filed a motion asking the Federal Circuit to reconsider its ruling in Amgen's favor, which is still pending before the court.

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Amgen Inc., et al., v. Ariad Pharmaceuticals, Inc.*

On April 20, 2006, Amgen, Immunex, Amgen USA Inc., Amgen Manufacturing, Limited and Immunex Rhode Island Corporation (the Amgen Entities) filed a complaint against Ariad Pharmaceuticals, Inc. (Ariad) in the U.S. District Court for the District of Delaware (the Delaware District Court) requesting that the court declare all of the claims of U.S. Patent Number 6,410,516 (the 516 Patent) invalid and not infringed by any activities related to ENBREL or Kineret®. The 516 Patent is exclusively licensed to Ariad. On April 13, 2007, the Amgen Entities filed an amended complaint for declaratory judgment of invalidity and non-infringement against Ariad and the Whitehead Institute for Biomedical Research (the Whitehead Institute). On April 13, 2007, Ariad, the Whitehead Institute, Massachusetts Institute of Technology (MIT) and The President and Fellows of Harvard College (Harvard) filed an answer to Amgen's amended complaint and a counterclaim against the Amgen Entities and Wyeth for patent infringement.

On May 30, 2007, Ariad filed a motion for leave to file amended counterclaims to assert additional claims for infringement of U.S. Patent Nos. 6,150,090 (the 090 Patent) and 5,804,374 (the 374 Patent), which was granted by The Delaware District Court on September 13, 2007. On October 9, 2007 Amgen filed its reply to Ariad's amended counterclaims. The Court scheduled a separate trial in March 2009 on the 090 Patent and 374 Patent. On December 11, 2007, Wyeth and Ariad filed a stipulated dismissal without prejudice and the Delaware District Court granted the motion on December 12, 2007. On January 31, 2008, Ariad agreed to dismiss with prejudice its claims of infringement with respect to the 090 Patent and 374 Patent for any of Amgen's activities as of the date of the dismissal. The Delaware District Court granted the dismissal with prejudice on February 1, 2008.

With respect to the 516 Patent, both parties filed dispositive motions on April 25, 2008. On June 19, 2008, the Delaware District Court held a hearing on the dispositive motions and issues of claim construction. On September 19, 2008, the Delaware District Court issued an order construing the claims of the 516 Patent and granted summary judgment that ENBREL does not infringe the 516 Patent. Also on September 19, 2008, the Delaware District Court granted summary judgment in-part in favor of Ariad, ruling that Amgen could not prove inequitable conduct on the basis of one of its claims, but that sufficient evidence exists for a trial on inequitable conduct on Amgen's alternative bases. The Delaware District Court also dismissed Amgen's claims of invalidity on the claims of the 516 Patent not asserted by Ariad to be infringed by sales of ENBREL (Ariad had asserted that only seven of the 203 patent claims were infringed), but the Delaware District Court maintained Amgen's unenforceability claims to all 203 claims of the 516 patent. The Delaware District Court acknowledged in its ruling that Ariad asserted it would no longer pursue its claim of infringement by Kineret®. On October 3, 2008, the Delaware District Court stayed Amgen's invalidity and unenforceability claims and entered final judgment of no infringement in favor of Amgen. The Delaware District Court declared the case administratively closed, to be reopened only by the parties after a decision on appeal.

On October 6, 2008, Ariad filed a notice of appeal. Ariad filed its Appellate brief on December 16, 2008 with the Federal Circuit, appealing the District Court's claim construction order and grant of summary judgment of noninfringement. Amgen filed its opposition brief on January 28, 2009. Ariad filed its reply brief on February 17, 2009. Oral argument on appeal remains to be scheduled.

*Human Genome Sciences Litigation*

On August 30, 2007, Human Genome Sciences (HGS) filed an action under 35 U.S.C. §146 against Amgen and Immunex in the Delaware District Court to review the judgment entered July 27, 2007 by the Board of Patent Appeals and Interferences in Interference No. 105,381. Amgen filed its Answer and Counterclaims to the complaint on October 22, 2007 and HGS filed its reply on November 9, 2007. On February 3, 2009, the Delaware District Court entered an order staying the case until further order of the court on a joint request by the parties.

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On November 30, 2007, 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 the complaint with prejudice pursuant to Rule 12(b)(1) for lack of subject matter jurisdiction and Rule 12(b)(6) for failure to state a claim. HGS filed a Notice of Appeal to the Federal Circuit and on January 7, 2009, HGS filed its opening brief on appeal.

*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 Pharmaceutical Industries Ltd. (collectively 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®. 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.

On November 13, 2008, the Delaware District Court entered a scheduling order setting a claims construction hearing for September 16 and 17, 2009 and indicating that the case will be placed in the trial pool on May 3, 2010.

*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. The California Central District Court granted plaintiffs leave to amend the complaint. Parties in the case are conducting class certification discovery. Plaintiff's motion for class certification is due before the California Central District Court on March 4, 2009 and Amgen's response in opposition is due 45 days later. The California Central District Court has not set a date for the hearing on the motion for class certification.

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

*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. A hearing on State Defendants' motion to dismiss and other motions was held on March 13, 2008.

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. Defendants' demurrers and alternative motion to stay this action were filed on April 14, 2008, and a hearing was held on June 10, 2008 in the Superior Court. 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 not yet been scheduled.

*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

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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 ( Board ) 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 U.S. Court of Appeals for the 9<sup>th</sup> Circuit, which remains pending before the 9<sup>th</sup> 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 of the Harris matter appeal.

*Third-Party Payors 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 payors 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.

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

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 payor 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 payor 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 July 2, 2008, the plaintiffs in the MDL filed an amended and consolidated complaint. Defendants' motion to dismiss before the California Central District Court was filed on August 4, 2008. On December 17, 2008, the MDL Court granted Defendants' motion to dismiss without prejudice and, on January 30, 2009, plaintiffs filed an Amended Consolidated Class Action Complaint, which is predicated on similar underlying allegations. Defendants' motion to dismiss the Amended Complaint is due before the MDL Court on March 6, 2009.

*Other*

On February 19, 2007, Amgen received an informal inquiry from the SEC's Atlanta District Office regarding the Danish Head and Neck Cancer ( DAHANCA ) 10 study. The SEC's Atlanta District Office transferred the inquiry to the Los Angeles office in late 2007. Amgen voluntarily produced certain information and documentation related to a number of ESA studies. On February 9, 2009, Amgen received a letter from the SEC's Los Angeles Regional Office indicating that this investigation has been completed and that the SEC's Office of Enforcement does not intend to recommend any enforcement action by the SEC.

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. Amgen continues to fully cooperate with the request.

On February 10, 2009, the presiding judge in the U.S. District Court for the District of Massachusetts partially unsealed a complaint previously filed in that court on July 3, 2007 by a confidential private plaintiff against Amgen, Immunex, Wyeth and a number of other defendants. The complaint unsealed by the court is titled First Amended Complaint, suggesting that it amends an earlier complaint previously filed by the private plaintiff and kept under seal by the court. The unsealed complaint was 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 Qui Tam Action ). The unsealed complaint alleges that various of the defendants engaged in unlawful sales and marketing activities with respect to two drugs, Aranesp® and ENBREL, in violation of federal and state laws, including the Federal and respective State False Claims Act(s), the Medicare and Medicaid Antikickback Statute, and the Federal Food, Drug and Cosmetic Act. Amgen has not yet been served

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

with the unsealed complaint. We believe that certain portions of the subpoenas Amgen received from the U.S. Attorney's Office, Eastern District of New York and the Attorney General of the State of New York may relate to allegations in the Qui Tam Action and that such allegations may also be related to an ongoing civil and criminal investigation by the U.S. Attorney's Office, Eastern District of New York.

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. Amgen is fully cooperating with the request. On July 18, 2008, Amgen received a supplemental 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. Amgen intends to fully cooperate with the government's document requests.

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.

**11. 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):

|                            | <b>Years ended December 31,</b> |               |               |
|----------------------------|---------------------------------|---------------|---------------|
|                            | <b>2008</b>                     | <b>2007</b>   | <b>2006</b>   |
| Product sales:             |                                 |               |               |
| Aranesp® U.S.              | \$ 1,651                        | \$ 2,154      | \$ 2,790      |
| Aranesp® International     | 1,486                           | 1,460         | 1,331         |
| EPOGEN® U.S.               | 2,456                           | 2,489         | 2,511         |
| Neulasta® U.S.             | 2,505                           | 2,351         | 2,217         |
| NEUPOGEN® U.S.             | 896                             | 861           | 830           |
| Neulasta® International    | 813                             | 649           | 493           |
| NEUPOGEN® International    | 445                             | 416           | 383           |
| ENBREL® U.S.               | 3,389                           | 3,052         | 2,736         |
| ENBREL® International      | 209                             | 178           | 143           |
| Sensipar® U.S.             | 412                             | 333           | 238           |
| Sensipar® International    | 185                             | 130           | 83            |
| Other U.S.                 | 151                             | 203           | 75            |
| Other International        | 89                              | 35            | 28            |
| <b>Total product sales</b> | <b>14,687</b>                   | <b>14,311</b> | <b>13,858</b> |
| Other revenues             | 316                             | 460           | 410           |

|                |           |           |           |
|----------------|-----------|-----------|-----------|
| Total revenues | \$ 15,003 | \$ 14,771 | \$ 14,268 |
|----------------|-----------|-----------|-----------|

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**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Geographic information*

Outside the United States, we principally sell Aranesp®, Neulasta® and NEUPOGEN® in Europe. We sell ENBREL only in the United States and Canada. Information regarding revenues and long-lived assets (consisting of property, plant and equipment) attributable to the United States and to all foreign 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.

Certain geographical information with respect to revenues and long-lived assets are as follows (in millions):

|                    | <b>Years ended December 31,</b> |               |               |
|--------------------|---------------------------------|---------------|---------------|
|                    | <b>2008</b>                     | <b>2007</b>   | <b>2006</b>   |
| <b>Revenues:</b>   |                                 |               |               |
| United States      | \$ 11,772                       | \$ 11,887     | \$ 11,782     |
| Foreign countries  | 3,231                           | 2,884         | 2,486         |
| <br>Total revenues | <br>\$ 15,003                   | <br>\$ 14,771 | <br>\$ 14,268 |

|                             | <b>December 31,</b> |              |
|-----------------------------|---------------------|--------------|
|                             | <b>2008</b>         | <b>2007</b>  |
| <b>Long-lived assets:</b>   |                     |              |
| United States               | \$ 3,836            | \$ 4,025     |
| Foreign countries           | 2,043               | 1,916        |
| <br>Total long-lived assets | <br>\$ 5,879        | <br>\$ 5,941 |

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***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. Outside the United States, Aranesp®, Neulasta® and NEUPOGEN® are principally distributed to hospitals and/or wholesalers depending upon the distribution practice in each country for which the product has been launched. 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, 2008, 2007 and 2006. On a combined basis, these distributors accounted for 71% and 87% of worldwide gross revenues and U.S. gross product sales, respectively, for 2008, as noted in the following table (dollar amounts in millions):

|                                      | <b>Years ended December 31,</b> |             |             |
|--------------------------------------|---------------------------------|-------------|-------------|
|                                      | <b>2008</b>                     | <b>2007</b> | <b>2006</b> |
| <b>AmerisourceBergen Corporation</b> |                                 |             |             |
| Gross product sales                  | \$ 7,099                        | \$ 6,124    | \$ 6,523    |
| % of total gross revenues            | 37%                             | 31%         | 35%         |
| % of U.S. gross product sales        | 46%                             | 39%         | 42%         |
| <b>McKesson Corporation</b>          |                                 |             |             |
| Gross product sales                  | \$ 3,594                        | \$ 2,398    | \$ 2,427    |
| % of total gross revenues            | 19%                             | 12%         | 13%         |
| % of U.S. gross product sales        | 23%                             | 15%         | 15%         |
| <b>Cardinal Health, Inc.</b>         |                                 |             |             |
| Gross product sales                  | \$ 2,823                        | \$ 2,715    | \$ 2,490    |
| % of total gross revenues            | 15%                             | 14%         | 13%         |
| % of U.S. gross product sales        | 18%                             | 17%         | 16%         |

At December 31, 2008 and 2007, amounts due from these three large wholesalers each exceeded 10% of gross trade receivables, and accounted for 58% and 57%, respectively, of net trade receivables on a combined basis. At December 31, 2008 and 2007, 40% and 35%, 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, 2008 and 2007 was not material.

**12. Accrued liabilities**

Accrued liabilities consisted of the following (in millions):

|                                    | <b>December 31,</b> |                 |
|------------------------------------|---------------------|-----------------|
|                                    | <b>2008</b>         | <b>2007</b>     |
| Sales incentives                   | \$ 876              | \$ 1,064        |
| Employee compensation and benefits | 799                 | 888             |
| Clinical development costs         | 429                 | 406             |
| Accrued royalties                  | 218                 | 212             |
| Other                              | 1,060               | 1,231           |
|                                    | <b>\$ 3,382</b>     | <b>\$ 3,801</b> |



**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****13. Fair values***Fair value measurement*

The Company adopted the provisions of the FASB's SFAS 157, effective January 1, 2008, for its financial assets and liabilities. The FASB subsequently issued FSP FAS 157-2, *Effective Date of FASB Statement No. 157*, which delayed the effective date of SFAS 157 until January 1, 2009, with respect to the fair value measurement requirements for non-financial assets and liabilities that are not remeasured on a recurring basis. Under this standard, fair value is 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 SFAS 157 did not have a material impact on the Company's consolidated financial statements.

In determining the fair value of its financial assets and liabilities, the Company uses various valuation approaches. SFAS 157 establishes a hierarchy for inputs used in measuring fair value 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 based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly |
| 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 input that is significant to the overall fair value measurement.

As of December 31, 2008, the Company's available-for-sale securities were comprised of U.S. Treasury securities, obligations of U.S. government agencies and FDIC guaranteed bank debt, corporate debt securities, mortgage and asset backed securities, other short-term interest bearing securities, including money market funds, and publicly traded equity investments. U.S. Treasury securities, money market funds and publicly traded equity investments are valued using quoted market prices with no valuation adjustments applied. 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 quoted market prices of recent transactions or are benchmarked to transactions of very similar securities. Accordingly, these securities are categorized in Level 2.

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

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2008 (in millions):

|                               | Fair value measurement at reporting date using:                               |                                                        |                                                    |                                       |
|-------------------------------|-------------------------------------------------------------------------------|--------------------------------------------------------|----------------------------------------------------|---------------------------------------|
|                               | Quoted prices in<br>active markets for<br>identical<br>assets<br>(Level<br>1) | Significant other<br>observable<br>inputs<br>(Level 2) | Significant<br>unobservable<br>inputs<br>(Level 3) | Balance as of<br>December 31,<br>2008 |
| <b>Assets:</b>                |                                                                               |                                                        |                                                    |                                       |
| Available-for-sale securities | \$ 3,575                                                                      | \$ 5,927                                               | \$                                                 | \$ 9,502                              |
| Derivatives                   |                                                                               | 415                                                    |                                                    | 415                                   |
| Total                         | \$ 3,575                                                                      | \$ 6,342                                               | \$                                                 | \$ 9,917                              |
| <b>Liabilities:</b>           |                                                                               |                                                        |                                                    |                                       |
| Derivatives                   | \$                                                                            | \$ (66)                                                | \$                                                 | \$ (66)                               |
| Total                         | \$                                                                            | \$ (66)                                                | \$                                                 | \$ (66)                               |

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

Following is a summary of the fair value of other financial instruments:

*Short-term assets and liabilities*

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

*Notes*

The following table presents fair value information for our convertible notes, modified convertible notes and other long-term notes. The fair values shown are based on significant other observable inputs (Level 2) (in millions):

|                          | December 31,<br>2008 | 2007     |
|--------------------------|----------------------|----------|
| 2011 Convertible Notes   | \$ 2,415             | \$ 2,282 |
| 2013 Convertible Notes   | 2,374                | 2,196    |
| 2008 Floating Rate Notes |                      | 1,994    |
| 2017 Notes               | 1,140                | 1,105    |
| 2014 Notes               | 994                  | 970      |
| 2009 Notes               | 1,017                | 994      |
| 2037 Notes               | 948                  | 897      |

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|                                 |           |           |
|---------------------------------|-----------|-----------|
| 2018 Notes                      | 536       |           |
| 2038 Notes                      | 567       |           |
| 2032 Modified Convertible Notes | 58        | 54        |
| Century Notes                   | 111       | 119       |
|                                 |           |           |
| Total                           | \$ 10,160 | \$ 10,611 |

### 14. Other charges

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 antitrust suit. In 2007, we recorded a loss accrual for an ongoing commercial legal proceeding, and recorded an expense of \$34 million. These amounts are included in Other charges in the Consolidated Statements of Income.

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**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In 2008 and 2007, we recorded restructuring charges of \$92 million and \$694 million, respectively. Such expenses are included in Other charges in the Consolidated Statements of Income. (See Note 2, *Restructuring* for further discussion.)

**15. Subsequent event**

On January 16, 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. We may redeem the notes 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 of 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 purchase price equal to 101% of the principal amount of the notes plus accrued interest.

**16. Quarterly financial data (unaudited)**

|                                     | Dec. 31 <sup>(1)</sup> | 2008 Quarters ended                  |                        |                        |
|-------------------------------------|------------------------|--------------------------------------|------------------------|------------------------|
|                                     |                        | Sept. 30 <sup>(2)</sup>              | June 30 <sup>(3)</sup> | Mar. 31 <sup>(4)</sup> |
|                                     |                        | (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                          | 961                    | 1,158                                | 941                    | 1,136                  |
| Earnings per share <sup>(9)</sup> : |                        |                                      |                        |                        |
| Basic                               | \$ 0.91                | \$ 1.09                              | \$ 0.87                | \$ 1.04                |
| Diluted                             | \$ 0.91                | \$ 1.09                              | \$ 0.87                | \$ 1.04                |

|                                     | Dec. 31 <sup>(5)</sup> | 2007 Quarters ended                  |                        |                        |
|-------------------------------------|------------------------|--------------------------------------|------------------------|------------------------|
|                                     |                        | Sept. 30 <sup>(6)</sup>              | June 30 <sup>(7)</sup> | Mar. 31 <sup>(8)</sup> |
|                                     |                        | (In millions, except per share data) |                        |                        |
| Product sales                       | \$ 3,618               | \$ 3,524                             | \$ 3,604               | \$ 3,565               |
| Gross profit from product sales     | 3,012                  | 2,732                                | 3,046                  | 2,973                  |
| Net income                          | 835                    | 201                                  | 1,019                  | 1,111                  |
| Earnings per share <sup>(9)</sup> : |                        |                                      |                        |                        |
| Basic                               | \$ 0.77                | \$ 0.19                              | \$ 0.90                | \$ 0.95                |
| Diluted                             | \$ 0.76                | \$ 0.18                              | \$ 0.90                | \$ 0.94                |

<sup>(1)</sup> In the fourth quarter 2008, we recorded the following in the Consolidated Statement of Income:

- a. charges of \$97 million primarily for asset impairments, loss accruals for leases for certain facilities that will not be used in our business and staff separation costs associated with our restructuring plan; and
- b. charge of \$21 million (\$15 million, net of tax) for loss accruals for settlements of certain commercial legal proceedings.

<sup>(2)</sup> In the third quarter 2008, we recorded the following in the Consolidated Statement of Income:

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- a. charges of \$17 million primarily for a loss on the disposal of certain less significant marketed products and loss accruals for leases for certain facilities that will not be used in our business associated with our restructuring plan;
- b. 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; and
- c. charge of \$4 million (\$3 million, net of tax) for loss accruals for settlements of certain commercial legal proceedings.

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**AMGEN INC.**

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

- (3) In the second quarter 2008, we recorded the following in the Consolidated Statement of Income:
- a. charges of \$22 million primarily for asset impairments and loss accruals for leases for certain facilities that will not be used in our business associated with our restructuring plan; and
  - b. charge of \$263 million (\$200 million, net of tax) for loss accruals for settlements of certain commercial legal proceedings.
- (4) In the first quarter of 2008, we recorded the following in the Consolidated Statement of Income:
- a. charges of \$12 million primarily for asset impairments, loss accruals for leases for certain facilities that will not be used in our business and staff separation costs associated with our restructuring plan.
- (5) In the fourth quarter 2007, we recorded the following in the Consolidated Statement of Income:
- a. charges of \$157 million primarily for staff separation costs, asset impairments and accelerated depreciation associated with our restructuring plan;
  - b. charge of \$34 million (\$25 million, net of tax) for a loss accrual for an ongoing commercial legal proceeding; and
  - c. severance-related expenses of \$21 million (\$13 million, net of tax) incurred in connection with our acquisition of the remaining 51% ownership interest of Dompé.
- (6) In the third quarter 2007, we recorded the following in the Consolidated Statement of Income:
- a. charges of \$293 million primarily for staff separation costs, asset impairments and accelerated depreciation associated with our restructuring plan;
  - b. charges of \$270 million and \$320 million related to the non-tax deductible write-off of IPR&D related to the Alantos and Ilypsa acquisitions, respectively; and
  - c. pre- and post-tax charge of \$90 million related to the write-off of excess inventory principally due to changing regulatory and reimbursement environments.

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<sup>(7)</sup> In the second quarter 2007, we recorded the following in the Consolidated Statement of Income:

- a. charges of \$289 million primarily for asset impairments associated with our restructuring plan; and
- b. income tax benefit of \$92 million recognized as the result of resolving certain non-routine transfer pricing issues with the IRS for prior periods.

<sup>(8)</sup> In the first quarter of 2007, we recorded the following in the Consolidated Statement of Income:

- a. pro-rata portion of the deferred financing and related costs of \$51 million (\$32 million, net of tax) that were immediately charged to interest expense as a result of certain holders of our 2032 Modified Convertible Notes due in 2032 exercising their March 1, 2007 put option and the related convertible notes being repaid in cash; and
- b. pre- and post-tax charge of \$26 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.

<sup>(9)</sup> EPS is computed independently for each of the quarters presented. Therefore, the sum of the quarterly EPS information may not equal annual EPS.

See Notes 1, 2, 5, 8 and 14 for further discussion of the items described above.

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**Table of Contents****SCHEDULE II****AMGEN INC.****VALUATION ACCOUNTS****Years ended December 31, 2008, 2007 and 2006****(In millions)**

|                                      | <b>Balance at<br/>beginning<br/>of period</b> | <b>Additions<br/>charged to<br/>costs<br/>and<br/>expenses</b> | <b>Other<br/>additions</b> | <b>Deductions</b> | <b>Balance<br/>at end<br/>of period</b> |
|--------------------------------------|-----------------------------------------------|----------------------------------------------------------------|----------------------------|-------------------|-----------------------------------------|
| <b>Year ended December 31, 2008:</b> |                                               |                                                                |                            |                   |                                         |
| Allowance for doubtful accounts      | \$ 39                                         | \$ 1                                                           | \$                         | \$ 2              | \$ 38                                   |
| <b>Year ended December 31, 2007:</b> |                                               |                                                                |                            |                   |                                         |
| Allowance for doubtful accounts      | \$ 38                                         | \$                                                             | \$ 3                       | \$ 2              | \$ 39                                   |
| <b>Year ended December 31, 2006:</b> |                                               |                                                                |                            |                   |                                         |
| Allowance for doubtful accounts      | \$ 35                                         | \$ 3                                                           | \$                         | \$                | \$ 38                                   |

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