

AMGEN INC  
Form 10-K  
February 28, 2007  
Table of Contents

---

**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, 2006

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 ☐

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 ☒

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

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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐

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 \$76,300,392,427 as of June 30, 2006(A)

---

(A) Excludes 591,682 shares of common stock held by directors and officers, and any stockholders whose ownership exceeds five percent of the shares outstanding, at June 30, 2006. 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.

**1,167,458,942**

(Number of shares of common stock outstanding as of January 31, 2007)

### DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2007 Annual Meeting of stockholders to be held May 9, 2007 are incorporated by reference into Part III of this annual report.

---

**Table of Contents****INDEX**

	<b>Page No.</b>
<b><u>PART I</u></b>	
Item 1.	1
<u>Business Overview</u>	1
<u>Principal Products</u>	2
<u>Marketing and Distribution</u>	5
<u>Reimbursement</u>	6
<u>Research and Development and Selected Product Candidates</u>	9
<u>Competition</u>	15
<u>Manufacturing and Raw Materials</u>	19
<u>Joint Ventures and Business Relationships</u>	21
<u>Government Regulation</u>	22
<u>Patents and Trademarks</u>	25
<u>Human Resources</u>	26
<u>Executive Officers of the Registrant</u>	27
<u>Geographic Area Financial Information</u>	28
<u>Investor Information</u>	28
Item 1A.	28
<u>Risk Factors</u>	28
Item 1B.	46
<u>Unresolved Staff Comments</u>	46
Item 2.	47
<u>Properties</u>	47
Item 3.	48
<u>Legal Proceedings</u>	48
Item 4.	56
<u>Submission of Matters to a Vote of Security Holders</u>	56
<b><u>PART II</u></b>	
Item 5.	57
<u>Market for Registrant's Common Equity and Related Stockholder Matters</u>	57
Item 5(c).	59
<u>Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities</u>	59
Item 6.	59
<u>Selected Financial Data</u>	59
Item 7.	61
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	61
Item 7A.	79
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	79
Item 8.	81
<u>Financial Statements and Supplementary Data</u>	81
Item 9.	81
<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosures</u>	81
Item 9A.	81
<u>Controls and Procedures</u>	81
Item 9B.	84
<u>Other Information</u>	84
<b><u>PART III</u></b>	
Item 10.	84
<u>Directors and Executive Officers of the Registrant</u>	84
Item 11.	84
<u>Executive Compensation</u>	84
Item 12.	85
<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	85
Item 13.	92
<u>Certain Relationships and Related Transactions</u>	92
Item 14.	92
<u>Principal Accountant Fees and Services</u>	92
<b><u>PART IV</u></b>	
Item 15.	93
<u>Exhibits, Financial Statement Schedules and Reports on Form 8-K</u>	93
<u>Signatures</u>	101

## **Table of Contents**

### **PART I**

#### **Item 1. BUSINESS Overview**

Amgen Inc. (including its subsidiaries, referred to as Amgen, we, our and us ) was incorporated in 1980 and is a global biotechnology company 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 in the areas of supportive cancer care, nephrology, inflammation and oncology. Vectibix (panitumumab), our first oncology therapeutic, received U.S. Food and Drug Administration ( FDA ) approval in late September 2006 and became commercially available in October. Our principal products include Aranesp® (darbepoetin alfa), Neulasta® (pegfilgrastim), NEUPOGEN® (Filgrastim), EPOGEN® (Epoetin alfa) and Enbrel® (etanercept), which is marketed under a co-promotion agreement with Wyeth in the United States and Canada. Aranesp® and EPOGEN® stimulate the production of red blood cells to treat anemia. 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 competitively inhibiting TNF, a substance induced in response to inflammatory and immunological responses, such as rheumatoid arthritis and psoriasis. Vectibix binds specifically to the human epidermal growth factor receptor ( EGFr ), a protein that is over expressed in many human cancers, and interferes with signals that might otherwise stimulate growth and survival of the cancer cell. For the years ended December 31, 2006, 2005 and 2004, our principal products represented 97%, 98% and 99% of total product sales, respectively.

We maintain sales and marketing forces in the United States, Europe, Canada and Australia. We market our principal products to healthcare providers including clinics, dialysis centers, hospitals and pharmacies. In addition, we have entered into licensing and/or co-promotion agreements to market our principal products in certain geographic areas. In the United States, we sell primarily to wholesale distributors. Outside the United States, we sell principally to hospitals and/or wholesalers depending upon the distribution practice in each country. Sales of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans. Further, we operate in an increasingly competitive environment in all areas of our business.

We focus our research and development ( R&D ) efforts on novel therapeutics for the treatment of grievous illness in the areas of inflammation, oncology and hematology, neuroscience and metabolic disorders. 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 are studying molecules in the areas of proteins, including monoclonal antibodies and peptibodies, and small molecules. We have major R&D facilities in the United States as well as small research centers in Germany and, as of the second quarter of 2006, in Canada. We also have development facilities in Europe, Canada, Australia and Japan and, as of the fourth quarter of 2006, in Mexico and the United Kingdom. To enhance our internal R&D efforts, we have acquired companies, acquired and licensed certain product and technology rights and have established R&D collaborations. Our R&D efforts are significant and are expected to continue to increase in support of our pipeline, especially in the number, size, duration and complexity of our clinical trials.

Our manufacturing operations consist of bulk manufacturing and/or formulation, fill and finish activities which produce Aranesp®, Neulasta®, NEUPOGEN®, Epoetin alfa, ENBREL, Vectibix and other 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. Third-party contract manufacturers produce additional supply and provide formulation, fill and finish of certain of our products and product candidates. As part of our previously announced strategy to increase manufacturing capacity, we are building a new process development, bulk manufacturing, formulation, fill and finish facility in Ireland and expanding our bulk manufacturing, formulation, fill and finish capacity in Puerto Rico.

## **Table of Contents**

### **Principal Products**

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

#### *Aranesp® (darbepoetin alfa)*

Aranesp® is Amgen's registered trademark for one of its novel erythropoiesis stimulating proteins, 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 could result in anemia, a condition where insufficient oxygen is delivered to the body's organs and tissues. Anemia can be associated with chronic renal failure, both in patients on dialysis and not on dialysis. Anemia can also result from chemotherapy treatments for patients with non-myeloid malignancies. Aranesp® relieves anemia symptoms and reduces the need for blood transfusions.

We were granted an exclusive license by Kirin-Amgen, Inc. ( "KA" ), a joint venture between Kirin Brewery Company, Limited ( "Kirin" ) and Amgen (see Joint Ventures and Business Relationships Kirin Brewery Company, Limited ) to manufacture and market 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.

We primarily market Aranesp® in the United States and Europe. Darbepoetin alfa is also marketed under the brand name Nespo® in Italy. Aranesp® was initially launched in 2001 in the United States and Europe and is indicated for the treatment of anemia associated with chronic renal failure (both in patients on dialysis and patients not on dialysis) as well as for the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies. In March 2006, the FDA approved label changes to include every-three-week dosing of Aranesp® for the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies.

Worldwide Aranesp® sales for the years ended December 31, 2006, 2005 and 2004 were \$4,121 million, \$3,273 million and \$2,473 million, respectively.

#### *Neulasta® (pegfilgrastim)*

Neulasta® is Amgen's 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 (see NEUPOGEN®/Filgrastim ). Neutrophils defend against infection. Treatments for various diseases and diseases themselves can result in extremely low numbers of neutrophils, a condition called neutropenia. Myelosuppressive chemotherapy, one treatment option for individuals with certain types of cancers, targets cell types that grow rapidly, such as tumor cells. Normal cells that also 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. By addressing the dose limiting side effect of neutropenia, full doses of chemotherapy can be given, resulting in the potential for an improved treatment success rate in certain types of cancer, such as early stage breast cancer and in intermediate grade non-Hodgkin's Lymphomas. As mentioned above, the pegfilgrastim molecule is based on the Filgrastim molecule. A polyethylene glycol molecule or ( 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® is 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.

## **Table of Contents**

We were granted an exclusive license to manufacture and market pegfilgrastim in the United States, Europe, Canada, Australia and New Zealand under a licensing agreement with KA.

We primarily market Neulasta® in the United States and Europe. Pegfilgrastim is marketed under the brand name Neupopeg® 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. Subsequently, the FDA approved an update to the Neulasta® prescribing information to include data from a landmark phase 3 study demonstrating that Neulasta® helps protect patients with breast cancer undergoing moderately myelosuppressive chemotherapy from infection, as manifested by febrile neutropenia. Administration of Neulasta® in all cycles of chemotherapy is now approved for patients receiving myelosuppressive chemotherapy associated with at least a 17% risk of febrile neutropenia.

Worldwide Neulasta® sales for the years ended December 31, 2006, 2005 and 2004 were \$2,710 million, \$2,288 million and \$1,740 million, respectively.

### *NEUPOGEN® (Filgrastim)*

NEUPOGEN® is Amgen's registered trademark for its recombinant-methionyl human granulocyte colony-stimulating factor ( G-CSF ), a protein that selectively stimulates production of certain white blood cells known as neutrophils (see Neulasta® pegfilgrastim for additional information on neutrophils). Similar to Neulasta®, NEUPOGEN® is 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 G-CSF in the United States, Europe, Canada, Australia and New Zealand under a licensing agreement with KA.

We market NEUPOGEN® primarily in the United States and Europe. Filgrastim is marketed under the brand name GRANULOKINE® in Italy. NEUPOGEN® was initially launched in the United States and Europe in 1991. NEUPOGEN® is indicated for the following: to reduce the incidence of infection as manifested by febrile neutropenia for patients with non-myeloid malignancies undergoing myelosuppressive chemotherapy; to reduce the duration of neutropenia and neutropenia-related consequences for patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation; to reduce the incidence and duration of neutropenia-related consequences in symptomatic patients with congenital neutropenia, cyclic neutropenia or idiopathic neutropenia (collectively, severe chronic neutropenia); to mobilize peripheral blood progenitor cells ( PBPC ) in cancer patients who have undergone myeloablative chemotherapy for stem cell transplantation; and to reduce 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 NEUPOGEN® sales for the years ended December 31, 2006, 2005 and 2004 were \$1,213 million, \$1,216 million and \$1,175 million, respectively.

### *EPOGEN® (Epoetin alfa)*

EPOGEN® is Amgen's registered trademark for its recombinant human erythropoietin product, a protein that stimulates red blood cell production. A reduced red blood cell count can result in anemia (see Aranesp® darbepoetin alfa ). People with chronic renal failure 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® 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 Products, L.P., a subsidiary of Johnson & Johnson, hereafter referred to as Ortho Biotech Products, L.P. or Johnson & Johnson ) a license to commercialize recombinant human erythropoietin as a human therapeutic in the United States in all markets other than dialysis

## **Table of Contents**

(see Joint Ventures and Business Relationships Johnson & Johnson ). Johnson & Johnson markets recombinant human erythropoietin under the trademark PROCRIT® in the United States (see Note 1, Summary of significant accounting policies Product sales to the Consolidated Financial Statements).

We launched EPOGEN® in the United States in 1989 for the treatment of anemia associated with chronic renal failure for patients who are on dialysis. EPOGEN® is approved for the treatment of anemic adult and pediatric patients with chronic renal failure who are on dialysis. EPOGEN® is indicated to elevate or maintain the red blood cell level (as determined by hematocrit or hemoglobin measurements) and to decrease the need for blood transfusions in these patients.

EPOGEN® sales for the years ended December 31, 2006, 2005 and 2004 were \$2,511 million, \$2,455 million and \$2,601 million, respectively.

### *Enbrel® (etanercept)*

ENBREL is Amgen's registered trademark for its TNF receptor fusion protein that inhibits the binding of TNF to TNF receptors, which can result in a significant reduction in inflammatory activity. TNF is one of the chemical messengers that help regulate the inflammatory process. When the body produces too much TNF, it overwhelms the immune system's ability to control inflammation of the joints or of psoriasis-affected skin areas. ENBREL is similar to a protein that the body produces naturally, and like this protein, it binds 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 rheumatoid arthritis. In addition, ENBREL is now indicated for reducing the signs and symptoms, improving physical function, inhibiting the progression of structural damage and inducing a Major Clinical Response (a Major Clinical Response represents a high level of disease control) in patients with moderately to severely active rheumatoid arthritis; for the treatment of chronic moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy; for reducing the signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying medicines; for reducing the signs and symptoms of active arthritis and inhibiting the progression of structural damage in patients with psoriatic arthritis; and to treat the signs and symptoms in patients with active ankylosing spondylitis. Also, the FDA approved an expanded indication for ENBREL as the first treatment to improve physical function in patients with psoriatic arthritis and approved an update to the ENBREL label to include new radiographic data demonstrating that ENBREL continued to inhibit the progression of joint destruction for two years among most psoriatic arthritis patients who received ongoing therapy. The recommended dosing form for ENBREL for treatment in all approved adult indications is a 50 mg/ml single-use prefilled syringe or a 50 mg/ml single-use prefilled SureClick auto injector. Each of the prefilled syringe and the prefilled SureClick auto injector eliminates the need to mix the drug prior to injecting and allows most patients receiving ENBREL to take only one injection per week, instead of two 25 mg injections per week.

ENBREL sales for the years ended December 31, 2006, 2005 and 2004 were \$2,879 million, \$2,573 million and \$1,900 million, respectively.

### *Other*

Other marketed products are principally comprised of Sensipar® (cinacalcet HCl) and Vectibix (panitumumab).

---

**Table of Contents**

*Sensipar® (cinacalcet HCl)*

Sensipar® (Mimpara® in Europe) is Amgen's registered trademark for its first small molecule medicine used in treating chronic kidney disease (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, Canada 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, 2006, 2005 and 2004 were \$321 million, \$157 million and \$37 million, respectively.

*Vectibix (panitumumab)*

Vectibix is Amgen's trademark for the first entirely human monoclonal antibody for the treatment of patients with EGFR expressing metastatic colorectal cancer after disease progression on, or following fluoropyrimidine-, oxaliplatin- and irinotecan- containing chemotherapy regimens. EGFRs are proteins that play an important role in cancer cell signaling. Vectibix is an entirely human IgG2 monoclonal antibody that binds with high affinity to EGF receptors. 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 late September 2006 and became commercially available in October 2006. We have applied for regulatory approval of Vectibix for the same indication in the EU and other countries.

We acquired full ownership of Vectibix as part of our acquisition of Abgenix, Inc. (Abgenix) in April 2006 (see Research and Development and Selected Product Candidates).

Vectibix sales for the year ended December 31, 2006 were \$39 million.

**Marketing and Distribution**

We primarily maintain sales and marketing forces in the United States, Europe, Canada and Australia. We market our principal products to healthcare providers including 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.



## Table of Contents

In the United States, we sell primarily to wholesale distributors of pharmaceutical products. With the exception of ENBREL, we utilize these wholesale distributors as the principal means of distributing our products to healthcare providers such as clinics, dialysis centers, hospitals and pharmacies. For wholesaler orders of ENBREL, we primarily drop-ship directly to pharmacies. Outside the United States, Aranesp®, Neulasta® and NEUPOGEN® are principally distributed to hospitals and 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 appropriate credit limits, requiring collateral and obtaining credit insurance, where 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, 2006, 2005 and 2004. On a combined basis, these distributors accounted for 61% and 73% of total gross revenues and U.S. gross product sales, respectively, for 2006, as noted in the following table (in millions):

	Years ended December 31,		
	2006	2005	2004
<b>AmerisourceBergen Corporation</b>			
Gross product sales	\$ 6,523	\$ 5,593	\$ 3,519
% of total gross revenues	35%	34%	26%
% of U.S. gross product sales	42%	41%	32%
<b>Cardinal Health, Inc.</b>			
Gross product sales	\$ 2,490	\$ 2,752	\$ 1,909
% of total gross revenues	13%	17%	14%
% of U.S. gross product sales	16%	20%	18%
<b>McKesson Corporation</b>			
Gross product sales	\$ 2,427	\$ 2,534	\$ 2,094
% of total gross revenues	13%	15%	16%
% of U.S. gross product sales	15%	19%	19%

We have granted Johnson & Johnson 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 ). Johnson & Johnson markets recombinant human erythropoietin under the trademark PROCRI® in the United States (see Note 1, Summary of significant accounting policies Product sales to the Consolidated Financial Statements). Under a co-promotion agreement with Wyeth, Amgen and Wyeth market ENBREL in the United States and Canada for all approved indications other than for use in oncology. The rights to detail and promote ENBREL in the United States and Canada for use in oncology are reserved to Amgen (see Joint Ventures and Business Relationships Wyeth ). Additionally, we have entered into agreements to market certain of our products including Aranesp®, Neulasta® and NEUPOGEN® in certain geographic areas outside of the United States.

## Reimbursement

In the United States, dialysis providers are primarily reimbursed for EPOGEN® by the federal government through the End Stage Renal Disease Program ( 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 rate is established by federal law and is monitored and implemented by the Center for Medicare & Medicaid Service ( CMS ). Most patients receiving Aranesp®, Neulasta® and NEUPOGEN® for approved indications are covered by both government and private payer healthcare programs. Since January 1, 2006, ENBREL and Sensipar® are eligible for coverage from the U.S. government under Medicare Part D. Although both ENBREL and Sensipar® have received broad formulary placement in 2006 and 2007, Part D formulary placements are made by individual Part D plan sponsors with oversight by CMS and are subject to revision in the future. Generally, in Europe and other countries outside the U.S., the government sponsored healthcare system is the primary payer of healthcare costs of patients. Governments may regulate access to,

## **Table of Contents**

prices or reimbursement levels of our products to control costs. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to healthcare providers in response to ongoing initiatives to reduce healthcare expenditures. Further, changes in guidelines or recommendations promulgated by government agencies, professional societies, insurance carriers, practice management groups, physicians, private health/science foundations and organizations involved in various diseases may negatively impact reimbursement of our products. Therefore, sales of all of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans.

The Medicare Prescription Drug Improvement and Modernization Act (or the Medicare Modernization Act (MMA)) was enacted into law in December 2003 and implemented January 1, 2005. Changes resulting from the MMA, which lowered reimbursement for our products, could negatively affect product sales of some of our marketed products however, we believe that our product sales for 2005 and 2006 were not significantly impacted by the reimbursement changes resulting from the MMA. We believe this was, in part, due to the effects of CMS 2005 and 2006 oncology demonstration projects on sales of our products used in supportive cancer care, especially Aranesp®. However, we believe it is unlikely that CMS will implement an oncology demonstration project for 2007. Furthermore, we believe that our sales for 2005 and 2006 were not significantly impacted, in part, due to increased reimbursement rates to physicians from CMS for services associated with drug administration. The 2006 Medicare Physician Fee Schedule Payment Final Rule reduced payments for physician services in 2006 by approximately 4.4% on average, although subsequent legislation eliminated this reduction for 2006. The Medicare Physician Fee Schedule Payment Final Rule for 2007 would have reduced payments for physician services in 2007 by approximately 5.0% on average, however, as in 2006, new legislation eliminated the reduction in payments for 2007.

Because we cannot accurately predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products, we cannot estimate the full impact of the MMA on our business, although we believe that it is not likely to be significant to our business in 2007. However, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales and related sales growth in the future.

The main components of the MMA that affect our currently marketed products are as follows:

Through 2004, the Average Wholesale Price (AWP) mechanism was the basis of Medicare Part B payment for covered outpatient drugs and biologics. Since January 1, 2005, in the physician clinic setting, Aranesp®, Neulasta® and NEUPOGEN® are being reimbursed under a Medicare Part B payment methodology that reimburses each product at 106% of its average sales price (ASP) (sometimes referred to as ASP+6%). ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. A product's ASP is calculated 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. For example, the ASP for Aranesp® that will be in effect for the second quarter of 2007 will be based in part on certain historical sales and sales incentive data for Aranesp® from January 1, 2006 through December 30, 2006. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. The ASPs for Aranesp® and Neulasta® trended downward during the first three quarters of 2005, began to stabilize during the fourth quarter of 2005 and remained relatively stable in 2006.

Since August 1, 2006, physicians in the physician clinic setting have had the choice between purchasing and billing for specific drugs under the ASP+6% system or obtaining those drugs from vendors selected by CMS under the competitive acquisition program (CAP). We believe CAP is unlikely to have a significant impact on our business in 2007.

Medicare's hospital outpatient prospective payment system (OPPS), which determines payment rates for specified covered outpatient drugs and biologics in the hospital outpatient setting, utilized AWP as the basis for reimbursement in 2005. CMS 2005 reimbursement rate, as in 2003 and 2004, continued the application of an equitable adjustment such that the 2005 Aranesp® reimbursement rate was based on the

## **Table of Contents**

AWP of PROCrit®. For 2005, the reimbursement rate for Aranesp® was 83% of the AWP for PROCrit®, down from 88% of the AWP for PROCrit® in 2004, with a dose conversion ratio of 330 U PROCrit® to 1 mcg Aranesp®, the same ratio as 2004. Effective January 1, 2006, the OPPS system changed from an AWP based reimbursement system to a system based on ASP. This change affected Aranesp®, Neulasta® and NEUPOGEN® when administered in the hospital outpatient setting. The OPPS rule for 2006 and 2007 based reimbursement for non-pass through products such as Aranesp®, Neulasta® and NEUPOGEN® on ASP+6% using the same payment amounts as used in the physician clinic setting and did not apply an equitable adjustment to tie the reimbursement rate for Aranesp® to PROCrit® using a dose conversion ratio. CMS noted in the 2005 final rule and has maintained that it reserves the right to apply an equitable adjustment to the payment rate for Aranesp® in future years.

Pursuant to final rules issued by CMS on November 3, 2004, Medicare reimbursement for EPOGEN® used in the dialysis setting for calendar year 2005 changed from the previous rate in 2004 of \$10 per 1,000 Units to \$9.76 per 1,000 Units, in 2005, a rate based upon an average acquisition cost for 2003 determined by the Office of the Inspector General (OIG) and adjusted for price inflation based on the Producer Price Index for pharmaceutical products. Pursuant to the CMS final rules, the difference between the 2004 reimbursement rates for all drugs separately billed outside the dialysis composite rate (including EPOGEN®) and the 2005 reimbursement rates for such drugs was added to the composite rate that dialysis providers receive for dialysis treatment. Pursuant to the Medicare Physician Fee Schedule Payment Final Rule for 2006, effective January 1, 2006, the payment mechanism for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN® and Aranesp®, is reimbursed by Medicare at ASP+6% using the same payment amounts used in the physician clinic setting and calculated quarterly in the same manner as described above for our products under the Medicare Part B payment methodology. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. Based upon the 2006 final rule, the reimbursement rate for EPOGEN® for 2006 decreased from the reimbursement rate in 2005. In the Medicare Physician Fee Schedule Payment Final Rule for 2007, CMS continued the 2006 payment mechanism of ASP+6% for EPOGEN® and other separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers. Because we cannot accurately predict the extent to which this reimbursement will impact how, or under what circumstances, healthcare providers will prescribe or administer EPOGEN®, we cannot estimate the full impact of the ASP+6% reimbursement rate on our EPOGEN® product sales. However, we believe that it was not significant in 2006 and is unlikely to be significant in 2007. In addition, the MMA required a demonstration project of a bundled payment system for dialysis, including separately billable drugs and EPOGEN®. The demonstration project was scheduled to start in January 2006, but has been delayed with no announced start date. Bundling initiatives that have been implemented in other healthcare settings have resulted in lower utilization of services that had not previously been a part of the bundled payment. Because CMS is continuing to study bundled payments in the ESRD setting, we cannot predict what impact a bundled payments system would have on sales of EPOGEN® or Aranesp® used in the treatment of persons receiving outpatient dialysis services.

The Medicare Physician Fee Schedule Proposed Rule for 2007 addressed several new topics regarding the ASP payment methodology. In the proposed rule, CMS invited comment on the need for future guidance concerning the methodology for calculating the ASP of drugs sold under market-based pricing arrangements, including bundled arrangements, described by CMS as, for example, when a purchaser's price for one or more drugs is contingent upon the purchase of other drugs or items. In the Medicare Physician Fee Schedule Final Rule for 2007, CMS chose not to establish a specific methodology that manufacturers must use for the treatment of bundled price concessions for the purposes of the ASP calculation at this time. However, CMS stated that it may provide more specific guidance in the future through rulemaking, program instruction or other guidance. On December 29, 2006, the Medicare Payment Advisory Commission (MedPAC) released its second Congressionally-mandated report on the impact of changes in Medicare payments for Part B Drugs specifically recommending that the Secretary of the Department of Health and Human Services clarify ASP reporting requirements to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug.

## **Table of Contents**

Under the ASP system, the Company allocates its discounts based on the prices paid for individual drugs, according to the terms of its contracts with physicians and other purchasers, and we believe that the resulting ASPs reflect the transaction prices for individual drugs. As it is premature to speculate on how CMS and other government organizations may react to the MedPAC's recommendations, we cannot predict the potential impact the report may have on our business.

Any changes to the ASP calculation could adversely affect the Medicare reimbursement for our products administered in the physician office and the hospital outpatient setting.

In addition, on November 9, 2005, CMS released a revision to the Hematocrit Measurement Audit Program Memorandum (HMA-PM), a Medicare payment review mechanism used by CMS to audit EPOGEN® and Aranesp® (when used in dialysis) utilization and appropriate hematocrit outcomes of dialysis patients. The new policy, Claims Monitoring Policy: Erythropoietin/darbepoetin alfa usage for beneficiaries with end stage renal disease (Claims Monitoring Policy), became effective April 1, 2006 and was further revised effective October 1, 2006. The revised Claims Monitoring Policy provides that if a patient's hemoglobin is greater than 13 grams per deciliter, providers are instructed to reduce the patient's EPOGEN® and Aranesp® dose and report this reduction on claims using a coding modifier. If the provider does not reduce the patient's EPOGEN® and Aranesp® dose and there is no medical documentation to support the higher dosage, reimbursement will be reduced to the level it would have been had the provider reduced dosage by twenty-five percent. Based on our preliminary evaluation, we do not expect the Claims Monitoring Policy to have a negative impact on EPOGEN® and Aranesp® sales and given the importance of EPOGEN® and Aranesp® for maintaining the quality of care for dialysis patients, we do not expect that the policy will substantially impact the utilization of EPOGEN® and Aranesp®. However, given the recent revisions, we are currently in the process of further evaluating the Claims Monitoring Policy. As a result, we cannot predict the potential full impact of this final guidance on our business.

Further, the Deficit Reduction Act of 2005 (DRA) included provisions, which are phased in over time, regarding state collection and submission of data for the purpose of collecting Medicaid drug rebates from manufacturers for physician-administered drugs. We expect that state compliance with elements of these provisions that become effective in 2007 will increase the level of Medicaid rebates paid by us. We are currently in the process of further evaluating the impact of the DRA, and as a result we cannot predict the potential full impact on our business. Related to this issue, CMS issued a proposed Medicaid rule on December 18, 2006 that covered a broad range of topics concerning the calculation and use of Average Manufacturer Price (AMP) and best price as well as a proposed definition for bundled sales under the Medicaid program. We are undergoing a review of the proposed rule and cannot speculate on the specific contents of the final rule prior to its issuance.

## **Research and Development and Selected Product Candidates**

Our vision is to deliver therapies that can make a meaningful difference in patients' lives and therefore we focus our R&D on novel human therapeutics for the treatment of grievous illness. We focus our R&D efforts in the areas of inflammation, oncology and hematology, neuroscience and metabolic disorders. 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.

In addition to product candidates and marketed products generated from our internal R&D efforts, we have acquired companies, licensed technologies and established R&D collaborations, which have enhanced our strategic position within the biotechnology industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. For example, on April 1, 2006 we completed the acquisition of Abgenix, a company with expertise in the discovery and development of monoclonal antibodies (see Note 7, Acquisitions Abgenix, Inc.). The acquisition of Abgenix provided us with full ownership of our first oncology therapeutic, Vectibix®, as well as Abgenix's proprietary entirely human monoclonal antibody technology, XenoMouse®. In addition, on October 24, 2006 we completed the acquisition of Avidia, Inc. (Avidia), a privately held company that discovered and developed a new class of human therapeutic known as Avimer® proteins (see Note 7, Acquisitions Avidia, Inc.). The transaction provided us with Avidia's lead product

## **Table of Contents**

candidate, an inhibitor of interleukin 6 (IL-6) for the treatment of inflammation and autoimmune diseases, which is in phase 1 clinical trials. See Item 1A. Risk Factors We may not be able to develop commercial products.

We have substantially expanded our R&D capabilities and plan to continue increasing our investments to expand these capabilities over the next several years. In 2006, R&D expense increased 45% primarily due to higher staff levels and increased funding necessary to support clinical trials for our late-stage programs, which include denosumab, our late-stage investigational product for osteoporosis and metastatic bone cancer, and the continued expansion of our research and pre-clinical organization to build the capacity to advance more compounds into and through the clinic. We began nine mega-site trials (involving 200 or more sites) in 2006 to support denosumab and our other late-stage programs. For 2007, we expect R&D expense to increase, although not to the extent experienced in 2006, due to the continuation of the nine mega-site trials previously started in 2006, additional studies beginning in 2007 in support of our late-stage programs, including studies for panitumumab and motesanib diphosphate, and advancing a number of additional molecules into phase 2. The nine mega-site trials, which we began in 2006, will continue to require significant time, resources and expense to execute.

To execute our large clinical trial programs, we need to continue to grow our development organization and associated R&D support organizations, implement new management structures and approaches and continue to partner with third-party contract clinical trial providers. Further, to increase the number of patients available for enrollment for our clinical trials, we partnered with third-party clinical providers to open clinical sites and enrolled patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, Mexico and some South American countries. In 2007, we plan to expand into Southeast Asia and India. We are conducting clinical trial activities in these new territories through both our staff and third-party contract clinical trial providers. We expect the growth of our development organization to continue in 2007 although not to the extent experienced in 2006. See Item 1A. Risk Factors Before we commercialize and sell any of our product candidates, 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 facilities in the United States as well as small research centers in Germany and Canada, and development facilities in Europe, Canada, Australia and Japan and as of the fourth quarter of 2006 in Mexico and the United Kingdom. (see Item 2. Properties ). In addition, we expect to continue expanding our existing R&D sites and to have clinical development staff in Hong Kong and India as of the first quarter of 2007. We are also planning to expand R&D capabilities at our Seattle, Washington and San Francisco, California sites to leverage existing facilities and infrastructure and to fully avail ourselves of the pool of qualified scientific personnel in the surrounding areas. Planned facilities will include a combination of lab and office space.

R&D expenses for the years ended December 31, 2006, 2005 and 2004 were \$3,366 million, \$2,314 million and \$2,028 million, respectively. In 2006, we recorded \$130 million and \$1,101 million for the write-off of acquired in-process R&D ( IPR&D ) resulting from the Avidia and Abgenix acquisitions, respectively, and in 2004 we recorded \$554 million for the write-off of acquired IPR&D resulting from the Tularik Inc. ( Tularik ) acquisition (see Note 7, Acquisitions to the Consolidated Financial Statements).

**Table of Contents**

The following table is a selection of certain of our product candidates in our therapeutic areas of focus and shows the status of these molecules as of January 25, 2007. 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>Status</b>
<b><i>Oncology</i></b>		
AMG 102	Cancer	Phase 2
AMG 386	Cancer	Phase 1
AMG 479	Cancer	Phase 1
AMG 531	Immune thrombocytopenic purpura (an autoimmune bleeding disorder)	Phase 3
AMG 531	Myelodysplastic syndromes	Phase 2
AMG 531	Chemotherapy-induced thrombocytopenia in non-small cell lung cancer and lymphoma	Phase 2
AMG 655	Cancer	Phase 1
AMG 745	Muscle wasting disorders	Phase 1
Motesanib diphosphate*	First-line non-small cell lung cancer	Phase 2
Motesanib diphosphate*	Thyroid cancer	Phase 2
Motesanib diphosphate*	First-line breast cancer	Phase 2
Apo2L/TRAIL	Cancer	Phase 1
Denosumab	Prevention of cancer-related bone damage	Phase 3
Denosumab	Prevention of bone metastases	Phase 3
Denosumab	Bone loss induced by hormone ablation therapy for breast cancer or prostate cancer	Phase 3
Palifermin	Oral mucositis associated with radiation therapy and chemotherapy for solid tumors	Phase 2
Panitumumab	First- and second-line colorectal cancer	Phase 3
Panitumumab	Head and neck cancer	Phase 2
<b><i>Inflammation</i></b>		
AMG 108	Rheumatoid arthritis	Phase 2
AMG 220	Crohn's disease	Phase 1
AMG 317	Asthma	Phase 1
AMG 557	Systemic lupus erythematosus (SLE)	Phase 1
AMG 623	SLE	Phase 1
AMG 714	Psoriasis	Phase 1
Denosumab	Rheumatoid arthritis	Phase 2
<b><i>Metabolic disorders</i></b>		
AMG 221	Type 2 diabetes	Phase 1
AMG 837	Type 2 diabetes	Phase 1
Denosumab	Postmenopausal osteoporosis	Phase 3
Sclerostin Ab	Bone loss	Phase 1
Cinacalcet HCl	Primary hyperparathyroidism	Phase 2
Cinacalcet HCl	Cardiovascular disease in patients with secondary hyperparathyroidism and chronic kidney disease undergoing maintenance dialysis	Phase 3
<b><i>General medicine</i></b>		
Darbepoetin alfa	Cardiovascular disease in patients with chronic kidney disease and type 2 diabetes	Phase 3
Darbepoetin alfa	Anemia in heart failure	Phase 3
<b><i>Neuroscience</i></b>		
AMG 379	Pain	Phase 1
AMG 403	Pain	Phase 1

\* Program formerly identified as AMG 706.

**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.

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

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

## **Table of Contents**

The following paragraphs provide additional information about certain of our product candidates that are in phase 2 or later human clinical trials.

### *Denosumab*

Denosumab is a fully human monoclonal antibody that specifically targets the receptor activator of nuclear factor kappa B ligand ( RANKL ), a key mediator of the resorptive phase of bone remodeling. Denosumab is being studied across a range of conditions, including osteoporosis, treatment-induced bone loss, rheumatoid arthritis, bone metastases and multiple myeloma.

Currently, we are conducting a number of phase 3 studies of denosumab in the prevention and treatment of postmenopausal osteoporosis. In 2006, we initiated two phase 3 studies. The first will compare the efficacy of treatment with denosumab versus alendronate in postmenopausal women with low bone mineral density and the second will evaluate the safety and efficacy of transitioning postmenopausal women with low bone mineral density from alendronate to denosumab compared to continuing with alendronate.

Denosumab is also being studied in metastatic bone disease for the treatment of bone metastases to prevent skeletal related events ( SREs ) and prevention of bone metastases in patients with prostate cancer. Three phase 3 clinical studies targeting SREs (breast cancer, prostate cancer and solid tumors studies) were initiated in 2006. In addition, we commenced a phase 3 trial for prevention of bone metastases in patients with prostate cancer. In 2007, we expect to see the first data sets from our registration-enabling phase 3 studies of denosumab in postmenopausal osteoporosis as well as hormone ablation-associated bone loss.

### *Vectibix (panitumumab)*

Panitumumab targets the EGFR. The EGFR pathway is important in normal and tumor cell growth. Panitumumab is a fully human monoclonal antibody directed against EGFR and is being evaluated for the treatment of various types of cancer (solid tumor). A pivotal phase 3 study examining panitumumab monotherapy against the standard of care showed that panitumumab significantly prolongs progression-free survival in patients with metastatic colorectal cancer ( CRC ).

Enrollment was completed in 2006 for a non-registrational phase 3b study to evaluate panitumumab plus Avastin® (bevacizumab) in first-line metastatic CRC (Panitumumab Advanced Colorectal Cancer Evaluation ( PACCE )). The primary endpoint of this study is progression-free survival, with secondary endpoints of response rate, overall survival and safety. An interim (12-week) response-rate analysis was recently performed and response rates in the first 500 patients were similar in the two treatment groups. Additionally, we have informed all investigators and regulatory authorities about safety information arising from this planned interim analysis of the PACCE trial. A review of the data by the Independent Data Monitoring Committee ( DMC ) showed an increased incidence of diarrhea, dehydration and infection when panitumumab was given in combination with bevacizumab and either irinotecan or oxaliplatin-based chemotherapy. These are recognized toxicities that are specifically noted in the Vectibix U.S. prescribing information and panitumumab Investigator's Brochure. The PACCE study is continuing in accordance with the DMC recommendation. We anticipate presenting the results of an interim analysis of safety and efficacy (including progression-free survival after 25 percent of events have accrued) at scientific meetings in the first half of 2007. The risks and benefits of using panitumumab in combination with chemotherapy and bevacizumab have yet to be established. Registrational (phase 3) studies in first-line and second-line treatment of metastatic CRC were started in 2006.

Panitumumab is also being studied in the treatment of head and neck cancer, and we intend to study the drug in the adjuvant CRC setting. In 2007, we expect to initiate a phase 3 study in metastatic squamous cell cancer of the head and neck ( SCCHN ) as well as two phase 2 studies addressing the safety and efficacy of panitumumab in the first-line treatment of locally advanced squamous cell cancer of the head and neck. We also expect to initiate two phase 3 studies in the adjuvant CRC setting. One of these studies will be a co-operative phase 3 study with the National Surgical Adjuvant Breast and Bowel Project ( NSABP ).



## **Table of Contents**

Panitumumab is also being studied in combination with motesanib diphosphate (AMG 706) in the treatment of various solid tumors. Phase 1b combination studies in CRC, non-small cell lung cancer ( NSCLC ) and SCCHN are ongoing.

### *Motesanib diphosphate (formerly known as AMG 706)*

Motesanib diphosphate is a highly selective, oral agent that is being evaluated for its ability to inhibit angiogenesis by targeting vascular endothelial growth factor receptors 1, 2 and 3 ( VEGFR1-3 ). It is also under investigation for its potential direct anti-tumor activity by targeting platelet-derived growth factor receptor ( PDGFR ) and stem cell factor receptor ( c-kit ) signaling, which may also confer direct anti-tumor activity.

A phase 2 clinical study evaluating motesanib diphosphate monotherapy in imatinib-resistant gastrointestinal stromal tumors ( GIST ) showed encouraging clinical activity. A phase 2 trial in advanced thyroid cancer has completed enrollment and recent six-month data showed that motesanib diphosphate was clearly active in this setting, as judged by response rate criteria.

Both cholecystitis and enlargement of the gall bladder have been observed in patients who had received motesanib diphosphate. We continue to study this issue. Based on data gathered to this point, we believe these events are manageable. We intend to review data with regulatory agencies in the coming months. Ongoing studies have continued, subject to protocol amendments to ensure that physicians are aware of the need to manage gall bladder enlargement or cholecystitis, should these occur.

Because of increasing comfort with the safety profile of motesanib diphosphate, we have re-launched a head-to-head phase 2 study of this agent versus Avastin® in the treatment of metastatic breast cancer. A second head-to-head phase 2 study against Avastin® in NSCLC is now under way. Additionally, we plan to conduct a new phase 3 study in NSCLC, which is expected to initiate in the second half of 2007.

Motesanib diphosphate is also being investigated in combination with multiple chemotherapy regimens, with and without panitumumab, in the treatment of solid tumors. Phase 1b combination studies in CRC, NSCLC and other solid tumors are ongoing.

### *AMG 531*

AMG 531 is a protein called a peptibody, which is a first-in-class molecule. The active peptide component stimulates the thrombopoietin ( TPO ) receptor resulting in increased platelet production. It is being investigated for the treatment of immune (idiopathic) thrombocytopenic purpura ( ITP ). ITP is an autoimmune bleeding disorder characterized by an abnormal decrease in platelets, a condition known as thrombocytopenia. Platelets are specialized blood cells that help prevent and stop bleeding by participating in clotting. ITP is characterized by thrombocytopenia that results in bruising and bleeding that is sometimes severe.

Two phase 3 clinical studies evaluating AMG 531 in the treatment of ITP were completed in 2006. In the first of these studies, patients with ITP despite prior splenectomy were randomized to receive either placebo or AMG 531 over a 6 month period. Review of the data from this study revealed a favorable efficacy and safety profile, with all clinical endpoints successfully met. We expect to review data from a second phase 3 study in pre-splenectomy ITP patients during the first quarter of 2007. Pending positive results from this study, we expect to file for approval of AMG 531 in the ITP indication in both the U.S. and Europe in 2007. We have previously received fast track designation for ITP from the U.S. FDA.

We are also evaluating AMG 531 in chemotherapy-induced thrombocytopenia ( CIT ) and myelodysplastic syndromes ( MDS ). Phase 2 studies in each setting were initiated in 2006.

### *AMG 108*

AMG 108 is a monoclonal antibody that inhibits the action of interleukin-1 ( IL-1 ), a cytokine known to play a role in the joint destruction associated with rheumatoid arthritis. A phase 2 clinical study is under way to investigate the treatment of rheumatoid arthritis with AMG 108.

## **Table of Contents**

### *Aranesp® (darbepoetin alfa)*

In 2006, we announced phase 2 data reporting the clinical effects of darbepoetin alfa compared to placebo in subjects with heart failure and anemia. Based on this data, we opened the Reduction in Events with Darbepoetin alfa in Heart Failure Trial ( RED-HF ) for enrollment in mid-2006. The RED-HF Trial is a large (3,400 subjects), global, randomized, double-blind, placebo-controlled phase 3 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 Trial to Reduce Cardiovascular Events with Aranesp® Therapy ( TREAT ) is an approximately 4,000-patient, multi-center, double-blind, randomized, controlled trial designed to determine the impact of anemia therapy with darbepoetin alfa on mortality and non-fatal cardiovascular events in patients with CKD and type 2 (insulin-resistant) diabetes.

In December 2005, we submitted a biologics license supplement to the FDA for a darbepoetin alfa once-monthly dosing regimen and a once every-two-week dosing regimen for CKD patients with anemia not on dialysis. The FDA has requested additional clinical data for the once-monthly dosing regimen, including an additional clinical study. The FDA has also requested additional label language and clarification of submitted data for the de novo once every-two-week dosing regimen. We are working closely with the FDA to resolve these questions.

We recently completed an initial analysis of our Anemia of Cancer phase 3 study. This study was a randomized, double-blind, placebo-controlled trial of darbepoetin alfa administered every four weeks in patients with active cancer not receiving chemo- or radiation therapy. All patients entering the study had anemia ( $Hb \leq 11$  g/dL) in the setting of active cancer (i.e., they were not in remission). These criteria identify a subset of patients with an especially grave prognosis. At the end of 16 weeks, there was no statistically significant difference in the frequency of transfusions in the population receiving placebo injections as opposed to those receiving darbepoetin alfa. There was a statistically significant increased risk of death in the darbepoetin alfa-treated group, however, the overall safety profile did not identify any other unexpected safety concerns. Since this study was not designed as a survival study, an effect of imbalances in potentially important prognostic factors that were present at baseline cannot be excluded. Nevertheless, in this population of patients with active cancer, not in remission and not receiving chemo- or radiation therapy, who have anemia, we concluded that the risk/benefit ratio for darbepoetin alfa use is at best neutral and perhaps negative.

### *Kepivance™ (palifermin)*

Kepivance is currently being evaluated to determine its safety and anti-mucositis activity in patients receiving radiation and/or chemotherapy for SCCN, NSCLC and colon cancer (all phase 2 studies).

### *Sensipar® (cinacalcet HCl)*

Cinacalcet HCl is approved for the treatment of secondary hyperparathyroidism in patients with CKD on dialysis. A phase 3 clinical trial has been initiated to assess the effects of cinacalcet HCl on mortality and cardiovascular morbidity in patients with CKD undergoing maintenance dialysis.

We recently completed an investigational phase 3 study to determine the safety and efficacy of cinacalcet HCl for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease stage 3 & 4 (CKD not on dialysis). We have elected not to file for the expanded indication of cinacalcet HCl in this setting. In the phase 3 trial, all efficacy endpoints were positive, supporting the ability of cinacalcet HCl to reduce parathyroid hormone levels in these patients. However, the incidence of asymptomatic hypocalcemia in cinacalcet HCl-treated patients was felt to be incompatible with routine use of cinacalcet HCl in this setting. Additional analyses are underway which may permit the identification of a dosing regimen that would allow the use of cinacalcet HCl in this patient group.

## **Table of Contents**

### **Competition**

Competition among biotechnology, pharmaceutical and other companies that research, develop, manufacture or market biologics and pharmaceuticals is intense and the environment we operate in is increasingly competitive. We compete with these entities in all areas of our business including competing to attract and retain qualified scientific, technical and operational personnel. (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. )

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. We remain committed to vigorously defending our intellectual property and growing our businesses as well as maintaining or increasing share. For example, the anemia area represents a significant and growing business opportunity. As such, we expect to face increasingly intense competition in this area, including new and existing technologies and competitive pressures associated with biosimilar and other products (see further discussion below). We are committed to growing our anemia business and maintaining our leadership in anemia management, which includes impacting patient health outcomes and supporting the development of new standards of care, exploring new technologies in anemia therapy, preparing to compete with F. Hoffmann-La Roche Ltd. ( Roche ) in the U.S. and with biosimilar and other competing products in Europe and defending our intellectual property. Roche is developing a pegylated recombinant human erythropoietin ( peg-EPO ) for which they have filed a biologic license application ( BLA ) with the FDA and, according to Roche's public statements, they expect to launch the molecule in the U.S. nephrology segment in 2007 despite our ongoing lawsuit and their acknowledgement of our U.S. erythropoietin patents (see Item 3. Legal Proceedings Roche Matters Amgen Inc. v. F. Hoffman-La Roche Ltd., et. al. ).

Certain of our products are expected to face competition in certain geographic areas from biosimilar products. 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. We believe that as these patents have expired, other companies could receive approval for and market biosimilar products to compete with our products in the European Union ( EU ). (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. ) Although we cannot predict with certainty when the first biosimilar products could appear on the market in the EU, we expect that the first biosimilar G-CSF product may be approved in the EU some time in 2007 and could be available shortly thereafter, and that it would compete with Neulasta® and NEUPOGEN®. While we do not market EPOGEN® in Europe as this right belongs to Johnson & Johnson (through KA), we do market Aranesp® in the EU, which competes with Johnson & Johnson's EPREX® product, Roche's NeoRecormon® product and others' erythropoietin products. We expect that biosimilar erythropoietin products may be approved in the EU in 2007 and could be available in the EU shortly after approval. Based on an announcement by Shire Pharmaceuticals Group plc ( Shire ), we expect that a competing erythropoietin product, manufactured by Shire, may appear on the market in the EU in 2007. In addition, Roche is developing its peg-EPO product which, upon regulatory approval, we expect they will launch in the EU nephrology segment in 2007. In 2006, the European Medicines Agency ( 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 follow-on biologic products. 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 promulgation of associated regulations and guidance by the FDA. (See Patents and Trademarks. )

Certain of our products face substantial competition from products marketed by large pharmaceutical companies, 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

## Table of Contents

competitors or new information about existing products may result in product replacements or price reductions, even for products protected by patents.

Some of our competitors are actively engaged in R&D in areas where we are also performing research and developing product candidates. 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, in some cases, the relative speed with which we can develop products, complete the clinical testing, receive regulatory approval and supply commercial quantities of the product to the market is expected to be important to our competitive position.

In addition, we compete with large pharmaceutical and biotechnology companies when entering into collaborative arrangements with companies primarily in the biotechnology industry, research organizations and other entities for the research, development and commercialization of technologies, product candidates and marketed products. Other 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.

The following provides additional information on competition related to our principal products and other selected products and product candidates in the therapeutic area(s) in which we market or expect to market them.

### *Supportive cancer care*

Any products or technologies that are directly or indirectly successful in addressing anemia associated with chemotherapy could negatively impact product sales for Aranesp®, 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 most of the conversion in the United States has occurred. In Europe, we have been actively converting NEUPOGEN® patients to Neulasta®, emphasizing its less frequent dosing requirements as compared to NEUPOGEN®. While conversion of NEUPOGEN® patients to Neulasta® in Europe is still occurring, we believe that this conversion has mainly stabilized.

The following table reflects companies and their currently marketed products that primarily compete with Aranesp®, Neulasta® and NEUPOGEN® in the United States and internationally in the supportive cancer care segment.

		Competitor
Amgen Marketed Product	Marketed Product	Competitor
Aranesp® U.S.	PROCrit®	Johnson & Johnson
Aranesp® International	EPREX®/ERYPO®	Janssen-Cilag(1)
Aranesp® International	NeoRecormon®	Roche
Neulasta®/NEUPOGEN® U.S.	Leukine®	Berlex, Inc.(2)
Neulasta®/NEUPOGEN® U.S.	Ethyol®	MedImmune Oncology, Inc.
Neulasta®/NEUPOGEN® International	Granocyte®	Chugai Pharmaceuticals Co., Ltd. and Sanofi-Aventis
Neulasta®/NEUPOGEN® International	Leucomax®	Novartis AG ( Novartis )
Neulasta®/NEUPOGEN® International	Neu-up®	Kyowa Hakko Kogyo Co., Ltd.

(1) A division of Johnson & Johnson.

(2) A division of Schering AG Germany.

## Table of Contents

In addition to potential competition from the above-noted biosimilar products, Transkaryotic Therapies ( TKT ) is developing its gene-activated erythropoietin for the treatment of anemia (see Item 3. Legal Proceedings Transkaryotic Therapies and Aventis Litigation ). Astellas Pharma Inc. ( Astellas )/FibroGen are co-developing an erythropoietic small molecule and Affymax Inc. ( Affymax ) is developing an erythropoietin mimetic for the treatment of anemia.

### *Nephrology*

Any products or technologies that are directly or indirectly successful in addressing anemia associated with CKD could negatively impact product sales for Aranesp® and EPOGEN®. In the United States, Aranesp® and EPOGEN® compete with each other, primarily in the U.S. hospital dialysis clinics. Aranesp® competes with Johnson & Johnson in the pre-dialysis setting. The conversion from EPOGEN® to Aranesp® in the U.S. hospital dialysis clinics had stabilized in mid-2006.

Additionally, Aranesp® competes internationally with other companies marketed products to treat anemia associated with CKD. The following table reflects other companies and their currently marketed products that primarily compete with Aranesp® in the United States and internationally in the nephrology segment.

Competitor		
Amgen Marketed Product	Marketed Product	Competitor
Aranesp® U.S.	PROCRIT®	Johnson & Johnson
Aranesp® International	EPREX®/ERYPO®	Janssen-Cilag(1)
Aranesp® International	NeoRecormon®	Roche

(1) A division of Johnson & Johnson.

In addition to potential competition from the above-noted biosimilar products, Roche is developing peg-EPO for which they have filed a BLA with the FDA and, according to Roche's public statements, expect to launch in the nephrology segment in 2007 (see Item 3. Legal Proceedings Roche Matters Amgen Inc. v. F. Hoffmann-La Roche Ltd., et al. ). Roche has also announced plans to launch a peg-EPO product for the treatment of anemia in the EU in the nephrology segment in 2007. TKT is also developing a gene-activated erythropoietin for the treatment of anemia (see Item 3. Legal Proceedings Transkaryotic Therapies and Aventis Litigation ). In addition, Astellas/FibroGen are co-developing an erythropoietic small molecule and Affymax is developing an erythropoietin mimetic for the treatment of anemia. A competing erythropoietin product, manufactured by Shire, may appear on the market in the EU in 2007.

Any products or technologies that are directly or indirectly successful in treating secondary hyperparathyroidism in patients with CKD on dialysis could negatively impact product sales for Sensipar®/Mimpara®.

Competitor		
Amgen Marketed Product	Marketed Product	Competitor
Sensipar® U.S.	Zemplar®	Abbott Laboratories ( Abbott )
Sensipar® U.S.	Hectorol®	Genzyme Corporation
Sensipar® U.S.	Rocaltrol®	Roche
Mimpara® International	Zemplar®	Abbott

### *Inflammatory disease*

Any products or technologies that are directly or indirectly successful in treating moderate-to-severe rheumatoid arthritis, moderate-to-severe juvenile rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and moderate-to-severe plaque psoriasis could negatively impact product sales for ENBREL. Current treatments for these indications include generic methotrexate and other products.

## Table of Contents

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>Amgen Marketed Product</b>	<b>Competitor</b>	<b>Marketed Product</b>	<b>Competitor</b>
ENBREL U.S. & Canada		REMICADE®	Centocor, Inc.(1)/Schering Plough Corporation
ENBREL U.S. & Canada		HUMIRA®	Abbott
ENBREL U.S. & Canada		Raptiva®	Genentech, Inc. ( Genentech )
ENBREL U.S. & Canada		Amevive®	Biogen IDEC Inc. ( Biogen )
ENBREL U.S. & Canada		Orencia®	Bristol-Myers Squibb Corporation ( Bristol-Myers Squibb )
ENBREL U.S. & Canada		Neoral®	Novartis
ENBREL U.S. & Canada		Arava®	Sanofi-Aventis
ENBREL U.S. & Canada		Rheumatrex®	DAVA Pharmaceuticals, Inc.
ENBREL U.S. & Canada		Trexall	Duramed Pharmaceuticals, Inc.(2)
ENBREL U.S. & Canada		Rituxan®	Genentech
ENBREL U.S. & Canada		Soriatane®	Connetics Corporation(3)

(1) A division of Johnson & Johnson.

(2) A subsidiary of Barr Pharmaceuticals, Inc.

(3) A subsidiary of Stiefel Laboratories, Inc.

In addition, a number of companies have cytokine inhibitors in development, including GlaxoSmithKline plc ( GlaxoSmithKline ), Pfizer Inc. ( Pfizer ), Repligen Corporation and Taisho Pharmaceutical Co., Ltd., which may compete with ENBREL.

### Oncology

Any products or technologies that are directly or indirectly successful in treating metastatic colorectal cancer after disease progression on, or following fluoropyrimidine-, oxaliplatin- and irinotecan- containing chemotherapy regimens could negatively impact product sales for Vectibix . In October 2006, Vectibix was launched in the United States.

<b>Amgen Marketed Product</b>	<b>Competitor</b>	<b>Marketed Product</b>	<b>Competitor</b>
Vectibix U.S.		Erbitux®	Imclone Systems Incorporated/ Bristol-Myers Squibb

### Product candidates

We are currently studying new product candidates, including denosumab, and currently marketed products for new indications, including Vectibix , 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.

## Table of Contents

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

Competitor		
Amgen Product Candidate	Marketed Product	Potential Competitor
Denosumab	Fosamax <sup>®</sup>	Merck & Co., Inc.
Denosumab	Actonel <sup>®</sup>	Procter & Gamble/Aventis
Denosumab	Boniva <sup>®</sup>	Roche/GlaxoSmithKline
Denosumab	Evista <sup>®</sup>	Eli Lilly and Company ( Eli Lilly )
Denosumab	Forteo <sup>®</sup>	Eli Lilly
Denosumab	Miacalcin <sup>®</sup>	Novartis
Denosumab	Zometa <sup>®</sup>	Novartis
Denosumab	Aredia <sup>®</sup>	Novartis

### Manufacturing and Raw Materials

#### Manufacturing

Our manufacturing operations consist of bulk manufacturing and/or formulation, fill and finish activities which produce Aranesp<sup>®</sup>, Neulasta<sup>®</sup>, NEUPOGEN<sup>®</sup>, Epoetin alfa, ENBREL, Vectibix 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 puts the formulated bulk protein into the vials or syringes used by patients or those that administer treatment to patients. 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 and in Puerto Rico (see Item 2. Properties ). Manufacturing of Sensipar<sup>®</sup>, our small molecule product, is performed by third-party contractors.

#### Commercial Bulk Manufacturing

We operate commercial bulk manufacturing facilities in several locations throughout the United States and in Puerto Rico (see Item 2. Properties ). To keep up with the growing demand of our products, we operate our bulk manufacturing facilities at nearly full capacity. Other than for ENBREL, we perform all of the bulk manufacturing for our proteins.

Commercial quantities of ENBREL produced at our Rhode Island facilities are insufficient to fill the current level of demand for this product. As a result, the Company 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, inventory and allocation of bulk supplies of ENBREL. Under this agreement, the Company and Wyeth share the total worldwide bulk supply of ENBREL produced by Amgen's Rhode Island manufacturing facilities, 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 (see Note 8, Commitments and contingencies to the Consolidated Financial Statements). 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 will be responsible for substantial payments to BI Pharma if we fail 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.

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

## **Table of Contents**

### *Commercial Formulation, Fill and Finish*

We operate commercial formulation, fill and finish manufacturing facilities in Puerto Rico and conduct certain finish activities in the Netherlands (see Item 2. Properties ). Other than for ENBREL and Vectibix , we perform all of the formulation, fill and finish activities for our proteins. 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 under the above-noted manufacturing agreement, formulation, finish and fill of a certain portion of ENBREL is also performed by a third-party contract manufacturer.

To keep up with the growing demand for our products, we are operating the Puerto Rico formulation, fill and finish facility at nearly full production capacity. In addition to the above-noted manufacturing activities, our operations in Puerto Rico perform key manufacturing support functions including quality control, process development, procurement and production scheduling. Our global supply of our principal products is significantly dependent on the uninterrupted and efficient operation of these Puerto Rico facilities (see Item 1A. Risk Factors ). We 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 clinical finishing is performed in the Netherlands. In addition, we also utilize third-party contract manufacturers to perform manufacturing activities for certain of our clinical products.

### *Manufacturing Initiatives*

We actively manage our inventory supply produced by our manufacturing facilities and the supply produced by our third-party contract manufacturers. Our manufacturing capacity and use of third-party contract manufacturing agreements have increased and are expected to continue to increase to supply the growth in our commercial products and to support our expanding R&D activities (see Item 1A. Risk Factors ). We have grown rapidly, and if we fail to adequately manage that growth our business could be adversely impacted. ).

In order to maintain adequate supply to keep up with growing demand for our products, mitigate risks associated with the vast majority of our formulation, fill and finish operations located in Puerto Rico and to adequately prepare to launch a number of our late-stage product candidates, we must successfully implement a number of manufacturing projects on schedule, operate our facilities at nearly full production capacity over the next few years, expand our use of third-party contract manufacturers, build inventory of our bulk drug substance and finished products and maintain a state of regulatory compliance. Key manufacturing projects include: 1) construction, qualification and licensure of our new process bulk and formulation, fill and finish plant in Ireland; 2) construction, qualification and licensure of new formulation, fill and finish facilities at our Puerto Rico site; and 3) expansion of existing bulk protein facilities at our Puerto Rico site including the licensure of our Puerto Rico plant for production of Epoetin and darbepoetin bulk drug substance and increased production of pegfilgrastim and Filgrastim bulk drug substance.

### *Raw Materials*

Certain raw materials, medical devices and components necessary for our commercial manufacturing of our products are proprietary products of other companies, and in some cases, such proprietary products are specifically cited in our drug application with the FDA such that they must be obtained from that specific, unaffiliated sole source. We currently attempt to manage the risk associated with such sole-sourced raw materials by active inventory management, relationship management and alternate source development, when feasible. We monitor the financial condition of certain suppliers, their ability to supply our needs and the market conditions for these raw materials. Also, certain of the raw materials required in the commercial manufacturing and formulation of our products are derived from biological sources, including mammalian tissues, bovine serum and human serum



## **Table of Contents**

albumin ( HSA ). We are investigating screening procedures with respect to certain biological sources and alternative manufacturing processes that do not require the use of biologically-sourced raw materials as these materials may be subject to contamination and/or recall and some countries may restrict the use of them in the manufacture of drugs. Raw materials, medical devices and components may be subject to contamination and/or recall. A material shortage, contamination, recall and/or restriction could adversely impact or disrupt the commercial manufacturing of our products or could result in a mandated withdrawal of our products from the market. See Item 1A. Risk Factors We rely on single 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.

### **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 and technology rights and have established R&D collaborations to enhance our R&D capabilities and internally developed product pipeline. Our R&D collaborations generally consist of non-refundable, upfront license fees, R&D and commercial performance milestones, cost sharing, royalties 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.

#### *Kirin Brewery Company, Limited*

We formed KA, a 50-50 joint venture with Kirin in 1984. KA develops and commercializes certain of our and Kirin's technologies, which have been transferred to this joint venture. KA has given exclusive licenses to us to manufacture and market: 1) 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, 2) pegfilgrastim and G-CSF in the United States, Europe, Canada, Australia and New Zealand and 3) recombinant human erythropoietin in the United States. We currently market darbepoetin alfa, pegfilgrastim, G-CSF and recombinant human erythropoietin under the brand names Aranesp®, Neulasta®, NEUPOGEN® and EPOGEN®, respectively.

KA has also given exclusive licenses to Kirin to manufacture and market: 1) darbepoetin alfa in Japan, the People's Republic of China ( China ), Taiwan, Korea and certain other countries in Southeast Asia, 2) G-CSF and pegfilgrastim in Japan, Taiwan and Korea and 3) recombinant human erythropoietin in Japan. 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 Johnson & Johnson rights to recombinant human erythropoietin in certain geographic areas of the world (see Johnson & Johnson ). Under its agreement with KA, Johnson & Johnson 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.

During 2005 certain of our and Kirin's technologies related to AMG 531 were transferred to KA. In return, KA has given us and Kirin exclusive licenses to manufacture and market AMG 531 in certain territories.

In connection with our various license agreements with KA, we pay KA royalties based on product sales and also receive payment for conducting certain R&D activities on behalf of KA (see Note 3, Related party transactions to the Consolidated Financial Statements).

#### *Johnson & Johnson*

We granted Johnson & Johnson a license to commercialize recombinant human erythropoietin as a human therapeutic in the United States in all markets other than dialysis. In the United States, all recombinant human

## **Table of Contents**

erythropoietin sold by Johnson & Johnson is manufactured by us and sold by Johnson & Johnson 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 Johnson & Johnson, we earn a 10% royalty on net sales of PROCrit® by Johnson & Johnson in the United States.

Outside the United States, with the exception of China and Japan, Johnson & Johnson was granted rights to manufacture and commercialize recombinant human erythropoietin as a human therapeutic for all uses under a licensing agreement with J&J. With respect to its sales outside of the United States, Johnson & Johnson manufactures and commercializes its own brand of Epoetin alfa which is then sold throughout the world by Johnson & Johnson under various trademarks such as EPREX® and ERYPO®. We are not involved in the manufacture of Epoetin alfa sold by Johnson & Johnson outside of the United States. (See Item 3. Legal Proceedings Johnson & Johnson Matters Arbitration/Demand for Separate BLA and Ortho Biotech Antitrust Litigation. )

### *Wyeth*

Amgen and Wyeth market and sell ENBREL under a co-promotion agreement in the United States and Canada for all approved indications other than for use in oncology. The rights to detail and promote ENBREL in the United States and Canada for oncology indications are reserved to Amgen. 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 includes a minimum level of financial and sales personnel commitment from each party, and is responsible for all sales activities. Further, pursuant to the co-promotion agreement, 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 of ENBREL, 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: 1) 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, excluding oncology and rheumatoid arthritis indications; 2) certain specified patent expenses related to ENBREL; and 3) 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, inventory and allocation of bulk supplies of ENBREL. Under this agreement, the Company and Wyeth share the total worldwide bulk supply of ENBREL produced by Amgen's Rhode Island manufacturing facilities, BI Pharma's manufacturing facility in Germany and Wyeth's manufacturing facility in Ireland.

### *Fresenius*

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, to purchase, and we have agreed to supply, all of Fresenius' commercial requirements for erythropoietic stimulating proteins for use in managing the anemia of its hemodialysis patients in the United States and Puerto Rico, based on forecasts provided by Fresenius and subject to the terms and conditions of the agreement.

## **Government Regulation**

Regulation by governmental authorities in the United States and other countries is a significant factor in the production and marketing of our products and our ongoing R&D activities.

In order to clinically test, manufacture and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. In the United States,

## **Table of Contents**

the Public Health Service Act and the Federal Food, Drug and Cosmetic Act, 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, testing, manufacture, labeling, storage, record keeping, approval, advertising and promotion of our products on a product-by-product basis. Product development and approval within this regulatory framework takes a number of years and involves our expenditure of substantial resources and, after approval, such approval remains costly for us to maintain (see Item 1a. Risk Factors). Before we commercialize and sell any of our product candidates, 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 application with the FDA to begin human testing. 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 number of human subjects. In phase 2, we conduct clinical trials to investigate side effect profiles and efficacy of our product candidates in a large 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 can vary and is substantial. For example, denosumab, our late-stage product candidate, 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. 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. Even after we have obtained initial FDA approval, we may be required to conduct further clinical trials and provide additional data on safety and effectiveness and are required to gain clearance to market the use of a product as a treatment for indications other than those initially approved. In addition, side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market. Any adverse event, either before or after marketing approval, can result in product liability claims against us (see Item 1a. Risk Factors). We may be required to defend lawsuits or pay damages for product liability claims. ).

In addition to regulating and auditing human clinical trials, the FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of such 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 the 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.

In the European countries, 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 countries: mutual recognition and the centralized procedure. These review mechanisms may ultimately lead to approval in all EU countries, but each method grants all participating countries some decision-making authority in product approval.

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 where possible. Due to the breadth of the

## **Table of Contents**

statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). If the government were to allege against or convict us of violating these laws, there could be a material adverse effect on us, 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 by the Omnibus Budget Reconciliation Act of 1990 and under amendments of that law that became effective in 1993. Participation in this program has included extending 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 product is set by law as a minimum 15.1% of the AMP of that product, or if it is greater, the difference between AMP and the best price available from us to any customer. The rebate amount also includes an inflation adjustment if AMP increases faster than inflation. The PHS pricing program extends 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 poor Medicare and Medicaid beneficiaries. The rebate amount is recomputed each quarter based on our reports of our current 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 (and interest, if any), 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.

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 product prices for purchases by the Veterans Administration, the Department of Defense, Coast Guard and the PHS (including the Indian Health Service) be discounted by a minimum of 24% off the AMP to non-federal customers (the non-federal average manufacturer price, non-FAMP ). Our computation and report of non-FAMP is used in establishing the price, and the accuracy of the reported non-FAMP may be audited by the government under applicable federal procurement laws. Among the remedies available to the government for infractions of these laws is recoupment of any overages paid by FSS users during the audited years. In addition, 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.

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. Our research and manufacturing activities also are conducted in voluntary compliance with the National Institutes of Health Guidelines for Recombinant DNA Research.

Additionally, the U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign

**Table of Contents**

government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Our present and future business has been and will continue to be subject to various other 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 if we or others identify side effects after our products are on the market. and Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products. )

**Patents and Trademarks**

We have filed applications for a number of patents, have been granted patents or have obtained rights relating to our products and various potential products. Our material patents are set forth in the table below.

Product		General Subject Matter	Expiration
<b>Epoetin alfa</b>	U.S.	Process of making erythropoietin	8/15/2012
		Product claims to erythropoietin	8/20/2013
		Pharmaceutical compositions of erythropoietin	8/20/2013
		Cells that make certain levels of erythropoietin	5/26/2015
<b>darbepoetin alfa</b>	Europe(2)	Glycosylation analogs of erythropoietin proteins	10/12/2010
		Glycosylation analogs of erythropoietin proteins	8/16/2014
<b>Filgrastim</b>	U.S.	G-CSF polypeptides	12/3/2013
		Methods of treatment using G-CSF polypeptides	12/10/2013
<b>pegfilgrastim</b>	U.S.	Pegylated G-CSF	10/20/2015
	Europe(2)	Pegylated G-CSF	2/8/2015
<b>etanercept</b>	U.S.	Methods of treating TNF dependent inflammatory response	9/5/2009
		TNFR proteins and pharmaceutical compositions	9/5/2009
		TNFR DNA vectors, cells and processes for making proteins	10/23/2012
<b>panitumumab</b>	U.S.	Human monoclonal antibodies to EGFr	5/5/2017
<b>cinacalcet HCl</b>	U.S.(1)	Calcium receptor-active molecules	12/14/2016
		Calcium receptor-active molecules	12/14/2016
		Calcium receptor-active molecules	12/14/2016
		Calcium receptor-active molecules	10/23/2015
	Europe(2)	Calcium receptor-active molecules	10/23/2015

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

(2) 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 country by country.

There can be no assurance that our patents or licensed patents will afford legal protection against competitors or provide significant proprietary protection or competitive advantage. In addition, our patents or licensed patents could be held invalid or unenforceable by a court, or infringed or circumvented by others, or others could obtain patents that we would need to license or circumvent. Competitors or potential competitors may have filed patent applications or received patents, and may obtain additional patents and proprietary rights relating to proteins, small molecules, compounds or processes competitive with ours. Additionally, for certain of our product candidates, competitors, or potential competitors may claim that their existing or pending patents prevent us from commercializing such product candidates in certain territories. Further, when our patents expire, other companies could develop new competitive products to our products. Our recent European patent expirations could result in new competitive products to our products in Europe. Our principal European patent relating

## **Table of Contents**

to erythropoietin expired on December 12, 2004 and our principal European patent relating to G-CSF expired on August 22, 2006. We believe that as these patents have expired, other companies could receive approval for and market follow-on or biosimilar products to compete with these products in the EU; presenting additional competition to our 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. ) Although we cannot predict with certainty when the first biosimilar products could appear on the market in the EU, we expect that the first biosimilar G-CSF product may be approved in the EU some time in 2007 and could be available shortly thereafter, and that it would compete with Neulasta® and NEUPOGEN®. While we do not market EPOGEN® in Europe as this right belongs to Johnson & Johnson (through KA), we do market Aranesp® in the EU, which competes with Johnson & Johnson's EPREX® product, Roche's NeoRecormon® product and others erythropoietin products. We expect that biosimilar erythropoietin products may be approved in the EU in 2007 and could be available in the EU shortly after approval. Based on an announcement by Shire, we expect that a competing erythropoietin product, manufactured by Shire, may appear on the market in the EU in 2007. In addition, Roche is developing its peg-EPO product which, upon regulatory approval, we expect they will launch in the EU nephrology segment in 2007. 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 follow-on biologics. 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 promulgation of associated regulations and guidance by the FDA.

In general, we have obtained licenses from various parties which we deem to be necessary or desirable for the manufacture, use or sale of our products. These licenses generally require us to pay royalties to the parties on product sales. In addition, other companies have filed patent applications or have been granted patents in areas of interest to us. There can be no assurance any licenses required under such patents will be available for license on acceptable terms or at all. We are engaged in various legal proceedings relating to certain of our patents (see Item 3. Legal Proceedings ).

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, scientific advisors and parties to collaboration and licensing agreements to execute confidentiality agreements upon the commencement of employment, the consulting relationship, or the collaboration or licensing arrangement with us. However, others could either develop independently the same or similar information or obtain access to our information.

(See Item 1A. Risk Factors 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. )

(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. )

## **Human Resources**

As of December 31, 2006, we had approximately 20,100 staff members, which includes approximately 100 part-time staff members. Of the total staff members as of December 31, 2006, approximately 8,200 were engaged in R&D, approximately 3,200 were engaged in selling and marketing, approximately 6,600 were engaged in commercial manufacturing activities and approximately 2,100 were engaged in other activities. There can be no assurance that we will be able to continue attracting and retaining qualified personnel in sufficient numbers to meet our needs. None of our staff members are covered by a collective bargaining agreement, and we have experienced no work stoppages. We consider our staff relations to be good. We expect to hire additional staff members throughout 2007, primarily in manufacturing and R&D.

## **Table of Contents**

### **Executive Officers of the Registrant**

The executive officers of the Company as of January 31, 2007 are as follows:

Mr. Kevin W. Sharer, age 58, 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 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 3M Company and Northrop Grumman Corporation.

Dr. Dennis M. Fenton, age 55, became Executive Vice President in March 2000 and in May 2003 became Executive Vice President, Operations. From January 1995 to March 2000, Dr. Fenton served as Senior Vice President, Operations; from August 1992 to January 1995 as Senior Vice President, Sales and Marketing; and from July 1991 to August 1992 as Vice President, Process Development, Facilities and Manufacturing Services. From October 1988 to July 1991, Dr. Fenton also served as Vice President, Pilot Plant Operations and Clinical Manufacturing; and from 1985 to October 1988, he served as Director, Pilot Plant Operations.

Mr. Thomas J. Flanagan, age 57, 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 50, 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 ( NBC ), a division of GE. From July 1988 to November 1999, Mr. McNamee held human resource positions at GE.

Mr. George J. Morrow, age 54, 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 plc. From January 1997 to December 1998, Mr. Morrow was Managing Director of Glaxo Wellcome U.K., also a subsidiary of GlaxoSmithKline plc. 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.

Mr. Richard D. Nanula, age 46, became Executive Vice President and Chief Financial Officer in August 2001. From November 1999 to February 2001, Mr. Nanula was Chairman and Chief Executive Officer of Broadband Sports, Inc. From March 1998 to May 1999, Mr. Nanula was President and Chief Operating Officer of Starwood Hotels & Resorts Worldwide. From August 1986 to March 1998, Mr. Nanula was at the Walt Disney Company; where he held several positions including Senior Executive Vice President and Chief Financial Officer and President of Disney Stores Worldwide. Mr. Nanula currently serves on the Board of Directors of The Boeing Company.

Dr. Roger M. Perlmutter, age 54, became Executive Vice President of 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.

## **Table of Contents**

Mr. David J. Scott, age 54, 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 9, 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 SEC.

## **Item 1A. RISK FACTORS**

This report and other documents we file with the Securities and Exchange Commission ( 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.

*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 patents 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. For example, Roche is developing peg-EPO for which they have filed a BLA with the FDA. On November 8, 2005, we filed a lawsuit against Roche for patent infringement of six of our U.S. patents. In addition, on April 11, 2006, we filed a complaint with the U.S. International Trade Commission ( ITC ) requesting that the ITC institute an investigation of Roche's importation of peg-EPO. This lawsuit and matter is described in Item 3. Legal Proceedings Roche Matters. According to Roche's public statements, they expect to launch the molecule in the U.S. nephrology segment in 2007 despite our ongoing lawsuit and their acknowledgement of our U.S. erythropoietin patents. (See Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do. ) If we lose or settle current or future litigations



## **Table of Contents**

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 HCl, panitumumab and our other products and potential products. We market our erythropoietin, recombinant G-CSF, darbepoetin alfa, pegfilgrastim, etanercept, cinacalcet HCl and panitumumab products as EPOGEN® (Epoetin alfa), NEUPOGEN® (Filgrastim), Aranesp® (darbepoetin alfa), Neulasta® (pegfilgrastim), Enbrel® (etanercept), Sensipar®/Mimpara® (cinacalcet HCl) and Vectibix™ (panitumumab) respectively. With respect to our material patents, we have had a number of G-CSF patent expiries in the United States and one expiry in the EU and one erythropoietin patent expiry in the EU. For additional information on our material patents see Item 1. Business Patents and Trademarks.

We also have been granted or obtained rights to patents in Europe relating to erythropoietin; G-CSF; pegfilgrastim (pegylated G-CSF); etanercept; two relating to darbepoetin alfa; hyperglycosylated erythropoietic proteins; and cinacalcet HCl. 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. We believe that as these patents have expired, other companies could receive approval for and market follow-on biologics or biosimilar products (as they are generally known in the EU) 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. ) Although we cannot predict with certainty when the first biosimilar products could appear on the market in the EU, we expect that the first biosimilar G-CSF product may be approved in the EU some time in 2007 and could be available shortly thereafter, and that it would compete with Neulasta® and NEUPOGEN®. While we do not market EPOGEN® in Europe as this right belongs to Johnson & Johnson (through KA), we do market Aranesp® in the EU, which competes with Johnson & Johnson's EPREX product, Roche's NeoRecormon product and others erythropoietin products. We expect that biosimilar erythropoietin products may be approved in the EU in 2007 and could be available in the EU shortly after approval. Based on an announcement by Shire, we expect that a competing erythropoietin product, manufactured by Shire, may appear on the market in the EU in 2007. In addition, Roche is developing its peg-EPO product which, upon regulatory approval, we expect they will launch in the EU nephrology segment in 2007. Although, we cannot predict whether or to what extent the entry of biosimilar products or other competing products would impact future Aranesp®, Neulasta® or NEUPOGEN® sales in the EU, biosimilar products or other products that effectively compete with our products could reduce sales which could have a material adverse affect 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 follow-on biologics. 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 promulgation of associated regulations and guidance by the FDA. Until such legislation is created, we cannot predict when follow-on biologics could appear in the United States.

## **Table of Contents**

*Before we commercialize and sell any of our product candidates, 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. The results of these clinical trials are used as the basis to obtain regulatory approval from government authorities such as the FDA. Clinical trials are experiments conducted using our product candidates in human patients having 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. 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 and therefore, we may spend as much as several years 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 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 and associated delays in product candidates reaching the market.

Patients may also suffer adverse medical events or side effects in the course of our clinical trials that may delay or prohibit regulatory approval of our product candidates or additional indications for our currently approved products, or may render the product candidate commercially infeasible. Additionally, adverse events or results from clinical trials or studies performed by us or by others may expand safety labeling for our approved products and may negatively impact healthcare provider prescribing behavior, use of our products, regulatory or private healthcare organization medical guidelines and reimbursement of our products. (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 if we or others identify side effects after our products are on the market. ; Our sales depend on payment and reimbursement from third-party payers, and, to the extent that 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. ) 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 diphosphate, we delayed our phase 3 mega-site trial (involving 200 or more sites) in first line non-small cell lung cancer, 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 on this basis.

The number, size, duration and complexity of our clinical trials has increased and we expect will continue to increase in 2007. Due to the number of large-scale clinical trials initiated in 2006, we expect to see further growth in R&D expense in 2007, but not to the same extent experienced in 2006. For example, the nine mega-site trials which we began in 2006 will continue to require significant time, resources and expense to execute. To execute our clinical trial programs, we need to continue the growth of our development organization and associated R&D support organizations, implement new management structures and approaches and continue to partner with third-party contract clinical trial providers. Further, to increase the number of patients available for enrollment for our clinical trials, we partnered with third-party contract clinical trial providers to open clinical sites and are enrolling patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, Mexico and some South American countries. In 2007, we plan to expand to Southeast Asia and India. Conducting clinical trials in locations where we have limited experience requires

## **Table of Contents**

substantial time and resources to identify and understand the unique regulatory environments of individual countries. If we fail to adequately manage the increasing number, size, complexity and regulatory diversity of our clinical trials, our clinical trials and corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates 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 adversely affected materially. 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.)

*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 if we or others identify side effects after our products are on the market.*

We and certain of our licensors and partners conduct research, preclinical testing and clinical trials for our product candidates. In addition, we manufacture and contract manufacture and certain of our licensors and partners manufacture our product candidates. We also 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. 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 of our products.

In our experience, obtaining regulatory approval is costly and takes many years, and after it is obtained, remains costly to maintain. With the occurrence of a number of high profile safety events with certain pharmaceutical products such as Vioxx and Bextra, regulatory authorities, members of Congress, the Government Accountability Office (GAO), 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. As a result, clinical trials are receiving greater scrutiny with respect to safety, which may lead to fewer treatments being approved by the FDA. Any safety concerns may result in the FDA or other regulatory authorities terminating clinical trials before completion or requiring longer or additional clinical trials that may result in substantial additional expense. (See Before we commercialize and sell any of our product candidates, 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. )

Adverse events or results from clinical trials or studies performed by us or by others may expand safety labeling for our approved products and may negatively impact healthcare provider prescribing behavior, use of our products, regulatory or private health organization medical guidelines and reimbursement for our products. For example, we recently announced an initial analysis of our Anemia of Cancer phase 3 study where Aranesp® was administered to patients with active cancer not receiving chemo- or radiation therapy. All patients entering the study had anemia (Hb ≤ 11g/dL) in the setting of active cancer (i.e. they were not in remission). This study was designed to establish the effectiveness of Aranesp® in the potential anemia of cancer indication and failed to meet its primary endpoint of reducing red blood cell transfusions in the Aranesp® treatment group. There was a statistically significant increased risk of death with the Aranesp® treated group. In the population of patients with active cancer, not in remission and not receiving chemo- or radiation therapy, who have anemia, we concluded that the risk/benefit ratio for Aranesp® use was at best neutral and perhaps negative and we will not pursue regulatory approval for anemia of cancer at this time. Further, the FDA has notified us that that an Oncology Advisory Committee Meeting (ODAC) has been scheduled for May 10, 2007, partially based upon initial data from our Anemia of Cancer study and preliminary data from the third-party investigator Danish Head and Neck Cancer (DAHANCA) 10 Study. It is our understanding that the ODAC meeting will review progress made by us

## **Table of Contents**

and others to understand the effects of erythropoiesis-stimulating agents ( ESAs ) on survival and tumor progression in cancer patients. In addition, the recent interim analysis of our PACCE study, a non-registration-enabling trial evaluating panitumumab in first- line treatment of metastatic CRC, showed an increased incidence of diarrhea, dehydration and infection when given in combination with bevacizumab and either irinotecan or oxaliplatin-based chemotherapy. (See Guidelines and recommendations published by various organizations can reduce the use of our products. and Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products. )

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 restrictions on the sale or use of such products, including potential withdrawal of the product from the market. If new medical data suggests an unacceptable safety risk or previously unidentified side-effects, we may voluntarily withdraw, or regulatory authorities may mandate the withdrawal of, such product from the market for some period or permanently. For example, we previously initiated a voluntary recall of the Neulasta® SureClick pre-filled pen in Europe because of the potential risk to patients of receiving an incomplete dose and we have previously 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 needle-less syringe filled with diluent liquid by a third-party contract manufacturer and packaged with the vials of ENBREL. Although there have been no observable adverse event trends associated with the Neulasta® SureClick pen or with the reports of missing, detached or loose rubber caps, we may experience the same or other problems in the future resulting in broader product recalls or adverse event trends. 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.

If we or others identify side effects before or after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and changes to or re-approvals of our manufacturing facilities may be required, any of which could have a material adverse effect on sales of the affected products and on our business and results of operations. Certain labels or label changes may be necessary for a number of reasons, including: the identification of actual or theoretical safety or efficacy concerns by regulatory agencies; the discovery of significant problems with a similar product that implicates an entire class of products or subsequent concerns about the sufficiency of the data or studies underlying the label. Before any of our products are approved for commercial use, regulatory bodies could decide that the product label include certain warning language as part of an evolving label change to a particular class of products. For example, the Vectibix prescribing information includes a boxed warning from the FDA on dermatologic toxicities and severe infusion reactions as part of an evolving FDA labeling to the anti-EGFr class. In addition, after any of our products are approved for commercial use, we or regulatory bodies could decide, and have in the past decided, that changes to our product labeling are required. For example, the FDA instituted a class label change for the three recombinant ESAs marketed in the United States. The label change to the class, which included EPOGEN® and Aranesp®, added information about pure red cell aplasia ( PRCA ) to the adverse event profile section to the three ESA product labels in the U.S. Additionally, the *New England Journal of Medicine* recently published results from Johnson & Johnson's Correction of Hemoglobin and Outcomes In Renal Insufficiency ( CHOIR ) study. The CHOIR study, involved non-dialysis patients in whom a hemoglobin target of 13.5 g/dL was established which is meaningfully higher than the FDA-approved target range of 10-12 g/dL described in the ESAs labels. In the CHOIR study, patients assigned to the higher 13.5 g/dL hemoglobin target group had worse outcomes than those patients treated to a target hemoglobin level of 11.3 g/dL. We are in discussions with the FDA with respect to all ESA labels and expect that we will add patient safety information in the form of a boxed warning that will apply to both the nephrology and oncology indications for the class of approved ESAs. This language is still in development, discussions with the FDA are on-going, and any label change is subject to FDA approval.

Any significant concerns raised about the safety or efficacy of our products could also result in the need to reformulate those products, to conduct additional clinical trials, to make changes to our manufacturing processes or to seek re-approval of our manufacturing facilities. Significant concerns about the safety and effectiveness of a

## **Table of Contents**

product could ultimately lead to the revocation of its marketing approval. The labeling of a new product, 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. If the labeling of a new product, a revision of product labeling or the regulatory actions described above resulted in decreased use of our products, it could have a material adverse effect on sales of the affected products and on our business and results of operations.

In addition, if regulatory authorities determine that we or our licensor or partner conducting R&D activities on our behalf have not complied with regulations in the R&D of a product candidate, then they may not approve the product candidate 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.

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

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 rate is established by federal law and is monitored and implemented by CMS. Most patients receiving Aranesp®, Neulasta® and NEUPOGEN® for approved indications are covered by both government and private payer healthcare programs. Since January 1, 2006, ENBREL and Sensipar® are eligible for coverage from the U.S. government under Medicare Part D. Although both ENBREL and Sensipar® have received broad formulary placement in 2006 and 2007, Part D formulary placements are made by individual Part D plan sponsors with oversight by CMS and are subject to revision in the future. Generally, in Europe and other countries outside the U.S., the government sponsored healthcare system is the primary payer of healthcare costs of patients. Governments may regulate access to, prices or reimbursement levels of our products to control costs. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to healthcare providers in response to ongoing initiatives to reduce healthcare expenditures. Further, changes in guidelines or recommendations promulgated by government agencies, professional societies, insurance carriers, practice management groups, physicians, private health/science foundations and organizations involved in various diseases may negatively impact reimbursement of our products. (See Guidelines and recommendations published by various organizations can reduce the use of our products. ) Therefore, sales of all of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans.

The MMA was enacted into law in December 2003 and implemented January 1, 2005. Changes resulting from the MMA, which lowered reimbursement for our products, could negatively affect product sales of some of our marketed products however, we believe that our product sales for 2005 and 2006 were not significantly impacted by the reimbursement changes resulting from the MMA. We believe this was, in part, due to the effects of CMS 2005 and 2006 oncology demonstration projects on sales of our products used in supportive cancer care, especially Aranesp®. However, we believe it is unlikely that CMS will implement an oncology demonstration project for 2007. Furthermore, we believe that our sales for 2005 and 2006 were not significantly impacted, in part, due to increased reimbursement rates to physicians from CMS for services associated with drug administration. The 2006 Medicare Physician Fee Schedule Payment Final Rule reduced payments for physician services in 2006 by approximately 4.4% on average, although subsequent legislation eliminated this reduction for 2006. The Medicare Physician Fee Schedule Payment Final Rule for 2007 would have reduced payments for physician services in 2007 by approximately 5.0% on average, however, as in 2006, new legislation eliminated the reduction in payments for 2007.

Because we cannot accurately predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products, we cannot estimate the full impact of the MMA on our business, although we believe that it is not likely to be significant to our business in 2007. However, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales and related sales growth in the future.

## **Table of Contents**

The main components of the MMA that affect our currently marketed products are as follows:

Through 2004, the AWP mechanism was the basis of Medicare Part B payment for covered outpatient drugs and biologics. Since January 1, 2005, in the physician clinic setting, Aranesp®, Neulasta® and NEUPOGEN® are being reimbursed under a Medicare Part B payment methodology that reimburses each product at 106% of its ASP (sometimes referred to as ASP+6%). ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. A product's ASP is calculated 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. For example, the ASP for Aranesp® that will be in effect for the second quarter of 2007 will be based in part on certain historical sales and sales incentive data for Aranesp® from January 1, 2006 through December 30, 2006. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. The ASPs for Aranesp® and Neulasta® trended downward during the first three quarters of 2005, began to stabilize during the fourth quarter of 2005 and remained relatively stable in 2006.

Since August 1, 2006, physicians in the physician clinic setting have had the choice between purchasing and billing for specific drugs under the ASP+6% system or obtaining those drugs from vendors selected by CMS under the CAP. We believe CAP is unlikely to have a significant impact on our business in 2007.

Medicare's hospital OPPS, which determines payment rates for specified covered outpatient drugs and biologics in the hospital outpatient setting, utilized AWP as the basis for reimbursement in 2005. CMS' 2005 reimbursement rate, as in 2003 and 2004, continued the application of an equitable adjustment such that the 2005 Aranesp® reimbursement rate was based on the AWP of PROCrit®. For 2005, the reimbursement rate for Aranesp® was 83% of the AWP for PROCrit®, down from 88% of the AWP for PROCrit® in 2004, with a dose conversion ratio of 330 U PROCrit® to 1 mcg Aranesp®, the same ratio as 2004. Effective January 1, 2006, the OPPS system changed from an AWP based reimbursement system to a system based on ASP. This change affected Aranesp®, Neulasta® and NEUPOGEN® when administered in the hospital outpatient setting. The OPPS rule for 2006 and 2007 based reimbursement for non-pass through products such as Aranesp®, Neulasta® and NEUPOGEN® on ASP+6% using the same payment amounts as used in the physician clinic setting and did not apply an equitable adjustment to tie the reimbursement rate for Aranesp® to PROCrit® using a dose conversion ratio. CMS noted in the 2005 final rule and has maintained that it reserves the right to apply an equitable adjustment to the payment rate for Aranesp® in future years.

Pursuant to final rules issued by CMS on November 3, 2004, Medicare reimbursement for EPOGEN® used in the dialysis setting for calendar year 2005 changed from the previous rate in 2004 of \$10 per 1,000 Units to \$9.76 per 1,000 Units, in 2005, a rate based upon an average acquisition cost for 2003 determined by the OIG and adjusted for price inflation based on the Producer Price Index for pharmaceutical products. Pursuant to the CMS final rules, the difference between the 2004 reimbursement rates for all drugs separately billed outside the dialysis composite rate (including EPOGEN®) and the 2005 reimbursement rates for such drugs was added to the composite rate that dialysis providers receive for dialysis treatment. Pursuant to the Medicare Physician Fee Schedule Payment Final Rule for 2006, effective January 1, 2006, the payment mechanism for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN® and Aranesp®, is reimbursed by Medicare at ASP+6% using the same payment amounts used in the physician clinic setting and calculated quarterly in the same manner as described above for our products under the Medicare Part B payment methodology. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. Based upon the 2006 final rule, the reimbursement rate for EPOGEN® for 2006 decreased from the reimbursement rate in 2005. In the Medicare Physician Fee Schedule Payment Final Rule for 2007, CMS continued the 2006 payment mechanism of ASP+6% for EPOGEN® and other separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers. Because we cannot accurately predict the extent to which this reimbursement will impact how, or under what circumstances, healthcare

**Table of Contents**

providers will prescribe or administer EPOGEN<sup>®</sup>, we cannot estimate the full impact of the ASP+6% reimbursement rate on our EPOGEN<sup>®</sup> product sales. However, we believe that it was not significant in 2006 and is unlikely to be significant in 2007. In addition, the MMA required a demonstration project of a bundled payment system for dialysis, including separately billable drugs and EPOGEN<sup>®</sup>. The demonstration project was scheduled to start in January 2006, but has been delayed with no announced start date. Bundling initiatives that have been implemented in other healthcare settings have resulted in lower utilization of services that had not previously been a part of the bundled payment. Because CMS is continuing to study bundled payments in the ESRD setting, we cannot predict what impact a bundled payments system would have on sales of EPOGEN<sup>®</sup> or Aranesp<sup>®</sup> used in the treatment of persons receiving outpatient dialysis services.

The Medicare Physician Fee Schedule Proposed Rule for 2007 addressed several new topics regarding the ASP payment methodology. In the proposed rule, CMS invited comment on the need for future guidance concerning the methodology for calculating the ASP of drugs sold under market-based pricing arrangements, including bundled arrangements, described by CMS as, for example, when a purchaser's price for one or more drugs is contingent upon the purchase of other drugs or items. In the Medicare Physician Fee Schedule Final Rule for 2007, CMS chose not to establish a specific methodology that manufacturers must use for the treatment of bundled price concessions for the purposes of the ASP calculation at this time. However, CMS stated that it may provide more specific guidance in the future through rulemaking, program instruction or other guidance. On December 29, 2006, the MedPAC released its second Congressionally-mandated report on the impact of changes in Medicare payments for Part B Drugs specifically recommending that the Secretary of the Department of Health and Human Services clarify ASP reporting requirements to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug. Under the ASP system, the Company allocates its discounts based on the prices paid for individual drugs, according to the terms of its contracts with physicians and other purchasers, and we believe that the resulting ASPs reflect the transaction prices for individual drugs. As it is premature to speculate on how CMS and other government organizations may react to the MedPAC's recommendations, we cannot predict the potential impact the report may have on our business.

Any changes to the ASP calculation could adversely affect the Medicare reimbursement for our products administered in the physician office and the hospital outpatient setting.

In addition, on November 9, 2005, CMS released a revision to the HMA-PM, a Medicare payment review mechanism used by CMS to audit EPOGEN<sup>®</sup> and Aranesp<sup>®</sup> (when used in dialysis) utilization and appropriate hematocrit outcomes of dialysis patients. The new policy, Claims Monitoring Policy: Erythropoietin/darbepoetin alfa usage for beneficiaries with end stage renal disease (Claims Monitoring Policy), became effective April 1, 2006 and was further revised effective October 1, 2006. The revised Claims Monitoring Policy provides that if a patient's hemoglobin is greater than 13 grams per deciliter, providers are instructed to reduce the patient's EPOGEN<sup>®</sup> and Aranesp<sup>®</sup> dose and report this reduction on claims using a coding modifier. If the provider does not reduce the patient's EPOGEN<sup>®</sup> and Aranesp<sup>®</sup> dose and there is no medical documentation to support the higher dosage, reimbursement will be reduced to the level it would have been had the provider reduced dosage by twenty-five percent. Based on our preliminary evaluation, we do not expect the Claims Monitoring Policy to have a negative impact on EPOGEN<sup>®</sup> and Aranesp<sup>®</sup> sales and given the importance of EPOGEN<sup>®</sup> and Aranesp<sup>®</sup> for maintaining the quality of care for dialysis patients, we do not expect that the policy will substantially impact the utilization of EPOGEN<sup>®</sup> and Aranesp<sup>®</sup>. However, given the recent revisions, we are currently in the process of further evaluating the Claims Monitoring Policy. As a result, we cannot predict the potential full impact of this final guidance on our business.

Further, the DRA included provisions, which are phased in over time, regarding state collection and submission of data for the purpose of collecting Medicaid drug rebates from manufacturers for physician-administered drugs. We expect that state compliance with elements of these provisions that become effective in 2007 will increase the level of Medicaid rebates paid by us. We are currently in the process of further evaluating the impact of the DRA, and as a result we cannot predict the potential full impact on our business. Related to this issue, CMS issued a proposed Medicaid rule on December 18, 2006 that covered a broad range of topics concerning the calculation and use of AMP and best price as well as a proposed definition for bundled sales under the

## **Table of Contents**

Medicaid program. We are undergoing a review of the proposed rule and cannot speculate on the specific contents of the final rule prior to its issuance.

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 end stage renal disease 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. 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. 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 economic 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 private payer reimbursement policies. Reduction in reimbursement for our products could have a material adverse effect on our product sales and results of operations.

*Guidelines and recommendations published by various organizations can reduce the use of our products.*

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. However, professional societies, practice management groups, insurance carriers, physicians, private health/science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to healthcare providers, administrators and payers, and patient communities. Recommendations of government agencies or these other groups/organizations may relate to such matters as usage, dosage, route of administration and use of related therapies and reimbursement of our products by government and private payers. (See Our sales depend on payment and reimbursement from third-party payers, and, to the extent that 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 guidelines include:

The GAO issued a report on December 5, 2006 recommending that ESRD drugs and biologics, including EPOGEN®, be bundled into the Medicare dialysis composite payment rate. A day after the GAO report was released, the House Ways and Means Committee held a hearing that focused on EPOGEN®, including discussion of the delay in the MMA mandated bundled payment demonstration, and the GAO report and recommendation. However, Congress did not take legislative action in 2006 to require bundling. Nevertheless, we expect the policy debate around a bundled payment system in ESRD to continue in 2007.

The National Kidney Foundation ( NKF ) announced it will formally review recent information that may have an impact on its Kidney Disease Outcomes Quality Initiative ( KDOQI ) Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease, which was published in May 2006. The 2006 guidelines recommended that hemoglobin levels for ESA treated patients should be at 11 g/dL or greater and that there was insufficient evidence to recommend routinely maintaining hemoglobin levels at 13.0 g/dL or greater. While we cannot predict whether any amendments to the KDOQI guidelines that reduce the target level will be made, amendments to the guidelines may have a negative impact on the use of our erythropoietin products.



## **Table of Contents**

The Agency for Healthcare Research and Quality ( AHRQ ) is currently drafting a comparative effectiveness review ( CER ) of drug therapies for rheumatoid arthritis or psoriatic arthritis the purpose of which is to compare the benefits and safety of rheumatoid arthritis and psoriatic arthritis disease modifying antirheumatic drug ( DMARD ) therapies to inform clinical decision making. A draft report that will be subject to public comment is expected to be released the first quarter of 2007. We cannot predict what effect, if any, the draft CER will have on DMARD utilization.

On February 2, 2007, the USP DI Drug Reference Guides removed Aranesp® for treatment of anemia of cancer. This may cause Medicare contractors or private payers to reconsider whether they will pay for some or all anemia of cancer treatment claims. 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.

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

We intend to continue an aggressive research and development program. Successful product development in the biotechnology industry is highly uncertain, and very few R&D projects produce a commercial product. 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 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 licensors or partners may fail to effectively conduct clinical development or clinical manufacturing activities. 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

## Table of Contents

preclinical data 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 and, as a part of that decision and based on thorough 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 supply of our products and limit our product sales. ; 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 if we or others identify side effects after our products are on the market. ; and Before we commercialize and sell any of our product candidates, 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 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 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 the FDA so that they must be obtained from that specific sole source and could not be obtained from another supplier unless and until the FDA 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 the FDA 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 a 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 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 manufacturing and the formulation of our products are derived from biological sources, including mammalian tissues, bovine serum and HSA. 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 manufacture of drugs. A material shortage, contamination, recall and/or restriction of the use of certain biologically derived substances in the manufacture of our products could adversely impact or disrupt our commercial manufacturing of our products or could result in a mandated withdrawal of our products from the market. This could adversely affect our ability to satisfy demand for our products, which could adversely affect our product sales and operating results materially.

## **Table of Contents**

*Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales.*

We currently manufacture and market all our principal products, and we plan to manufacture and market many of our potential products. 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 if we or others identify side effects 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 and Juncos, Puerto Rico (See We 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 and Sensipar®/Mimpara® and in the formulation, fill and finish of Vectibix™ and plan to use contract manufacturers to produce a number of our 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 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

facility capacity of our facilities or those of our contract manufacturers

facility contamination by microorganisms or viruses

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 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, 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 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 a

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

new contract manufacturer. In order to maintain adequate supply to keep up with growing demand for our products, mitigate risks associated with the vast majority of our formulation, fill and finish operations located in Puerto Rico, and to adequately prepare to launch a number of our late-stage product candidates, we must successfully implement a number of manufacturing projects on schedule, operate our facilities at nearly full production capacity over the next few years, expand our use of third-party contract manufacturers, build inventory of our bulk and finished products and maintain a

## **Table of Contents**

state of regulatory compliance. Key manufacturing projects include: 1) construction, qualification and licensure of our new process bulk and formulation, fill and finish plant in Ireland; 2) construction, qualification and licensure of new formulation, fill and finish facilities at our Puerto Rico site; and 3) expansion of existing bulk protein facilities at our Puerto Rico site including the licensure of our Puerto Rico plant for production of Epoetin and darbepoetin bulk drug substance and increased production of pegfilgrastim and Filgrastim bulk drug substance.

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 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. For example, we are dependent upon a single FDA approved third-party contract manufacturer for the formulation, fill and finish of Vectibix™. 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.

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

We currently perform all of the formulation, fill and finish for EPOGEN®, Aranesp®, Neulasta® and NEUPOGEN® and some formulation, fill and finish operations for ENBREL 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. Additionally, to keep up with the growing demand for our products, we are operating this facility at nearly full production capacity. A number of factors could adversely affect our formulation, fill and finish 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 a pandemic flu outbreak, or otherwise

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

natural or other disasters, including hurricanes

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

For example, this facility in Puerto Rico has experienced manufacturing component shortages and has had evidence of adverse trends in the microbial bioburden of the production environment that reduced the production output. 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 could result in such losses adversely affecting 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. )



**Table of Contents**

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

We currently produce a substantial portion of annual ENBREL supply at our Rhode Island manufacturing facilities. 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 due to 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 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 the Rhode Island facilities' 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 facilities are 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 facilities, 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 drug substance manufactured at our Rhode Island facilities. 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.

Under a collaboration and global supply agreement, the Company and Wyeth share the total worldwide bulk supply of ENBREL produced by Amgen's Rhode Island manufacturing facilities, BI Pharma's manufacturing facility in Germany and Wyeth's manufacturing facility in Ireland. 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 expectations, 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.

*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 Johnson & Johnson, Abbott, Biogen, Genentech, Bristol-Meyers Squibb, Novartis and Sanofi-Aventis, as well as the generic drug methotrexate, and may face competition from other potential therapies being developed. While ENBREL continues to maintain a leading position in both rheumatology and dermatology, it has experienced share loss to competitors. Additionally, Aranesp® competes with products marketed by Johnson & Johnson in the United States and the EU and with products marketed by Roche in the EU. Also, Aranesp® may face competition in the EU in 2007 from another erythropoietin product produced by Shire. Aranesp® and EPOGEN® may also face competition in the U.S. from Roche's peg-EPO for which they have



## **Table of Contents**

filed a BLA with the FDA. According to Roche's public statements, they expect to launch the molecule in the U.S. nephrology segment in 2007, despite our ongoing lawsuit and their acknowledgement of our U.S. erythropoietin patents. (See [Table of Contents](#) 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. ) In addition, Astellas/FibroGen are co-developing an erythropoietic small molecule and Affymax is developing an erythropoietin mimetic for the treatment of anemia. Vectibix™, our recently launched oncology therapeutic to treat patients with metastatic colorectal cancer, competes with Imclone's Erbitu®. Further, if our currently marketed products are approved for new uses, or if we sell new products, we may face new, additional competition that we do not face today. 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.

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. We believe that as these patents have expired, other companies could receive approval for and market biosimilar products to compete with our products in the EU, presenting additional competition to our products. Although we cannot predict with certainty when the first biosimilar products could appear on the market in the EU, we expect that the first biosimilar G-CSF product may be approved some time in 2007 and could be available shortly thereafter, and that it would compete with Neulasta® and NEUPOGEN®. While we do not market EPOGEN® in Europe as this right belongs to Johnson & Johnson (through KA), we do market Aranesp® in the EU, which competes with Johnson & Johnson's EPREX® product, Roche's NeoRecormon® product and others' erythropoietin products. In addition, Roche is developing its peg-EPO product which, upon regulatory approval, we expect they will launch in the EU nephrology segment in 2007. We believe that biosimilar erythropoietin products may be approved in the EU in 2007 and could be available in the EU shortly after approval. We cannot predict whether or to what extent the entry of biosimilar products or other competing products would 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 follow-on biologics. 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 promulgation of associated regulations and guidance by the FDA. Until such legislation is created, we cannot predict when follow-on biologics 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. 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.

---

**Table of Contents**

*We have grown rapidly, and if we fail to adequately manage that growth our business could be adversely impacted.*

We have had an aggressive growth plan that has included substantial and increasing investments in research and development, sales and marketing and facilities. We plan to continue to grow and our plan has a number of risks, some of which we cannot completely control. For example:

we need to generate higher revenues to cover a higher level of operating expenses, and our ability to do so may depend on factors that we do not control

we need to attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, including a significant number of new personnel to support our R&D organization and manufacturing operations in 2007

we will need to assimilate new staff members and we will need to manage complexities associated with a larger, faster growing and more geographically diverse organization

we will need to expand our clinical development resources to manage and execute increasingly global, larger and more complex clinical trials

we will need to significantly expand our sales and marketing resources to launch a number of late-stage product candidates close in time

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

we will need to start up our new manufacturing facilities and enter into and manage new third-party contract manufacturing arrangements, while operating our existing manufacturing facilities at near or full capacity

we are implementing an enterprise resource planning system to support our increasingly complex business and business processes and such implementation is costly and carries substantial operations risk, including loss of data or information, unanticipated increases in costs, disruption of operations or business interruption

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 manage our growth in these ways or others, such failure could result in a material adverse affect 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 clinics, dialysis centers, hospitals and pharmacies. One of these products, EPOGEN<sup>®</sup>, is primarily sold to free-standing dialysis clinics, which have recently 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<sup>®</sup> 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, to purchase, and we have agreed to supply, all of Fresenius' commercial requirements for erythropoietic stimulating proteins 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.

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

This concentration and consolidation has increased these entities' purchasing leverage and 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.

## **Table of Contents**

*Our marketing of ENBREL will be dependent in part upon Wyeth.*

Under a co-promotion agreement, the Company 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, product pricing 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 market ENBREL effectively or if the Company and Wyeth fail to coordinate our efforts effectively, our sales of ENBREL may be adversely affected materially.

*Our business may be impacted 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 Item 3. Legal Proceedings 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 (in the case of monetary damages, in the period in which such damages are incurred).

The federal government, state governments and private payers are investigating, and many have filed actions against numerous pharmaceutical and biotechnology companies, including Amgen and Immunex, now a wholly owned subsidiary of ours, alleging that the reporting of prices for pharmaceutical products has resulted in false and overstated AWP, which in turn is alleged to have improperly inflated the reimbursement paid by Medicare beneficiaries, insurers, state Medicaid programs, medical plans and other payers to healthcare providers who prescribed and administered those products. A number of these actions have been brought against us and/or Immunex. Additionally, a number of states have pending investigations regarding our Medicaid drug pricing practices and the U.S. Departments of Justice and Health and Human Services have requested that Immunex produce documents relating to pricing issues. Further, certain state government entity plaintiffs in some of these AWP cases are also alleging that companies, including ours, were not reporting their best price to the states under the Medicaid program. These cases and investigations are described in Item 3. Legal Proceedings – Average Wholesale Price Litigation and are updated as required in subsequent Form 10-Qs. Other states and agencies could initiate investigations of our pricing practices. A decision adverse to our interests on these actions and/or investigations could result in substantial economic damages and could have a material adverse effect on our results of operations 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 been named as defendants in product liability actions for certain of our products.

*Our stock price is volatile, which could adversely affect your investment.*

Our stock price, like that of other biotechnology companies, is volatile. For example, in the fifty-two weeks prior to December 31, 2006, the trading price of our common stock has ranged from a high of \$80.36 per share to a low of \$63.92 per share. Our stock price may be affected by a number of factors, such as:

changes in the government's or private payers' reimbursement policies or prescribing guidelines for our products

## **Table of Contents**

adverse developments regarding the safety or efficacy of our products

actual or anticipated clinical trial results of ours or other companies and organizations

actual or anticipated product supply constraints

product development or other business announcements by us or our competitors

regulatory matters or actions

announcements in the scientific and research community

intellectual property and legal matters

broader economic, industry and market trends unrelated to our performance

pronouncements and rule changes by applicable standards authorities that change the manner in which we account for certain transactions

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.

*Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable U.S. federal and state regulations and all potentially applicable foreign regulations.*

The development, manufacturing, distribution, pricing, sales, marketing and reimbursement of our products, together with our general operations, is 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 if we or others identify side effects 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. ) While we have developed and instituted a corporate compliance program based on what we believe to be current best practices, we cannot assure you that we or our employees 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 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, including withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation.

*Our revenues may fluctuate, and this fluctuation could cause financial results to be below expectations.*

Our operating results may fluctuate from period to period for a number of reasons. In budgeting our operating expenses for the foreseeable future, we assume that revenues will continue to grow; however, some of our operating expenses are fixed in the short term. Because of this, even a relatively small revenue shortfall may cause a period's results to be below our expectations or projections. A revenue shortfall could arise from any number of factors, some of which we cannot control. For example, we may face:

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

changes in the government's or private payers' reimbursement policies or prescribing guidelines for our products

adverse developments regarding the safety or efficacy of our products

inability to maintain regulatory approval of marketed products or manufacturing facilities

changes in our product pricing strategies

lower than expected demand for our products

## **Table of Contents**

inability to provide adequate supply of our products

changes in wholesaler buying patterns

increased competition from new or existing products

fluctuations in foreign currency exchange rates

Of course, there may be other factors that affect our revenues in any given period. Similarly if investors or the investment community are uncertain about our financial performance for a given period, our stock price could also be adversely impacted.

*Continual manufacturing process improvement efforts may result in the carrying value of certain existing manufacturing facilities or other assets becoming impaired.*

In connection with our ongoing process improvement activities associated with products we manufacture, we continually invest in our various manufacturing practices and related processes with the objective of increasing production yields and success rates to gain increased cost efficiencies and capacity utilization. We are investigating alternative manufacturing processes that do not require the use of certain biologically-sourced raw materials. The development or implementation of such processes could result in changes to or redundancies with our existing manufacturing operations. Depending on the timing and outcomes of these efforts and our other estimates and assumptions regarding future product sales, the carrying value of certain manufacturing facilities or other assets may not be fully recoverable and could result in the recognition of an impairment in the carrying value at the time that such effects are identified. The potential recognition of impairment in the carrying value, if any, could have a material and adverse affect on our results of operations.

### **Item 1B. UNRESOLVED STAFF COMMENTS**

None.

**Table of Contents**

**Item 2. PROPERTIES**

The following table summarizes our significant properties and their primary functions as of December 31, 2006. For additional information regarding ongoing R&D and manufacturing initiatives see Item 1. Business Research and Development and Selected Product Candidates and Item 1. Business Manufacturing and Raw Materials.



## **Table of Contents**

In addition, we have undeveloped land at some of our sites, principally in Longmont, CO, Thousand Oaks, CA, West Greenwich, RI, Louisville, KY, Seattle and Bothell, WA and Juncos, Puerto Rico, to accommodate future expansion. In addition, we lease a number of facilities/space that were assumed in acquisitions that we sublease to third-party tenants. As part of our global expansion, we purchased land in Ireland in 2006 for the construction of a process development, bulk manufacturing, formulate, fill and finish facility and have initiated significant projects in Puerto Rico for additional bulk manufacturing, formulation, fill and finish.

Our facilities are deemed suitable for their intended use and, in conjunction with our third-party contracting manufacturing agreements, provide adequate capacity (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. ). We also believe that our existing facilities, third-party contract manufacturing agreements and our anticipated additions are sufficient to meet our expected needs (see Item 1A. Risk Factors We 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. and 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. ). There are no material encumbrances on our properties.

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

Certain of our legal proceedings are discussed below. While it is not possible to predict accurately or to determine the eventual outcome of these items, we do not believe any such proceedings currently pending will have a material adverse effect on our annual consolidated financial position or liquidity, although an adverse resolution in any quarterly or annual reporting period of one or more of these items could have a material impact on the consolidated results of our operations for that period.

#### *Transkaryotic Therapies and Aventis Litigation*

On April 15, 1997, Amgen filed suit 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 Defendants ) alleging infringement of three U.S. patents owned by Amgen that claim an erythropoietin product and processes for making erythropoietin. Amgen sought an injunction preventing the Defendants from making, importing, using or selling erythropoietin in the United States. On October 7, 1999, Amgen filed an amended complaint, which added two additional patents to the litigation. Defendants' amended answer asserted that all five of the patents-in-suit were not infringed, were invalid or were unenforceable due to inequitable conduct.

Amgen's motion for summary judgment of literal infringement was granted by the Massachusetts District Court on April 26, 2000 with respect to claim 1 of U.S. Patent No. 5,955,422 (the 422 Patent ). On May 15, 2000, trial began in the Massachusetts District Court. On June 9, 2000, the Massachusetts District Court granted Defendants' motion for non-infringement of U.S. Patent No. 5,618,698 (the 698 Patent ), removing the 698 Patent from this action. On July 21, 2000, the Massachusetts District Court granted Amgen's motion for judgment on the Defendants' defenses of invalidity based upon anticipation and obviousness.

On January 19, 2001, the Massachusetts District Court ruled that claims 2-4 of U.S. Patent No. 5,621,080 (the 080 Patent ), claims 1, 3, 4 and 6 of U.S. Patent No. 5,756,349 (the 349 Patent ) and claim 1 of the 422 Patent were valid, enforceable and infringed by TKT's erythropoietin product and the cells used to make such product. The Massachusetts District Court also held that claim 7 of the 349 patent and claims 1, 2 and 9 of U.S. Patent No. 5,547,933 (the 933 Patent ) were not infringed, and that if infringed, the claims of the 933 patent would be invalid.

On January 26, 2001, the Defendants filed a Notice of Appeal and on February 14, 2001, Amgen filed a Notice of Cross-Appeal, to the U.S. Court of Appeals for the Federal Circuit. On March 22, 2001, Amgen filed an Amended Notice of Cross-Appeal to include claim 9 of the 698 patent. After the parties briefed the issues on appeal, oral arguments were heard on May 7, 2002 by the U.S. Court of Appeals for the Federal Circuit.

## **Table of Contents**

On January 6, 2003, the U.S. Court of Appeals for the Federal Circuit upheld the Massachusetts District Court's decision that the Defendants infringe the 349 and 422 patents and held that claims 1 and 2 of the 933 patent were invalid. The court further upheld the enforceability and validity of all of the asserted claims except for validity over two references which was vacated and remanded to the Massachusetts District Court. The court vacated and remanded to the Massachusetts District Court for further consideration of (i) the finding of infringement of the 080 patent, (ii) the holding of non-infringement of the 698 patent, and (iii) the effect of two references on the validity of the asserted claims of the patents. On January 20, 2003, the Defendants filed a Combined Motion for Panel Rehearing and Rehearing En Banc with the U.S. Court of Appeals for the Federal Circuit regarding the court's affirmance of the validity of the asserted claims under 35 U.S.C. §112. On March 3, 2003, the U.S. Court of Appeals for the Federal Circuit denied the Defendant's Motions for Panel Rehearing and Rehearing En Banc. The Massachusetts District Court held a trial on the remanded issues on October 7-8 and 15-17 and November 3-6, 2003. On October 30, 2003, the Massachusetts District Court ruled that claims 2-4 of the 080 patent are infringed.

On October 15, 2004, the Massachusetts District Court decided the remaining issues remanded from the U.S. Court of Appeals for the Federal Circuit in Amgen's favor. In the October 15, 2004 decision, the court ruled that claims 4-9 of the 698 patent are valid and infringed, claims 2-4 of the 080 claims are valid, claim 1 of the 422 is valid and claim 7 of the 349 patent is valid and infringed. On December 10, 2004, TKT filed a Notice of Appeal to the U.S. Court of Appeals for the Federal Circuit. After the parties briefed the issues, on December 6, 2005, the U.S. Court of Appeals for the Federal Circuit heard oral argument on the appeal filed by TKT.

On August 3, 2006, the U.S. Court of Appeals for the Federal Circuit affirmed the Massachusetts District Court's decision that the Defendants infringe claims 4-9 of the 698 patent and claims 1, 3, 4, 6 and 7 of the 349 patents. The court further affirmed the validity of claims 4-9 of the 698 patent and claim 7 of the 349 patent. The court found that claims 2-4 of the 080 patent were not infringed under the doctrine of equivalents. The court vacated and remanded to the Massachusetts District Court for further consideration of the validity of claim 1 of the 422 patent. The August 3, 2006 decision, in conjunction with the court's prior rulings, upholds infringement by TKT of 12 claims in 3 patents owned by Amgen (349, 698 and 422).

On August 17, 2006, Amgen filed a combined petition for panel rehearing and rehearing en banc with the U.S. Court of Appeals for the Federal Circuit regarding the claim construction with respect to claim 1 of the 422 Patent. On November 22, 2006, the Court of Appeals denied the petition for panel rehearing and petition for rehearing en banc.

### *Israel Bio-Engineering Project Litigation*

On September 3, 2002, Israel Bio-Engineering Project (IBEP), filed a patent infringement lawsuit against Amgen's wholly-owned subsidiary, Immunex, Wyeth and Wyeth Pharmaceuticals (collectively, Wyeth) in the U.S. District Court for the Central District of California (the California District Court), relating to a U.S. Patent No. 5,981,701 (the 701 Patent). Although not the title owner of record, IBEP alleges that it owns the 701 Patent. IBEP asserts that the manufacture and sale of ENBREL infringes claim 1 of this patent. IBEP seeks an accounting of damages and of any royalties or license fees paid to a third-party and seeks to have the damages trebled on account of alleged willful infringement. IBEP also seeks to force the defendants to take a compulsory non-exclusive license. On September 4, 2003, Yeda Research and Development Co. Ltd. (Yeda), the title owner of record of the 701 patent, joined as an intervenor-defendant. On February 18, 2004, the court granted summary judgment in favor of Yeda on the issue of ownership.

On March 31, 2004, judgment was entered in favor of the defendants, including Amgen and Immunex. IBEP filed a Notice of Appeal. Oral argument was heard by the U.S. Court of Appeals for the Federal Circuit on January 11, 2005.

On March 15, 2005, the U.S. Court of Appeals for the Federal Circuit affirmed in part, reversed in part and remanded to the California District Court. The U.S. Court of Appeals for the Federal Circuit affirmed the California District Court's findings that IBEP did not gain title to the U.S. Patent No. 5,981,701 under its contract

## **Table of Contents**

interpretation theory. However, the U.S. Court of Appeals for the Federal Circuit reversed and remanded the issue whether IBEP gained title under its employment theory. On December 22, 2005, the California District Court granted Intervenor Yeda's motion for summary judgment that the plaintiff, IBEP, lacked standing to sue Amgen, Immunex and Wyeth for patent infringement. On January 26, 2006, IBEP filed a Notice of Appeal with the U.S. Court of Appeals for the Federal Circuit and on April 5, 2006 IBEP filed its brief. On June 1, 2006, Amgen and Yeda each filed its opposition brief with the U.S. Court of Appeals for the Federal Circuit and IBEP filed its reply brief on June 29, 2006. The U.S. Court of Appeals for the Federal Circuit held oral argument on October 4, 2006. On January 29, 2007, the Federal Circuit affirmed the California District Court's finding that IBEP lacked standing to sue Amgen.

### *Average Wholesale Price 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 the 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 that are, or are in the process of being 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 Corp.; 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, et al.; State of Montana v. Abbott Laboratories, Inc., et al.; State of Nevada v. American Home Products Corp., 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 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.*

**Table of Contents**

*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.*

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. The Massachusetts District Court held a hearing on May 22, 2006, for defendants' motions to dismiss the California Attorney General (California AG) complaint (State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et. al.). Immunex, and not Amgen, was a defendant in the California AG complaint until Immunex was dismissed from the case on January 17, 2007, following a settlement agreement entered into between the parties, executed on December 14, 2006. 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. Summary judgment motions were filed in the State of Montana v. Abbott Laboratories, Inc., et al. and State of Nevada v. American Home Products Corp., et al., cases and a hearing on both motions has been scheduled for May 2, 2007 in the Massachusetts District Court. Immunex is the sole defendant in both the Montana and Nevada cases.

Certain AWP 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 Court set a hearing on plaintiffs' motion to certify a statewide class for May 13, 2005; however, the Court stayed the entire case on March 10, 2005. This case remains stayed and another status conference is scheduled for April 2, 2007.

*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 Commonwealth Court to the U.S. District Court for the Eastern District of Pennsylvania. 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 Commonwealth of Pennsylvania's amended complaint on April 6, 2006. On October 11, 2006, this case was removed to the United States District Court for the Eastern District of Pennsylvania. Plaintiffs filed a motion to remand and on January 22, 2007, and the U.S. District Court for the Eastern District of Pennsylvania stayed the case pending transfer to the MDL proceeding. A hearing on Plaintiff's motion to remand was held on February 1, 2007.

*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 Circuit Court to the U.S. District Court for the Western District of Wisconsin. This case has been remanded to state court by order dated September 29, 2005. On October 11, 2006, this case was removed to the United States District Court for the Western District of Wisconsin. Plaintiffs filed a motion to remand and on January 16, 2007, the U.S. District Court for the Western District of Wisconsin remanded the case to state court.

## **Table of Contents**

*Commonwealth of Kentucky v. Alphapharma, 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 has been remanded to state court by order dated March 16, 2006. A hearing on defendants' motion to dismiss was held on June 6, 2006.

*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 Circuit Court to U.S. District Court for the Middle District of Alabama. 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 United States District Court for the Middle District of Alabama. 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 is scheduled to commence on November 26, 2007.

*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 United States 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.

*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 Supreme Court of New York to the U.S. District Court for the Western District of New York. 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 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 United States District Court for the Western District of New York.

*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 United States 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.

*State of Arizona, etc., et al., vs. 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 United States District Court for the District of Massachusetts and was transferred to the MDL proceeding. Plaintiff's motion to remand was denied on October 25, 2006.

## **Table of Contents**

*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.

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

*IUOE, Local 68 v. AstraZeneca, PLC, et al.* This case was filed against Amgen and Immunex, along with several other pharmaceutical manufacturers, on June 30, 2003 in the Superior Court of New Jersey, Monmouth County. 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 New Jersey state Medicaid program. Defendants filed a motion to remove the case to federal court; however, the case was remanded to state court on April 14, 2006. A hearing on Defendants' motion to dismiss is scheduled for April 20, 2007.

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

### *Immunex Governmental Investigations*

According to press reports, many pharmaceutical companies are under investigation by the U.S. Department of Justice, the U.S. Department of Health and Human Services, and/or state agencies related to the pricing of their products. Immunex received notices from the U.S. Department of Justice requesting the production of documents in connection with a Civil False Claims Act investigation of the pricing of Immunex's current and former products for sale and eventual reimbursement by Medicare or state Medicaid programs. Immunex also received similar requests to procure documents from the U.S. Department of Health and Human Services and state agencies. Several of Immunex's current and former products are or were regularly sold at substantial discounts from list price. The Company does not know what action, if any, the federal government or any state agency may take as a result of their investigations.

### *State Attorney General Investigations*

Amgen and/or Immunex have been advised by the Attorneys General for 14 states of pending investigations regarding drug pricing practices pertaining to the calculation of AMP and Best Price calculations under the Medicaid Drug Rebate Act, as those terms are defined in 42 U.S.C. 1396r-8. These states have requested that Amgen and Immunex preserve records relating to AMP and best price calculations. Immunex has also been advised that the Attorney General for the State of Idaho is investigating claims relating to AWP as to numerous companies, including Immunex. The Company does not know what actions, if any, may be taken as a result of these investigations.

### *Johnson & Johnson Matters*

#### *Arbitration/Demand for Separate BLA*

On November 11, 2003, Ortho Biotech Products, L.P., Ortho Biotech Inc., and Ortho-McNeil Pharmaceutical (each a wholly owned subsidiary of Johnson & Johnson, collectively, "Ortho") filed a demand for arbitration

## **Table of Contents**

against the Company before the American Arbitration Association in Chicago, Illinois. In its demand, Ortho seeks declaratory relief that, among other things, (1) Ortho has the right under the parties' Product License Agreement to apply for its own FDA license to market its brand of recombinant erythropoietin, PROCRIT®, based on bulk product supplied by the Company, (2) the Company must cooperate with Ortho to achieve Ortho's separate FDA licensure, (3) pending FDA approval of Ortho's separate license, the Company must continue to supply Ortho with Ortho's commercial requirements of finished erythropoietin products and (4) pending FDA approval of Ortho's separate license, the Company must cooperate with Ortho on erythropoietin development projects, including Ortho's proposal for a 120,000 unit per ml formulation. Amgen contests Ortho's claims and will respond accordingly.

On July 12, 2006, a hearing was held on the motions for summary judgment submitted by Amgen and Ortho before the arbitration panel. Both parties' motions were denied. From September 11-15, 2006, a final arbitration hearing was held before the arbitration panel in Chicago, Illinois. Closing arguments were held before the panel on November 29, 2006.

### *Ortho Biotech Antitrust Litigation*

On October 11, 2005, Ortho Biotech Products, L.P. (Ortho Biotech) filed suit in the United States District Court for the District of New Jersey (the New Jersey District Court) against Amgen alleging violations of §§ 1 & 2 of the Sherman Act, §15 U.S.C. Sections 1 and 2. The complaint sought a preliminary injunction to enjoin Amgen from offering discounts to oncology clinics on its G-CSF products (NEUPOGEN® (Filgrastim) and Neulasta® (pegfilgrastim)) and Aranesp® (darbepoetin alfa), if customers purchased certain amounts of both types of products. Ortho Biotech also seeks a permanent injunction against such discounts, as well as damages it has allegedly sustained by virtue of Amgen's contracting program.

The parties engaged in extensive discovery, for the purpose of Ortho Biotech's motion for a preliminary injunction, from October 2005 through June 2006.

From June 12-15, 2006, a hearing was held on Ortho Biotech's motion for preliminary injunction in Trenton, New Jersey before the New Jersey District Court. By order of the Court, the parties filed findings of fact and conclusions of law, along with the evidentiary record, in addition to providing post-hearing briefs and oral closing arguments once the evidentiary hearing concluded.

On November 22, 2006, the New Jersey District Court ruled that Ortho Biotech had not demonstrated irreparable harm to justify the granting of a preliminary injunction and therefore, denied Ortho Biotech's motion. In December 2006, the New Jersey District Court held a scheduling conference setting discovery deadlines, summary judgment deadlines and scheduled a final pre-trial conference for April 14, 2008, during which a trial date will be discussed.

### *Roche Matters*

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

On November 8, 2005, Amgen filed a lawsuit in the Massachusetts District Court in Boston, Massachusetts against F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively, Roche) seeking a declaration by the Court that defendants' importation, use, sale or offer to sell peg-EPO infringes Amgen's patents. Amgen alleges infringement of six of its U.S. Patents that claim erythropoietin products (EPO), pharmaceutical compositions, and processes for making erythropoietin, specifically U.S. Patent Nos. 5,756,349; 5,621,080; 5,618,698; 5,955,422; 5,547,933; and 5,441,868. Amgen is seeking a permanent injunction preventing the defendants from making, importing, using, offering for sale or selling recombinant human EPO, including pegylated EPO, in the United States. On March 9, 2006, Ortho Biotech filed a motion to intervene as a plaintiff in the lawsuit.

On April 11, 2006, Roche filed motions to dismiss the lawsuit arguing a lack of subject matter jurisdiction and lack of personal jurisdiction over F. Hoffmann-La Roche Ltd. and Roche Diagnostics GmbH. Amgen filed its response to the motions to dismiss on April 25, 2006. On May 10, 2006, oral arguments were held before the

## **Table of Contents**

Massachusetts District Court on the motions by Ortho Biotech to intervene in the lawsuit and motions by Roche to dismiss the lawsuit based on a lack of subject matter jurisdiction and lack of personal jurisdiction over F. Hoffmann-La Roche Ltd. and Roche Diagnostics GmbH. On May 18, 2006, Roche withdrew its motion to dismiss based upon lack of personal jurisdiction.

On October 20, 2006, the Massachusetts District Court denied Roche motion to dismiss based upon lack of subject matter jurisdiction and denied Ortho Biotech's motion to intervene in the lawsuit. On October 23, 2006, a scheduling conference was held in which the judge set September 2007 as the target date for the trial to commence. On November 6, 2006, Roche filed an answer to the complaint in which Roche denies that they infringe the patents-in-suit, assert legal and equitable defenses and counterclaims including non-infringement, patent invalidity, patent unenforceability, patent misuse, as well as accusing Amgen of violating state and federal antitrust and unfair competition law. On November 27, 2006, Amgen filed a motion to dismiss Roche's counterclaims I-IX and XII and a motion to strike certain of Roche's affirmative defenses. Roche opposed the motions on December 8, 2006. On December 15, 2006, Ortho Biotech filed an appeal to the Court of Appeals for the Federal Circuit to overturn the denial of its motion to intervene. On December 20, 2006, the Massachusetts District Court denied Amgen's motion to dismiss counterclaims I and VI, allowed without prejudice Amgen's motion to dismiss counterclaim II and denied Amgen's motion to strike except Roche's equitable estoppel defense, for which the Court granted the motion to strike without prejudice. The Massachusetts District Court has not yet ruled on Amgen's motion to strike counterclaims III-V and VII-IX. On February 26, 2007, the parties filed a stipulation to dismiss with prejudice Ortho's appeal before the Court of Appeals of the Massachusetts District Court's denial of its motion to intervene.

### *U.S. International Trade Commission*

On April 11, 2006, Amgen filed a complaint with the U.S. 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.

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). The ITC made no determination with respect to the merits of Amgen's claim that Roche's future importation and sale of peg-EPO will infringe Amgen's patents. The decision does not prevent Amgen from re-filing its complaint with the ITC at a later time.

On October 11, 2006, Amgen filed a petition for review of the ITC's decision with the United States Court of Appeals for the Federal Circuit. On January 29, 2007, Amgen timely filed its brief in support of its petition for review.

### *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 filed a complaint against Ariad Pharmaceuticals, Inc. (Ariad) in the United States 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. Ariad was served with the complaint on April 24, 2006.



## **Table of Contents**

On June 14, 2006, Ariad filed a motion to dismiss with the Delaware District Court, which Amgen opposed on June 28, 2006. The Court has scheduled trial to begin on February 4, 2008.

On September 11, 2006, the Delaware District Court denied Ariad's motion to dismiss for lack of subject matter jurisdiction and denied without prejudice Ariad's motion to dismiss for failure to name indispensable parties. On September 25, 2006, Ariad filed a motion seeking certification for interlocutory appeal of the Delaware District Court's denial of Ariad's motion to dismiss for lack of subject matter jurisdiction. On October 5, 2006, Ariad filed a renewed motion to dismiss for failure to name indispensable parties. The Court heard oral argument on these motions on November 3, 2006 and granted Ariad's motion seeking certification for an interlocutory appeal. The Delaware District Court denied without prejudice Ariad's renewed motion to dismiss and motion to transfer. On November 17, 2006, Ariad petitioned the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") for leave to file an interlocutory appeal of the Delaware District Court's September 11, 2006 denial of its motion to dismiss for lack of subject matter jurisdiction. Ariad's petition to the Federal Circuit was denied on December 29, 2006.

### *Other*

In February 2006, Amgen received service of a subpoena from the U.S. Attorney's Office for the District of Massachusetts for the production of documents relating to Amgen's business relationship with a long-term care pharmacy organization concerning several of our products. We intend to cooperate in responding to the subpoena.

On July 12, 2006, teams of prosecutors and police conducted separate site visits to the offices of Amgen GmbH, our German affiliate in Munich, Germany, and our European Logistics Center in Breda, The Netherlands and seized numerous files and computer tapes. The search warrant issued by a Munich court alleges improper payments by our German affiliate to a single hospital physician in Germany in 2001.

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 "Study"). The SEC's Atlanta District Office has requested that Amgen voluntarily provide certain information and documentation related to the Study. We intend to fully cooperate with the request.

## **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, 2006.

**Table of Contents****PART II****Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

Our common stock trades on The NASDAQ Stock Market under the symbol AMGN. As of January 31, 2007, there were approximately 13,000 holders of record of our common stock. No cash dividends have been paid on the common stock to date, and we currently intend to utilize any earnings for development of our business and to repurchase our common stock.

The following table sets forth, for the periods indicated, the range of high and low quarterly closing sales prices of the common stock as quoted on The NASDAQ Stock Market:

	<b>High</b>	<b>Low</b>
<b>Year ended December 31, 2006</b>		
4th Quarter	\$ 76.50	\$ 68.31
3rd Quarter	72.14	63.92
2nd Quarter	72.86	63.94
1st Quarter	80.36	71.01
<b>Year ended December 31, 2005</b>		
4th Quarter	\$ 84.42	\$ 73.37
3rd Quarter	86.17	60.86
2nd Quarter	63.18	57.20
1st Quarter	64.87	57.98

**Table of Contents***Performance Graph*

The chart set forth below shows the value of an investment of \$100 on December 31, 2001 in each of Amgen Common Stock, the Amex Biotech Index, the Amex Pharma 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 31 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 Pharma and S&P 500 Indices**

	<b>12/31/2001</b>	<b>12/31/2002</b>	<b>12/31/2003</b>	<b>12/31/2004</b>	<b>12/31/2005</b>	<b>12/31/2006</b>
Amgen	\$ 100.00	\$ 85.65	\$ 109.48	\$ 113.66	\$ 139.72	\$ 121.03
Amex Biotech	\$ 100.00	\$ 58.26	\$ 84.42	\$ 93.74	\$ 117.28	\$ 129.91
Amex Pharma	\$ 100.00	\$ 79.84	\$ 91.67	\$ 88.39	\$ 91.56	\$ 101.35
S&P 500	\$ 100.00	\$ 78.03	\$ 100.16	\$ 110.92	\$ 116.28	\$ 134.43

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****Item 5(c). UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES**

During the three months ended December 31, 2006, we had two outstanding stock repurchase programs. 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 and blackout periods in which we are restricted from repurchasing shares and may include private block purchases as well as market transactions. Repurchases under our stock repurchase program reflect, in part, our confidence in the long-term value of Amgen common stock. Additionally, we believe that it is an effective way of returning cash to our stockholders. A summary of our repurchase activity for the three months ended December 31, 2006 is as follows:

		Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum \$ Value that May Yet Be Purchased Under the Programs(1)
October 1	October 31	1,843,513	\$ 75.99	1,840,800	\$ 1,644,422,516
November 1	November 30	1,438,025	73.05	1,437,400	1,539,425,046
December 1	December 31	3,751	69.92		6,539,425,046
		3,285,289(2)	74.70	3,278,200(2)	

- (1) In December 2005, the Board authorized us to repurchase up to \$5.0 billion of common stock. Additionally, in December 2006, the Board authorized us to repurchase up to \$5.0 billion of common stock.
- (2) The difference between total number of shares purchased and the total number of shares purchased as part of publicly announced programs is due to shares of common stock withheld by us for the payment of taxes upon vesting of certain employees' restricted stock.

**Item 6. SELECTED FINANCIAL DATA**

Consolidated Statement of Operations Data:	2006	Years ended December 31,			2002
		2005	2004	2003	
		(In millions, except per share data)			
Revenues:					
Product sales(1)	\$ 13,858	\$ 12,022	\$ 9,977	\$ 7,868	\$ 4,991
Other revenues	410	408	573	488	532
Total revenues	14,268	12,430	10,550	8,356	5,523
Operating expenses(2):					
Cost of sales (excludes amortization of acquired intangible assets presented below)	2,095	2,082	1,731	1,341	736
Research and development	3,366	2,314	2,028	1,655	1,117
Write off of acquired in-process research and development(3)	1,231		554		2,992
Selling, general and administrative	3,366	2,790	2,556	1,957	1,449
Amortization of acquired intangible assets	370	347	333	336	155
Other items, net		49		(24)	(141)
Net income (loss)	2,950	3,674	2,363	2,259	(1,392)
Diluted earnings (loss) per share	2.48	2.93	1.81	1.69	(1.21)
Cash dividends declared per share					

Consolidated Balance Sheet Data:	2006	At December 31,			2002
		2005	2004	2003	

# Edgar Filing: AMGEN INC - Form 10-K

	(In millions)				
Total assets(4)	\$ 33,788	\$ 29,297	\$ 29,221	\$ 26,113	\$ 24,456
Total debt(5)(6)(7)	9,012	3,957	3,937	3,080	3,048
Stockholders' equity(8)	18,964	20,451	19,705	19,389	18,286

## **Table of Contents**

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 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) We began recording ENBREL sales subsequent to our acquisition of Immunex in July 2002.
- (2) Included in operating expenses are acquisition charges of \$41 million, \$12 million, \$53 million, \$70 million and \$87 million, in 2006, 2005, 2004, 2003 and 2002, respectively. Acquisition charges consist of 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 and external, incremental consulting and systems integration costs directly associated with integrating the acquisition.
- (3) As part of the accounting for the acquisitions of Avidia and Abgenix in 2006, Tularik in 2004 and Immunex in 2002, we recorded charges to write-off acquired IPR&D of \$130 million and \$1,101 million in 2006, \$554 million in 2004 and \$2,992 million in 2002. The IPR&D charge represents an estimate of the fair value of the in-process R&D for projects and technologies that, as of the acquisition date, had not reached technological feasibility and had no alternative future use.
- (4) In October 2006, we acquired all of the outstanding stock of 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 for a purchase price of approximately \$1.5 billion. In July 2002, we acquired all of the outstanding common stock of Immunex for a purchase price of approximately \$17.8 billion.
- (5) 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) in a private placement. 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. 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.
- (6) In March 2002, we issued convertible notes with a face amount at maturity of \$3.95 billion. Holders of the convertible notes may require us to purchase all or a portion of the notes on specific dates, the earliest of which was March 1, 2005, at the accreted principal amount through the purchase dates. On March 2, 2005, as a result of certain holders of the convertible notes exercising their March 1, 2005 put option, we repurchased \$1.2 billion, or approximately 40%, of the outstanding convertible notes at their then-accreted value for cash. Accordingly, the convertible notes repurchased were classified as current liabilities at December 31, 2004. Holders of the remaining outstanding convertible notes may require us to purchase, generally for cash, all or a portion of the notes on various dates at a price equal to the accreted principal amount through the purchase date. The next available put date was March 1, 2006, however, the holders of substantially all of the then outstanding convertible notes did not require us to repurchase such notes on this date. Accordingly, as of December 31, 2005, the convertible notes were classified as non-current liabilities. The next date that the holders of these notes may require us to repurchase all or a portion of these notes is on March 1, 2007. Accordingly, as of December 31, 2006, the convertible notes were classified as current liabilities.
- (7) In November 2004, we issued \$1.0 billion aggregate principal amount of 4.00% senior notes due in 2009 and \$1.0 billion aggregate principal amount of 4.85% senior notes due in 2014.

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

- (8) We have a share repurchase program through which we have repurchased \$5.0 billion, \$4.4 billion, \$4.1 billion, \$1.8 billion and \$1.4 billion of Amgen common stock in 2006, 2005, 2004, 2003 and 2002, respectively.

**Table of Contents****Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***Forward looking statements*

This report and other documents we file with the SEC contain forward looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business or others on our behalf, our beliefs and our management's assumptions. In addition, we, or others on our behalf, may make forward looking statements in press releases or written statements, or in our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. 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 Inc., including its subsidiaries (referred to as Amgen, we, our and us). 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®, Neulasta®/NEUPOGEN®, EPOGEN® and ENBREL. ENBREL is marketed under a co-promotion agreement with Wyeth in the United States and Canada. (See Item 1. Business Principal Products for additional information about our principal products, their approved indications and where they are marketed.) In October 2006, we launched Vectibix®, our first cancer therapeutic, after receiving FDA approval in late September. Product sales of Vectibix® were not significant for 2006.

For the year ended December 31, 2006, total revenues were \$14,268 million and net income was \$2,950 million, or \$2.48 per share on a diluted basis. The results of our operations for the year ended December 31, 2006 reflect the \$130 million and \$1.1 billion write-offs of acquired IPR&D costs associated with the Avidia and Abgenix acquisitions, respectively. As of December 31, 2006, cash, cash equivalents and marketable securities were \$6.3 billion, of which approximately \$4.2 billion was generated from operations in foreign tax jurisdictions and is intended for use outside the United States. Our total debt outstanding was \$9.0 billion as of December 31, 2006.

For both years ended December 31, 2006 and 2005, product sales represented 97% of total revenues, which was mainly comprised of our principal products. Over the last several years, our product sales growth has been



## **Table of Contents**

primarily driven by sales of Aranesp®, Neulasta® and ENBREL, which have benefited primarily from share gains and/or segment growth. We expect these products to continue to drive year-over-year sales growth in the near term and that Vectibix will also contribute to this growth. However, we believe that maintaining or increasing share will be more of a challenge than in previous years as we experienced share loss with ENBREL in 2006 compared to 2005 and we operate in an increasingly competitive environment. For example, Roche is developing a peg-EPO product for the United States for which they have filed a BLA with the FDA and have announced plans to launch in the nephrology segment in 2007 despite our ongoing lawsuit and their acknowledgement of our U.S. erythropoietin patents (see Item 3. Legal Proceedings Roche Matters Amgen Inc. v. F. Hoffmann-La Roche Ltd., et al. ). (See Item 1. Business Competition for further information on the impact of competition on our business.) In addition, as discussed below, we also anticipate increased competition internationally from biosimilar and other competing products. Going forward, we will focus on growing our segments, including increasing our penetration in the therapeutic areas in which our products are used, while also continuing to focus on maintaining or increasing share. Over the last few years, our principal products have attained significant sales levels and have experienced strong year-over-year sales growth. However, the rate of growth has declined in each of the past several years and, in the near term, we expect this trend will continue.

Most patients receiving Aranesp® and Neulasta®/NEUPOGEN® for approved indications are covered by both government and private payer healthcare programs. In the United States, approved dialysis providers are primarily reimbursed for EPOGEN® by the federal government through the ESRD Program of Medicare. The ESRD program reimburses 80% of allowed dialysis costs, with the remainder being paid by other sources including patients, state Medicaid programs, private insurance and, to a lesser extent, state kidney patient programs. Beginning in the first quarter of 2006, ENBREL and Sensipar® also became eligible for coverage from the U.S. Government under Medicare Program Part D. Generally, in Europe and other countries outside the U.S., the government sponsored healthcare system is the primary payer of healthcare costs of patients. Governments may regulate access to, prices or reimbursement levels of our products to control costs. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to healthcare providers in response to ongoing initiatives to reduce healthcare expenditures. Therefore, sales of our principal products and sales growth are, and will be, affected by the availability and extent of reimbursement from third-party payers, including government and private insurance plans. While we believe that our product sales for 2006 and 2005 have not been nor, for 2007, are expected to be significantly impacted by the reimbursement changes resulting from the MMA enacted in 2005, additional provisions of the MMA and other regulations affecting reimbursement that have gone, or may go, into effect could affect our product sales and related sales growth in the future. For additional information on reimbursement and its impact on our business, see Item 1. Business Reimbursement.

International product sales for both years ended December 31, 2006 and 2005 represented 18% of total product sales and consisted principally of European sales. International product sales have grown significantly over the last several years driven by Aranesp® and Neulasta® reflecting continued penetration. However, we anticipate facing greater competition in Europe from the availability of biosimilar and other competing products. Although we cannot predict with certainty when the first biosimilar products could appear on the market in the EU, we believe that the first biosimilar G-CSF product, which would compete with Neulasta® and NEUPOGEN®, and that the first biosimilar erythropoietin products, which would compete with Aranesp®, may be approved in 2007 and could be available in the EU shortly after approval. Based on an announcement by Shire, we expect that a competing erythropoietin product, manufactured by Shire, may appear on the market in the EU in 2007. In addition, Roche is developing its peg-EPO product which, upon regulatory approval, we expect they will launch in the EU nephrology segment in 2007. We cannot predict whether or to what extent the entry of biosimilar or other competing products would impact future Aranesp®, Neulasta® or NEUPOGEN® sales in the EU. (See Item 1. Business Competition for further information regarding biosimilar products.)

Our international product sales are impacted by foreign currency changes (see Results of Operations discussion below). International product sales growth during 2006 was unfavorably impacted by \$13 million, while 2005 was favorably impacted by \$46 million, from foreign currency exchange rate changes. However, both the

**Table of Contents**

positive and negative impacts that movements in foreign exchange rates have on our international product sales are mitigated, in part, by the natural, opposite impact these exchange rate movements have on our international operating expenses and as a result of our foreign currency hedging activities. Our hedging activities seek to offset the impact, both positive and negative, that foreign exchange rate changes may have on our net income. As such, the impact to our net results of operations from changes in foreign currency exchange rates has been largely mitigated.

For the years ended December 31, 2006 and 2005, operating income was as follows (amounts in millions):

	2006	Change	2005
Operating Income	\$ 3,840	(21)%	\$ 4,848

Operating income as a percentage of product sales was 28% for 2006 and 40% for 2005. The decline in operating income as a percentage of product sales for the year ended 2006 compared to the year ended 2005 primarily reflects the impact of the acquired IPR&D charges related to the Abgenix and Avidia acquisitions in 2006, the increase in R&D expenses to expand our R&D activities as discussed below, higher selling, general and administrative ( SG&A ) expenses to support our growing organization and the expensing of stock options, which commenced January 1, 2006.

We focus our R&D on novel human therapeutics for the treatment of grievous illness. (See Item 1. Business Research and Development and Selected Product Candidates for further information on our R&D vision and product pipeline.) We have substantially expanded our R&D capabilities and plan to continue increasing our investments to expand these capabilities to manage and execute increasingly larger and more complex clinical trials and to build the capacity to advance more compounds into and through the clinic. We began nine mega-site trials (involving 200 or more sites) in 2006 to support denosumab and our other late-stage programs. For 2007, we expect R&D expense to increase, although not to the extent experienced in 2006, due to the continuance of the mega-site trials previously started, including the nine started in 2006, beginning additional studies in 2007 in support of our late-stage programs, including studies for panitumumab and motesanib diphosphate, and advancing a number of additional molecules into phase 2. The nine mega-site trials, which we began in 2006, will continue to require significant time, resources and expense to execute. (See Item 1A. Risk Factors Before we commercialize and sell any of our product candidates, 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. ) To execute our clinical trial programs, we need to continue the growth of our development organization and associated R&D support organizations, implement new management structures and approaches and continue to partner with third-party contract clinical trial providers. Further, to increase the number of patients available for enrollment for our clinical trials, we partnered with third-party contract clinical trial providers to open clinical sites and are enrolling patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, Mexico and some South American countries. In 2007, we plan to expand into Southeast Asia and India.

On April 1, 2006, we paid shareholders of Abgenix \$22.50 in cash per common share for a total value of approximately \$2.1 billion to acquire all of the outstanding shares and assumed Abgenix's outstanding debt with a fair value of approximately \$686 million. Abgenix was a company with expertise in the discovery and development of monoclonal antibodies and was our co-development partner for Vectibix. The results of Abgenix's operations have been included in our consolidated financial statements commencing April 1, 2006.

On October 24, 2006, we completed our acquisition of Avidia. Pursuant to the merger agreement, we paid in cash 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. Avidia focused on the discovery and development of a new class of human therapeutic known as Avimer proteins. The transaction provides Amgen with Avidia's lead product candidate, an inhibitor of interleukin 6 (IL-6) for the treatment of inflammation and autoimmune diseases, which is in phase 1 clinical trials. The results of Avidia's operations have been included in our consolidated financial statements commencing October 25, 2006.

In December 2006, we entered into a collaboration agreement with Cytokinetics Incorporated ( Cytokinetics ) to discover, develop and commercialize novel small-molecule therapeutics that activate cardiac

## Table of Contents

muscle contractility for potential application in the treatment of heart failure. In addition, we obtained an option to participate in future developments and commercialization of Cytokinetics' lead drug candidate arising from this program, CK-1827452, which recently entered two phase 1 clinical trials. The collaboration is worldwide, excluding Japan.

There are many economic and industry-wide factors that affect our business generally and uniquely, 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; increasingly intense competition for marketed products and product candidates; broad reimbursement changes; 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.)

In addition to these economic and industry-wide factors, we, as a company, face certain additional challenges and have a number of opportunities as well. Our principal products have established leadership positions attaining significant sales levels over the last few years and have experienced strong year-over-year sales growth. However, the rate of growth has declined in each of the past several years and, in the near term, we expect this trend to continue. We believe that future sales growth for certain of our principal products should benefit from segment growth, including increased penetration through new areas of treatment and/or greater awareness. At the same time in 2007, however, they will be subject to increasing competition, which includes the expected introduction of biosimilars in Europe. In addition, future sales growth may be impacted by healthcare provider prescribing behavior or use of our products, or regulatory or private healthcare organization medical guidelines and reimbursement of our products. Also, with the promise of our growing pipeline comes the challenge of delivering on the pipeline, including executing on large and complex clinical trials. To execute on these clinical trial programs we will need to increase the growth of our R&D organization, open clinical sites and enroll patients in new geographic locations and continue reliance on third-party contractors. Further, the growth of our clinical and commercial operations will require increased manufacturing capacity, which is a lengthy and costly process.

In the near term, our 2007 objectives to assist in meeting these challenges and to be successful in taking advantage of our opportunities are to: i) balance short term financial performance with increased R&D investment to allow us to execute key clinical trials for our late-stage product candidates and advance a number of additional molecules further along the development process; ii) grow our markets and hold or increase share; iii) vigorously defend our intellectual property and increase our leadership in anemia management; and iv) proactively expand production capacity as we grow.

## Results of Operations

### Product sales

For the years ended December 31, 2006, 2005 and 2004, worldwide product sales and total product sales by geographic region were as follows (amounts in millions):

	2006	Change	2005	Change	2004
Aranesp®	\$ 4,121	26%	\$ 3,273	32%	\$ 2,473
Neulasta®/NEUPOGEN®	3,923	12%	3,504	20%	2,915
EPOGEN®	2,511	2%	2,455	(6)%	2,601
ENBREL	2,879	12%	2,573	35%	1,900
Sensipar®	321	104%	157	324%	37
Vectibix	39	n/a		n/a	
Other	64	7%	60	18%	51
Total product sales	\$ 13,858	15%	\$ 12,022	20%	\$ 9,977
Total U.S.	\$ 11,397	15%	\$ 9,892	19%	\$ 8,279
Total International	2,461	16%	2,130	25%	1,698
Total product sales	\$ 13,858	15%	\$ 12,022	20%	\$ 9,977

## Table of Contents

Product sales are influenced by a number of factors, including demand, third-party reimbursement availability and policies, regulatory developments, clinical trial outcomes, clinical practice, pricing strategies, wholesaler and end-user inventory management practices, fluctuations in foreign exchange rates, new product launches and indications, competitive products, product supply and acquisitions. (See Item 1. Business Principal Products for a discussion of our principal products and their approved indications.)

Sales growth in 2006 and 2005 was principally driven by demand for Aranesp®, Neulasta® and ENBREL, which benefited from share gains and/or market growth. International product sales growth in 2005 benefited by \$46 million from foreign currency exchange rate changes.

We expect Aranesp®, Neulasta® and ENBREL to continue to drive year-over-year sales growth in 2007 and that Vectibix will also contribute to that growth. However, we expect that maintaining or increasing share will be more of a challenge than in previous years as we experienced share loss with ENBREL in 2006 compared to 2005 and we operate in an increasingly competitive environment. Going forward, we will focus on growing our segments, including increasing our penetration in the therapeutic areas in which our products are used, while also continuing to focus on maintaining or increasing share.

We believe that our product sales for 2005 and 2006 were not significantly impacted by the reimbursement changes resulting from the MMA implemented in 2005. We believe this was, in part, due to the effects of CMS' 2005 and 2006 oncology demonstration projects on sales of our products used in supportive cancer care, especially Aranesp®. However, we believe it is unlikely that CMS will implement an oncology demonstration project for 2007. Furthermore, we believe that our sales for 2005 and 2006 were not significantly impacted, in part, due to increased reimbursement rates to physicians from CMS for services associated with drug administration. The 2006 Medicare Physician Fee Schedule Payment Final Rule reduced payments for physician services in 2006 by approximately 4.4% on average, although subsequent legislation eliminated this reduction for 2006. The Medicare Physician Fee Schedule Payment Final Rule for 2007 would have reduced payments for physician services in 2007 by approximately 5.0% on average, however, as in 2006, new legislation eliminated the reduction in payments for 2007. Because we cannot accurately predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products, we cannot estimate the full impact of the MMA on our business, although we believe that it is not likely to be significant to our business in 2007. However, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales and related sales growth in the future. For additional information on reimbursement and its impact on our business, see Item 1. Business Reimbursement.

### Aranesp®

For the years ended December 31, 2006, 2005 and 2004, total Aranesp® sales by geographic region were as follows (amounts in millions):

	2006	Change	2005	Change	2004
Aranesp® U.S.	\$ 2,790	33%	\$ 2,104	37%	\$ 1,533
Aranesp® International	1,331	14%	1,169	24%	940
<b>Total Aranesp®</b>	<b>\$ 4,121</b>	<b>26%</b>	<b>\$ 3,273</b>	<b>32%</b>	<b>\$ 2,473</b>

The increase in U.S. Aranesp® sales for the year ended December 31, 2006 was primarily driven by demand reflecting segment growth and share gains. The growth in U.S. Aranesp® sales also reflects increased Aranesp® usage in U.S. hospital dialysis clinics from continued conversion from EPOGEN®, which we believe stabilized in mid-2006. The increase in international Aranesp® sales for the year ended December 31, 2006 was also principally driven by demand.

The increase in U.S. Aranesp® sales for the year ended December 31, 2005 was primarily driven by market growth and share gains. Sales growth for 2005 was slightly impacted by higher incentives earned by customers attaining higher sales volumes and growth under performance-based contracts. Although ASPs for U.S. Aranesp® trended downward during 2005, they began to stabilize during the fourth quarter of 2005. In 2005,

## Table of Contents

Aranesp® usage in U.S. hospital dialysis clinics increased, reflecting a conversion from EPOGEN®. International Aranesp® sales growth for 2005 was principally driven by demand, benefiting only slightly, \$20 million, from changes in foreign currency exchange rates.

For 2007, we believe that Aranesp® sales growth will be driven primarily by segment growth. Further, sales of Aranesp® have benefited, and may continue to benefit, by its use in U.S. hospital dialysis clinics to treat anemia associated with chronic renal failure instead of EPOGEN®, however, we believe this conversion stabilized as of mid-2006. In addition, we believe future worldwide Aranesp® sales growth may also be dependent, in part, on such factors as reimbursement by third-party payers (including governments and private insurance plans); cost containment pressures from governments and private insurers on healthcare providers; governmental or private organization regulations or guidelines relating to the use of our products; government programs; adverse events or results from clinical trials or studies performed by us or by others which may expand safety labeling and may negatively impact healthcare provider prescribing behavior, use of our product, regulatory or private healthcare organization medical guidelines and reimbursement practices; penetration of existing and new segments, including potential new indications; patient population growth; the effects of pricing strategies; an increasingly competitive environment of products or therapies, which in 2007 in the United States could potentially include competition in the nephrology segment from Roche's peg-EPO, which Roche has indicated they intend to bring to the U.S. market in 2007 despite our ongoing lawsuit and their acknowledgement of our U.S. erythropoietin patents (see Item 3. Legal Proceedings Roche Matters Amgen Inc. v. F. Hoffmann-La Roche Ltd., et al. ) and in the EU in 2007 could potentially include biosimilars, Shire's erythropoietin product, Roche's peg-EPO product and other competing products (see Item 1. Business Competition for further information on the impact of competition on our business); our ability to differentiate Aranesp® from current and potential future competition; and changes in foreign currency exchange rates (see Item 1A. Risk Factors Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products. ).

### Neulasta®/NEUPOGEN®

For the years ended December 31, 2006, 2005 and 2004, total Neulasta®/NEUPOGEN® sales by geographic region were as follows (amounts in millions):

	2006	Change	2005	Change	2004
Neulasta® U.S.	\$ 2,217	17%	\$ 1,900	29%	\$ 1,476
NEUPOGEN® U.S.	830	3%	805	3%	778
<b>U.S. Neulasta®/NEUPOGEN® Total</b>	<b>3,047</b>	<b>13%</b>	<b>2,705</b>	<b>20%</b>	<b>2,254</b>
Neulasta® International	493	27%	388	47%	264
NEUPOGEN® International	383	(7)%	411	4%	397
<b>International Neulasta®/NEUPOGEN® Total</b>	<b>876</b>	<b>10%</b>	<b>799</b>	<b>21%</b>	<b>661</b>
<b>Total Worldwide Neulasta®/NEUPOGEN®</b>	<b>\$ 3,923</b>	<b>12%</b>	<b>\$ 3,504</b>	<b>20%</b>	<b>\$ 2,915</b>

The increase in U.S. Neulasta®/NEUPOGEN® sales for the year ended December 31, 2006 was driven primarily by demand for Neulasta®, reflecting segment growth. In addition, the increase in demand for Neulasta® for the year ended December 31, 2006 also includes the impact of a 2 percent U.S. price increase in April 2006. U.S. demand for Neulasta® continued to benefit from a product label extension based on clinical data demonstrating the value of first cycle utilization in moderate-high risk chemotherapy regimens. The increase in international Neulasta®/NEUPOGEN® sales for the year ended December 31, 2006 was driven primarily by demand for Neulasta®.

The increase in U.S. Neulasta®/NEUPOGEN® sales for the year ended December 31, 2005 was driven primarily by demand for Neulasta®, which benefited from guidelines recommending earlier use. U.S. Neulasta®/NEUPOGEN® sales, Neulasta® in particular, also benefited from a label extension based on clinical data demonstrating the value of first cycle use in moderate risk chemotherapy regimens. In addition, U.S. sales growth was

**Table of Contents**

slightly impacted by higher incentives earned by customers attaining higher sales volumes and growth under performance-based contracts. Although ASPs for U.S. Neulasta® trended downward during 2005, they began to stabilize during the fourth quarter of 2005. The increase in international Neulasta®/NEUPOGEN® sales for the year ended December 31, 2005, was driven primarily by demand for Neulasta®. International Neulasta®/NEUPOGEN® sales for 2005 also benefited by \$18 million from foreign currency exchange rate changes.

We believe that 2007 sales growth for Neulasta®/NEUPOGEN® will depend on further segment penetration of Neulasta® in the moderate-risk population that would benefit from its earlier use and by focusing on the value of its treatment in first and subsequent chemotherapy cycles. In addition, future worldwide Neulasta®/NEUPOGEN® sales growth will be dependent, in part, on such factors as reimbursement by third-party payers (including governments and private insurance plans); cost containment pressures from governments and private insurers on healthcare providers; adverse events or results from clinical trials or studies performed by us or by others which may expand 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 products; government programs (see Item 1A. Risk Factors Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products. ); penetration of existing segments; patient population growth; the effects of pricing strategies; competitive products or therapies, including biosimilar products that may be approved in 2007 in the EU and be available shortly thereafter; changes in foreign currency exchange rates and the development of new treatments for cancer. Future chemotherapy treatments that are less myelosuppressive may require less Neulasta®/NEUPOGEN®, however, other future chemotherapy treatments that are more myelosuppressive, such as dose dense chemotherapy, could require more Neulasta®/NEUPOGEN®. 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 most of the conversion in the United States and in Europe has occurred.

**EPOGEN®**

For the years ended December 31, 2006, 2005 and 2004, total EPOGEN® sales were as follows (amounts in millions):

	2006	Change	2005	Change	2004
EPOGEN® U.S.	\$ 2,511	2%	\$ 2,455	(6)%	\$ 2,601

Reported EPOGEN® sales for the year ended December 31, 2006 increased modestly primarily due to the increased demand in the free-standing dialysis centers partially offset by the increased use of Aranesp® in the hospital setting. We believe that conversion to Aranesp® in the hospital setting stabilized in mid-2006. We believe demand for EPOGEN® in the free-standing dialysis centers, which account for the majority of the EPOGEN® sales, remained consistent with patient population growth at approximately 3 to 4 percent.

EPOGEN® sales for the year ended December 31, 2005 decreased primarily due to lower demand, unfavorable changes in wholesaler inventory levels and an unfavorable revised estimate of dialysis demand, primarily spillover, for prior quarters. Demand for 2005 was affected by conversion to Aranesp® in the U.S. hospital dialysis clinics, which represented approximately 10% of the EPOGEN® business, and reflected higher sales incentives. Demand for EPOGEN® in the free-standing dialysis clinics remained consistent with patient population growth at approximately 3 to 4 percent. Spillover is a result of our contractual relationship with Johnson & Johnson (see Summary of Critical Accounting Policies EPOGEN® revenue recognition below and Note 1, Summary of significant accounting policies Product sales to the Consolidated Financial Statements).

EPOGEN® sales in 2007 may be negatively impacted by certain external developments such as the possibility of competition from Roche's peg-EPO, which Roche has indicated they intend to bring to the U.S. market in 2007 despite our ongoing lawsuit and their acknowledgement of our U.S. erythropoietin patents (see Item 3. Legal Proceedings Roche Matters Amgen Inc. v. F. Hoffmann-La Roche Ltd., et al. ) (see Item 1. Business Competition for further information on the impact of competition on our business) as well as adverse events or results from clinical trials or studies performed by us or by others which may expand safety labeling

**Table of Contents**

and may negatively impact healthcare provider prescribing behavior, use of our product, regulatory or private healthcare organization medical guidelines and reimbursement practices. Sales for EPOGEN® in 2007 could, however, be favorably impacted to a certain degree by underlying demand in the free-standing dialysis centers, which we believe will remain consistent with the annual patient population growth of 3 to 4 percent, and the lessened impact of conversion to Aranesp® in the U.S. hospital dialysis clinics, which we believe stabilized in mid-2006. Dialysis patients receiving treatment for anemia associated with end stage renal disease with EPOGEN® are covered primarily under medical programs provided by the federal government. Therefore, going forward, we believe EPOGEN® sales growth will further depend on changes in reimbursement rates or a change in the basis for reimbursement by the federal government. We believe EPOGEN® sales growth will also be dependent, in part, on future governmental or private organization regulations or guidelines relating to the use of our products, cost containment pressures from the federal government on healthcare providers and the effects of pricing strategies (see Item 1A. Risk Factors). Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products. ).

**ENBREL**

For the years ended December 31, 2006, 2005 and 2004, total ENBREL sales by geographic region were as follows (amounts in millions):

		2006	Change	2005	Change	2004
ENBREL	U.S.	\$ 2,736	11%	\$ 2,470	35%	\$ 1,827
ENBREL	International	143	39%	103	41%	73
Total ENBREL		\$ 2,879	12%	\$ 2,573	35%	\$ 1,900

ENBREL sales growth for the year ended December 31, 2006 was driven by increased demand in both the rheumatology and dermatology segments. The increase in demand for the year ended December 31, 2006 also includes the impact of a 4.9 percent U.S. price increase that went into effect May 1, 2006. While ENBREL continued to maintain a leading position in both rheumatology and dermatology, we have experienced moderate share loss in both segments in 2006 compared to 2005. ENBREL sales growth was also affected in 2006 by slowing segment growth in dermatology and by increased competitive activities in both segments.

ENBREL sales growth for the year ended December 31, 2005 was driven by demand, reflecting strong growth in both rheumatology and dermatology. ENBREL sales growth benefited from its competitive profile and significant growth of biologics in both the rheumatology and dermatology segments.

Sales growth for ENBREL in 2007 will depend on growing both the rheumatology and dermatology segments. In addition, future ENBREL sales growth will be dependent on such factors as the effects of competing products or therapies and, in part, our ability to differentiate ENBREL based on safety and efficacy; segment growth; the availability, extent and access to reimbursement by government and third-party payers; cost containment pressures from governments and private insurers on healthcare providers; adverse events or results from clinical trials or studies performed by us or by others which may expand 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 products; and the effects of pricing strategies (see Item 1A. Risk Factors). Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products. ).



**Table of Contents***Selected operating expenses*

The following table summarizes selected operating expenses for the years ended December 31, 2006, 2005 and 2004 (amounts in millions):

	2006	Change	2005	Change	2004
Product sales	\$ 13,858	15%	\$ 12,022	20%	\$ 9,977
Operating expenses:					
Cost of sales (excludes amortization of acquired intangible assets)	\$ 2,095	1%	\$ 2,082	20%	\$ 1,731
% of product sales	15%		17%		17%
Research and development	\$ 3,366	45%	\$ 2,314	14%	\$ 2,028
% of product sales	24%		19%		20%
Selling, general and administrative	\$ 3,366	21%	\$ 2,790	9%	\$ 2,556
% of product sales	24%		23%		26%
Write-off of acquired in-process research and development	\$ 1,231		\$		\$ 554
Amortization of acquired intangible assets	\$ 370		\$ 347		\$ 333
Cost of sales					

Cost of sales, which excludes the amortization of acquired intangible assets (see Consolidated Statements of Operations ), increased 1% for the year ended December 31, 2006. Cost of sales grew much slower than revenue for the year ended December 31, 2006 due primarily to lower royalties as well as a more favorable product mix and cost efficiencies at our factories. Royalty expenses were lower due to the expiration of certain contractual royalty obligations on Neulasta® and NEUPOGEN® sales and the acquisition of certain royalty rights on sales of ENBREL and EU Neulasta® and NEUPOGEN® sales.

Cost of sales increased 20% for the year ended December 31, 2005, primarily due to higher sales volumes. Costs of sales for 2005 were also impacted by the \$47 million write-off of a semi-completed manufacturing asset that was determined to be unusable due to a change in manufacturing strategy.

*Research and development*

R&D expenses are primarily comprised of costs and expenses for salaries and benefits associated with R&D personnel, overhead and occupancy, clinical trial and related clinical manufacturing, including contract services and other outside costs, process development, quality assurance, information systems and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include such costs related to activities performed on behalf of corporate partners. R&D expenses increased 45% for the year ended December 31, 2006, primarily due to higher staff levels and increased funding necessary to support clinical trials for our late-stage programs, which include denosumab, our late-stage investigational product for osteoporosis and metastatic bone cancer, and the continued expansion of our research and pre-clinical organization to build the capacity to advance more compounds into and through the clinic. We began nine mega-site trials (involving 200 or more sites) in 2006 to support denosumab and our other late-stage programs. In addition, R&D for the year ended December 31, 2006, includes approximately \$104 million in stock option expense, which was not reflected in our Consolidated Results of Operations prior to January 1, 2006 (see Recent accounting pronouncements below) and approximately \$48 million in non-cash amortization expense for the intangible asset, XenoMouse® technology, acquired in the Abgenix acquisition. In 2006, staff-related costs, including stock option compensation, and clinical trial and clinical manufacturing costs increased approximately \$467 million and \$355 million, respectively.

In 2005, R&D expenses increased 14% over the prior year, primarily driven by higher staff-related costs, which included the full year integration of the Tularik operations and the buildup of our R&D organization to support the growth in our pipeline. The 2005 growth also reflected higher costs relating to key clinical trials and clinical manufacturing, including the continued ramp up of large-scale phase 3 trials for denosumab, Amgen's investigational therapy for bone loss. In 2005, staff-related costs and clinical manufacturing and clinical trial costs increased approximately \$171 million and \$118 million, respectively.



## **Table of Contents**

### *Selling, general and administrative*

SG&A expenses are primarily comprised of salaries and benefits associated with sales and marketing, finance, legal and other administrative personnel; outside marketing expenses; overhead and occupancy costs; other legal costs; and other general and administrative costs. SG&A increased 21% for the year ended December 31, 2006, reflecting higher staff levels and additional infrastructure costs to support the growing organization, in particular our Global Enterprise Resource Planning ( ERP ) system, higher Wyeth profit share expenses related to ENBREL sales and higher legal costs associated with ongoing litigation. In addition, SG&A costs for the year ended December 31, 2006 included approximately \$120 million in stock option expense, which was not reflected in our Consolidated Results of Operations prior to January 1, 2006 (see Recent accounting pronouncements below). In 2006, staff-related costs, including stock option compensation, and additional infrastructure costs increased over 2005 by \$323 million and \$59 million, respectively. In addition, we incurred \$38 million for the above-noted higher outside legal costs and \$198 million in increased outside marketing expenses in support of our principal products, including the Wyeth profit share related to ENBREL in 2006 as compared to 2005. Outside marketing expenses include the Wyeth profit share related to ENBREL, which has increased due to ENBREL sales growth.

In 2005, SG&A increased 9% for the year ended December 31, 2005, primarily due to higher outside marketing expenses in support of our principal products. Outside marketing expenses include the Wyeth profit share related to ENBREL, which has increased due to ENBREL sales growth. During 2005, outside marketing expenses and staff-related costs increased approximately \$241 million and \$42 million, respectively.

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

The fair value of acquired IPR&D projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are immediately expensed. In 2006, we incurred charges of \$1,101 million and \$130 million, associated with writing off the fair value of IPR&D acquired in the Abgenix and Avidia acquisitions, respectively (see Note 7, Acquisitions to the Consolidated Financial Statements). In 2004, we incurred a charge of \$554 million, associated with writing off the fair value of IPR&D acquired in the Tularik acquisition (see Note 7, Acquisitions to the Consolidated Financial Statements).

### *Amortization of acquired intangible assets*

Amortization of acquired intangible assets relates to the acquired products technology rights acquired in connection with the Immunex acquisition. In 2006, this amortization also included \$49 million related to the impairment of a non-ENBREL related intangible asset previously acquired in the Immunex acquisition.

### *Other items, net*

In 2005, other items, net consisted of a \$49 million charge, net of amounts previously accrued, for settling certain legal matters associated with a patent legal proceeding. (See Note 12, Other to the Consolidated Financial Statements for further discussion.)

### *Income taxes*

Our effective tax rate was 26.6%, 24.5% and 30.4% for 2006, 2005 and 2004, respectively.

Our effective tax rate for 2006 increased primarily due to the write-off of acquired IPR&D costs in connection with the acquisitions of Abgenix and Avidia, which is not deductible for tax purposes. The increase in the rate was partially offset by an increase in the amount of foreign earnings intended to be invested indefinitely outside of the United States and favorable audit settlements. In addition, the 2005 tax rate was negatively impacted by the tax on the repatriation of foreign earnings in 2005 under the American Jobs Creation Act of 2004. 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 the United States.

## Table of Contents

The 2005 effective tax rate was lower than the 2004 effective tax rate due to the favorable resolution of prior year foreign tax credit claims and R&D tax credits with the Internal Revenue Service ( IRS ), and the absence of the write-off of non-deductible IPR&D costs in connection with the acquisition of Tularik in 2004. This decrease was partially offset by the tax on the repatriation of foreign earnings in 2005 under the American Jobs Creation Act. In the fourth quarter of 2005, we repatriated \$500 million of foreign earnings, which was the maximum amount of foreign earnings qualifying for the reduced tax rate. The tax expense incurred on the repatriation was approximately \$43 million.

(See Note 4, *Income taxes* to the Consolidated Financial Statements for further discussion.)

### *Recent accounting pronouncements*

On January 1, 2006 we adopted Statement of Financial Accounting Standards ( SFAS ) No. 123(R), *Share-Based Payment*. SFAS No. 123(R) requires us to account for our stock options using a fair-value-based method as described in such statement and recognize the resulting compensation expense in our financial statements. Prior to January 1, 2006, we accounted for our employee stock options using the intrinsic value method under APB No. 25, *Accounting for Stock Issued to Employees* and related interpretations, as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*, which generally did not result in any employee stock option expense. We adopted SFAS No. 123(R) using the modified-prospective-transition method. Under this transition method, compensation expense recognized subsequent to adoption includes (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the values estimated in accordance with the original provisions of SFAS No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair values estimated in accordance with the provisions of SFAS No. 123(R). The modified-prospective-transition method did not require recognition of related compensation expense in our financial statements for prior periods. Comparability, therefore, of the current period financial statements to prior periods has been and will be impacted.

The adoption of SFAS No. 123(R) had a material impact on our results of operations for 2006. The annual stock option expense is dependent on a number of factors including the number of stock options granted, our common stock price and related expected volatility and other inputs utilized in estimating the fair value of the stock options at the time of grant. As a result of recognizing compensation expense for stock options pursuant to the provisions of SFAS No. 123(R), our income before income taxes for the year ended December 31, 2006, was \$233 million lower, and our net income was \$152 million lower than if we had continued to account for stock options under APB No. 25. In addition, both basic and diluted earnings per share for the year ended December 31, 2006 were \$0.14 lower, than if we had continued to account for stock options under APB No. 25.

In June 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. ( FIN ) 48, *Accounting for Uncertainty in Income Taxes*, effective for fiscal years beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing rules for recognition, measurement, classification and disclosure in our financial statements of uncertain tax positions taken or expected to be taken in a tax return. Based on our evaluations, we currently believe that the only impact to us of adopting this new standard is to reclassify certain liabilities for uncertain tax positions from current to non-current liabilities in our accompanying Consolidated Balance Sheet. We adopted this new standard effective January 1, 2007.

### **Financial Condition, Liquidity and Capital Resources**

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

	December 31,	
	2006	2005
Cash, cash equivalents, and marketable securities	\$ 6,277	\$ 5,255
Total assets	33,788	29,297
Current debt	1,878	
Non-current debt	7,134	3,957
Stockholders' equity	18,964	20,451

## **Table of Contents**

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our working capital, capital expenditure and debt service requirements for the foreseeable future, as well as to support our stock repurchase programs and other business initiatives, including acquisitions and licensing activities. However, in order to provide for greater financial flexibility and liquidity, we are currently reviewing additional borrowing opportunities. We would expect to use any proceeds raised by such borrowing primarily for purchases of shares under our stock repurchase program and for general corporate purposes, including satisfying our obligation to repay borrowings under our 2032 Modified Convertible Notes if the note holders elect to put the notes to us for payment on March 1, 2007, capital expenditures and other working capital needs.

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

Of the total cash, cash equivalents and marketable securities at December 31, 2006, approximately \$4.2 billion was generated from operations in foreign tax jurisdictions and is intended for use outside the United States. If these funds are repatriated for use in our U.S. operations, substantial additional taxes on certain of these amounts would be required to be paid. In the fourth quarter of 2005, we repatriated \$500 million of foreign earnings, which was the maximum amount of foreign earnings qualifying for the reduced tax rate under the American Jobs Act. The repatriation of these funds resulted in an increase in our 2005 tax provision of \$43 million.

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

### *Financing arrangements*

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) in a private placement. 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 the 2013 Convertible Notes may be convertible 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 the 2013 Convertible Notes may only be converted 1) during any calendar quarter beginning after June 30, 2006 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, 2) if we make specified distributions to holders of our common stock or specified corporate transactions occur or 3) one month prior to the respective maturity date. Upon conversion, a holder would receive 1) cash equal to the lesser of the principal amount of the note or the conversion value, as defined, and 2) 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 and unpaid interest, if any. Moody's and Standard & Poor's rate our outstanding convertible notes A2 and A+, respectively.

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 the 2013 Convertible Notes, we purchased convertible note hedges in private transactions. 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 pay to the holders of the 2011 Convertible Notes and the 2013 Convertible Notes upon conversion. These transactions will terminate 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 and 2013 Convertible Notes, the repurchase of common stock and the purchase of the convertible note hedges was \$439 million.

## **Table of Contents**

Also concurrent with the issuance of the 2011 Convertible Notes and the 2013 Convertible Notes, we sold warrants to acquire shares of our common stock at an exercise price of \$107.90 per share in a private placement. 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 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, 2006 we had zero coupon convertible notes due in 2032 with an accreted value of \$1.8 billion outstanding and having an aggregate face amount of \$2.36 billion and yield to maturity of 1.125%. The holders of these convertible notes may require us to purchase, for cash, all or a portion of their convertible notes on specified dates (the Put Option), at a price equal to the original issuance price plus the accrued original issue discount through the purchase date. The next available Put Option date is on March 1, 2007. Accordingly, the convertible notes were classified as current liabilities in the accompanying Consolidated Balance Sheet as of December 31, 2006. Moody's and Standard & Poor's rate our outstanding convertible notes A2 and A+, respectively.

As of December 31, 2006 we had \$2.0 billion of long-term notes outstanding. These long-term notes consisted of 1) \$1.0 billion of notes that bear interest at a fixed rate of 4.00% and mature in 2009 and 2) \$1.0 billion of notes that bear interest at a fixed rate of 4.85% and mature in 2014. Moody's and Standard & Poor's rate our outstanding long-term senior notes A2 and A+, respectively.

As of December 31, 2006, we had \$235 million of additional debt securities outstanding. These debt securities consisted of 1) \$100 million of debt securities that bear interest at a fixed rate of 6.5% and mature in 2007 under a \$500 million debt shelf registration statement (the \$500 Million Shelf), 2) \$100 million of long-term debt securities that bear interest at a fixed rate of 8.1% and mature in 2097 and 3) \$35 million in long-term notes due in 2013 with an effective rate of 5.35% assumed in the Abgenix acquisition. Our outstanding long-term debt is rated A2 by Moody's and A+ by Standard & Poor's. Under the \$500 Million Shelf, all of the remaining \$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.

We have a \$1.0 billion unsecured revolving credit facility to be used for general corporate purposes, including commercial paper support, which matures in November 2010. Additionally, we have a commercial paper program, which provides for unsecured, short-term borrowings of up to an aggregate of \$1.2 billion. No amounts were outstanding under the credit facility or commercial paper program as of December 31, 2006.

We have a \$1.0 billion shelf registration statement (the \$1 Billion Shelf) which allows us to issue debt securities, common stock and associated preferred share purchase rights, preferred stock, warrants to purchase debt securities, common stock or preferred stock, securities purchase contracts, securities purchase units and depository shares. The \$1 Billion Shelf was established to provide for further financial flexibility and the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. As of December 31, 2006, no securities had been issued under the \$1 Billion Shelf.

To protect against the potential increase in the fair value of our non-convertible, fixed interest rate notes due to a decline in interest rates, we entered into interest rate swap agreements that effectively convert the payment of our fixed rate notes to LIBOR-based variable interest payments over the life of the respective notes. These interest rate swap agreements qualify and are designated as fair value hedges. As of December 31, 2006 and 2005, \$2.2 billion and \$1.7 billion, respectively, aggregate face amount of our outstanding non-convertible, fixed interest rate debt was covered by these interest rate swap agreements.

Certain of our financing arrangements contain non-financial covenants and as of December 31, 2006, we were in compliance with all applicable covenants.

**Table of Contents***Cash flows*

The following table summarizes our cash flow activity for the years ended December 31, 2006, 2005 and 2004 (amounts in millions):

	2006	2005	2004
Net cash provided by operating activities	\$ 5,389	\$ 4,911	\$ 3,697
Net cash used in investing activities	(5,131)	(59)	(1,399)
Net cash used in financing activities	(815)	(4,538)	(1,609)

*Operating*

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. The increase in cash provided by operating activities during the year ended December 31, 2006 resulted primarily from higher cash receipts from customers driven by the growth in product sales and the timing of payments in the ordinary course of business (see Consolidated Statements of Cash Flows).

The increase in cash provided by operations for 2005 resulted primarily from higher cash receipts from customers driven by growth in product sales and timing differences of cash payments relating to our tax and other accrued liabilities (see Consolidated Statements of Cash Flows).

*Investing*

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.

Capital expenditures totaled \$1.2 billion in 2006 compared with \$867 million in 2005 and \$1.3 billion in 2004. Capital expenditures in 2006 were primarily associated with ongoing manufacturing capacity and site expansions in Ireland, Puerto Rico and other locations and costs associated with implementing our ERP system. Capital expenditures in 2005 primarily related to the Puerto Rico manufacturing expansion which included a new manufacturing plant for the commercial production of Neulasta® and NEUPOGEN® approved by the FDA in September 2005, Thousand Oaks site expansion, Colorado manufacturing expansion and site development to support the new ENBREL manufacturing plant in Rhode Island, also approved by the FDA in September 2005. Capital expenditures in 2004 primarily related to the Thousand Oaks site expansion, the new ENBREL manufacturing plant in Rhode Island and the Puerto Rico manufacturing expansion.

We currently estimate 2007 spending on capital projects and equipment to be in the range of \$1.9 to \$2.2 billion as we continue to increase our manufacturing and R&D operations globally and proceed with the implementation of our ERP system. The most significant of these expenditures are expected to be incurred with the further expansion of the Puerto Rico bulk manufacturing, formulation, fill and finish facilities, the start of construction of a new bulk manufacturing, formulation, fill and finish facility and other site infrastructure support in Ireland and the expansion of R&D operations in the United States. For additional information on our planned capital projects, see Item 1. Business Manufacturing and Raw Materials.

*Financing*

In December 2006, the Board authorized us to repurchase up to an additional \$5.0 billion of common stock. As of December 31, 2006, we had \$6.5 billion available for stock repurchases under this and the previously authorized stock repurchase programs. 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 and blackout periods in which we are restricted from repurchasing shares, and may include private block purchases as well as market transactions.

**Table of Contents**

Repurchases under our stock repurchase program reflect, in part, our confidence in the long-term value of Amgen common stock. Additionally, we believe that it is an effective way of returning cash to our stockholders. A summary of our repurchase activity under our stock repurchase programs for the years ended December 31, 2006, 2005 and 2004 is as follows (amounts in millions):

	2006		2005		2004	
	Shares	Dollars	Shares	Dollars	Shares	Dollars
First quarter	46.6	\$ 3,374	26.8	\$ 1,675	10.1	\$ 650
Second quarter	13.0	876	12.1	750	17.4	1,000
Third quarter	7.3	505	9.5	769	24.0	1,398
Fourth quarter	3.3	245	14.8	1,236	17.6	1,024
<b>Total</b>	<b>70.2</b>	<b>\$ 5,000</b>	<b>63.2</b>	<b>\$ 4,430</b>	<b>69.1</b>	<b>\$ 4,072</b>

(See Item 5(c). Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities for additional information regarding our stock repurchase programs.)

In February 2006, we issued \$5.0 billion 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. For further information on these transactions, see Financing arrangements above.

On March 2, 2005, as a result of certain holders of the zero coupon convertible notes due in 2032 exercising their March 1, 2005 Put Option, we repurchased \$1.59 billion aggregate principal amount or approximately 40% of the then outstanding convertible notes at their then-accreted value for \$1,175 million in cash.

We receive cash from the exercise of employee stock options and proceeds from the sale of stock pursuant to the employee stock purchase plan. Employee stock option exercises and proceeds from the sale of stock by us pursuant to the employee stock purchase plans provided \$528 million, \$1.1 billion and \$453 million of cash during the years ended December 31, 2006, 2005 and 2004 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.

In November 2004, we issued \$1.0 billion aggregate principal amount of 4.00% senior notes due 2009 and \$1.0 billion aggregate principal amount of 4.85% senior notes due 2014. The net proceeds totaled \$1,989 million and were intended for purchases of stock under the stock repurchase program then in affect and for general corporate purposes, including capital expenditures and working capital.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements that are currently material or reasonably likely to be material to our financial position or 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. Accordingly, the table below excludes contractual obligations relating to milestone and royalty payments due to third parties, all of which are contingent upon certain future events. Such events could include, but are not limited to, development



**Table of Contents**

milestones, regulatory approvals and product sales. 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 chart represents our contractual obligations as of December 31, 2006, aggregated by type (amounts in millions):

Contractual obligations	Total	Payments due by period			
		Less than 1 year	1-3 years	4-5 years	More than 5 years
Long-term debt obligations(1)	\$ 10,328	\$ 1,997(2)	\$ 1,215	\$ 2,635	\$ 4,481
Operating lease obligations	1,230	96	197	185	752
Purchase obligations(3)	3,724	1,911	1,209	435	169
Total contractual obligations	\$ 15,282	\$ 4,004	\$ 2,621	\$ 3,255	\$ 5,402

- (1) The long-term obligation amounts in the above table differ from the related carrying amounts on the Consolidated Balance Sheet as of December 31, 2006 due to the accretion of the original issue discount on the 2032 Convertible Notes and 2032 Modified Convertible Notes and the inclusion of future interest payments. Future interest payments are included on the 2007 Notes, the 2009 Notes, the 2011 Convertible Notes, the 2013 Convertible Notes, the 2014 Notes and the Century Notes at fixed rates of 6.5%, 4.00%, 0.125%, 0.375%, 4.85% and 8.1%, respectively, through maturity in 2007, 2009, 2011, 2013, 2014 and 2097, respectively.
- (2) Holders of the 2032 Modified Convertible Notes may require us to purchase all or a portion of the notes on specific dates the next of which is March 1, 2007 at the original issuance price plus accrued original issue discount ( accreted value ) through the purchase dates. Consequently, the amounts above reflect the 2032 Modified Convertible Notes accreted value on March 1, 2007, the next put date. (See Note 5, Financing arrangements to the Consolidated Financial Statements for further discussion of the terms of the convertible notes.)
- (3) Purchase obligations primarily relate to (1) 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; (2) R&D commitments (including those related to clinical trials) for new and existing products; (3) capital expenditures for further expansion of the Puerto Rico bulk manufacturing, formulation, fill and finish facilities, the start of construction of a new bulk manufacturing, formulation, fill and finish facility and other site infrastructure support in Ireland, the expansion of R&D operations in the United States; and (4) open purchase orders for the acquisition of goods and services in the ordinary course of business. Our obligation to pay certain of these amounts may be reduced based on certain future events.

**Summary of Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the 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.



## Table of Contents

### *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. For additional discussion regarding revenue recognition, see EPOGEN® revenue recognition below.

In the United States, we utilize wholesalers as the principal means of distributing our products to healthcare providers such as clinics, 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 reasonable 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, 2006, 2005 and 2004, reductions in product sales relating to sales incentives are comprised of the following (amounts in millions):

	2006	2005	2004
Rebates	\$ 2,164	\$ 1,344	\$ 1,033
Wholesaler chargebacks	1,636	1,559	1,069
Discounts and other incentives	653	891	490
 Total sales incentives	 \$ 4,453	 \$ 3,794	 \$ 2,592
 Percent of gross product sales	 24%	 24%	 20%

Rebates earned by healthcare providers such as clinics, hospitals and pharmacies in the United States are the sales incentives that are most difficult to estimate. These rebates are performance-based offers that are primarily based on attaining contractually-specified sales volumes and growth. 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 \$2,164 million in 2006, \$1,344 million in 2005 and \$1,033 million in 2004. 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 1.5% 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 1.5% change in our rebate estimate attributable to rebates recognized in 2006 would have had an impact of approximately \$32 million on our 2006 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 list 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 \$1,636 million in 2006, \$1,559 million in 2005 and \$1,069 million in 2004. 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.

**Table of Contents**

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 (amounts in millions):

	Balance at Beginning of Period	Amounts Charged Against Product Sales*	Payments	Balance at End of Period
Year ended:				
December 31, 2006	\$ 864	\$ 4,453	\$ 4,238	\$ 1,079
December 31, 2005	\$ 589	\$ 3,794	\$ 3,519	\$ 864

\* Includes immaterial amounts related to prior year product sales based on changes in estimates. Such amounts represented approximately 1% of incentive amounts charged against product sales for both 2006 and 2005.

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 returns have been insignificant, amounting to approximately 1% of gross product sales.

*EPOGEN® revenue recognition*

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 Johnson & Johnson 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 Johnson & Johnson and do recognize the product sales made by Johnson & Johnson into our exclusive market.

The amount of EPOGEN® product sales we recognize each period consists of: (i) the amount of EPOGEN® we ship to our customers who are wholesale distributors of pharmaceutical products and (ii) adjustments for spillover, as described below. Sales to our customers are evidenced by binding written agreements and purchase orders, and accordingly, the amounts are fixed and determinable. The calculated spillover amount has no impact on the amounts owed to us by our customers.

We are employing an arbitrated audit methodology to measure each party's spillover based on independent third-party data on shipments to end users and their estimated usage. Data on end user usage is derived in part using market sampling techniques, and accordingly, the results of such sampling can produce variability in the amount of recognized spillover. We initially recognize spillover based on estimates of shipments to end users and their usage, utilizing historical third-party data and subsequently adjust such amounts based on revised third-party data as received. Differences between initial estimates of spillover and amounts based on revised third-party data could produce materially different amounts for recognized EPOGEN® sales. However, such differences to date have not been material.

*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 which could materially impact our future effective tax rate.

## **Table of Contents**

The American Jobs Creation Act was enacted on October 22, 2004. One provision of the American Jobs Creation Act effectively reduced the tax rate on a qualifying repatriation of earnings by providing for an 85% dividend-received deduction. In the fourth quarter of 2005, we repatriated \$500 million under the American Jobs Creation Act, which was the maximum amount of foreign earnings qualifying for the reduced rate. The tax expense incurred on this repatriation was approximately \$43 million. We intend to continue to indefinitely reinvest any undistributed earnings of foreign subsidiaries that were not repatriated under the American Jobs Creation Act.

### *Contingencies*

In the ordinary course of business, we are involved in various legal proceedings such as intellectual property disputes, contractual disputes, tax claims and governmental investigations. Certain of these proceedings are discussed in Item 3. Legal Proceedings. 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.

Our income tax returns are routinely audited by the 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. We periodically evaluate our exposures associated with tax filing positions. While we believe our positions comply with applicable laws, we record liabilities based upon estimates of the ultimate outcomes of these matters.

While it is not possible to accurately predict or determine the eventual outcome of these items, we do not believe any such items currently pending will have a material adverse effect on our consolidated financial position or liquidity, although an adverse resolution in any quarterly or annual reporting period of one or more of these items could have a material impact on the consolidated results of operations for that period.

### *Valuation of acquired intangible assets*

We have acquired and continue to acquire intangible assets primarily via the acquisition of 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. When significant identifiable intangible assets are acquired, an independent third-party valuation firm is engaged to assist in determining the fair values of these assets as of the acquisition date. Discounted cash flow 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.

## **Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to market risk that may result from changes in interest rates, foreign currency exchange rates and prices of equity instruments. To reduce certain of these risks, we enter into various types of derivative hedging transactions as part of our risk management program. We do not use derivatives for speculative purposes.



## **Table of Contents**

### *Interest rate sensitive financial instruments*

Our investment portfolio of available-for-sale debt securities, comprised primarily of corporate debt instruments and treasury securities, had a fair value of \$6.1 billion and \$5.0 billion at December 31, 2006 and 2005. The fair values of these securities and the income they generate is impacted by fluctuations in U.S. interest rates. A hypothetical change in interest rates of 10% relative to interest rates at December 31, 2006 and 2005 would not have a material effect on the fair values of these securities or our cash flows or income.

On December 31, 2006, we had outstanding debt with a fair value of \$8.9 billion (including debt with a fair value \$6.7 billion, which may be converted into our common stock in certain circumstances). On December 31, 2005, we had outstanding debt with a fair value of \$4.0 billion (including debt with a fair value of \$1.8 billion, which may be converted into our common stock). Changes in interest rates do not affect interest expense incurred on our outstanding debt because they bear interest at fixed rates. However, changes in interest rates would affect their fair values. To protect against possible increases in the fair value of our non-convertible debt, we entered into interest rate swap agreements, which qualify and are designated as fair value hedges. These agreements swapped the receipt of fixed interest payments for LIBOR-based variable interest payments over the lives of the respective notes. A hypothetical 10% increase in interest rates relative to interest rates at December 31, 2006 and 2005 would not have a material impact on the fair values of our outstanding debt and would not have a material impact on the fair values, cash flows or income with respect to the interest rate swap agreements.

### *Market price sensitive instruments*

As noted above, a portion of our outstanding debt may be converted into our common stock. Accordingly, the price of our common stock may affect the fair value of our convertible debt. A hypothetical 10% decrease in the price of Amgen stock from the price at December 31, 2006 and 2005 would have reduced the fair value of our then outstanding convertible debt by approximately \$274 million and \$71 million, respectively.

On December 31, 2006 and 2005, 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. Also, on December 31, 2005, we had equity forward contracts to hedge against changes in the fair market value of a portion of our equity investment portfolio. Price risk relative to our equity investment portfolio and equity forward contracts on December 31, 2006 and 2005 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. Both positive and negative impacts to our international product sales from movements in foreign exchange rates are partially mitigated by the natural, opposite impact that foreign exchange rates have on our international operating expenses. To further reduce our exposure to foreign exchange rate fluctuations in our results of operations, we enter into foreign currency forward exchange contracts and foreign currency option contracts. On December 31, 2006, we had outstanding forward exchange and options contracts with notional amounts of \$1,576 million and \$902 million, respectively, that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. These contracts had net unrealized losses totaling \$15 million on December 31, 2006. Also on December 31, 2006, we had outstanding forward exchange contracts with notional amounts totaling \$326 million 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, 2006. With regard to these contracts, a hypothetical 10% adverse movement in foreign exchange rates compared with the U.S. dollar relative to exchange rates on December 31, 2006 would result in a reduction in fair value, cash flows and income of \$186 million and \$33 million on contracts that have and have not been designated as hedges for accounting purposes, respectively.

On December 31, 2005, we had outstanding forward exchange and options contracts with notional amounts of \$1,023 million and \$167 million, respectively, that are designated for accounting purposes as cash flow hedges

## **Table of Contents**

of certain anticipated foreign currency transactions. These contracts had net unrealized gains totaling \$29 million on December 31, 2005. Also, on December 31, 2005, we had outstanding forward exchange contracts with notional amounts totaling \$162 million 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 on December 31, 2005. With regard to these contracts, a hypothetical 10% adverse movement in foreign exchange rates compared with the U.S. dollar relative to exchange rates on December 31, 2005 would result in a reduction in fair value, cash flows and income of \$106 million and \$16 million on contracts that have and have not been designated as hedges for accounting purposes, respectively.

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.

### **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, 2006.

Further, management determined that, as of December 31, 2006, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **Table of Contents**

### **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, 2006. 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, 2006, based on those criteria.

Management's assessment of 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 unqualified opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting as of December 31, 2006.

---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm  
on Internal Control over Financial Reporting**

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

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Amgen Inc. (the Company) maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company'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. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management's assessment that Amgen Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Amgen Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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, 2006 and 2005, and the related consolidated statements of income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2006 of Amgen Inc. and our report dated February 22, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Los Angeles, California

February 22, 2007



**Table of Contents**

**Item 9B. OTHER INFORMATION**

Not applicable.

**PART III**

**Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

Information about our Directors is incorporated by reference from the section entitled **ELECTION OF DIRECTORS** in our Proxy Statement for the 2007 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2006 (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, including members of the committee, and our Audit Committee financial experts is incorporated by reference from the section entitled **CORPORATE GOVERNANCE** Board Committees *Audit committee* in our Proxy Statement. Information about our executive officers is contained in the discussion entitled **Item 1. Business** Executive Officers of the Registrant.

**Code of Ethics**

We maintain a code of ethics applicable to our principal executive officer, principal financial officer, principal accounting officer or controller, and other persons performing similar functions. To view this code of ethics free of charge, please visit our website at [www.amgen.com](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 Section entitled **EXECUTIVE COMPENSATION** 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, 2006 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, 2006:

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	(b) Weighted Average Exercise Price Outstanding Options and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by Amgen security holders:			
Amended and Restated 1991 Equity Incentive Plan	17,964,266	\$ 47.78	30,722,145
Amended and Restated Employee Stock Purchase Plan		\$ (1)	9,354,551
<b>Total Approved Plans</b>	<b>17,964,266</b>	<b>\$ 47.78</b>	<b>40,076,696</b>
Equity compensation plans not approved by Amgen security holders:			
Amended and Restated 1993 Equity Incentive Plan(2)	2,347,092	\$ 31.27	
Amended and Restated 1999 Equity Incentive Plan(2)	14,839,189	\$ 64.76	
Amended and Restated 1997 Equity Incentive Plan(3)	2,448,004	\$ 46.68	15,628
Tularik Inc. 1991 Stock Plan(4)	928	\$ 6.66	
Amended and Restated 1997 Special Non-Officer Equity Incentive Plan	31,913,141	\$ 60.97	22,569
Amended and Restated 1996 Stock Incentive Plan(5)	512,202	\$ 63.73	
Amended and Restated 1999 Stock Incentive Plan(5)	2,019,577	\$ 59.09	680,600
Amended and Restated Assumed Avidia Equity Plan(6)	261,441	\$ 1.98	
<i>Foreign Affiliate Plans:</i>			
Amgen Limited Sharesave Plan		\$ (7)	372,839
The Amgen Limited 2000 UK Company Employee Share Option Plan(8)		\$	300,000
<b>Total Unapproved Plans</b>	<b>54,341,574</b>	<b>\$ 59.75</b>	<b>1,391,636</b>
<b>Total All Plans</b>	<b>72,305,840</b>	<b>\$ 56.77</b>	<b>41,468,332</b>

(1) The purchases occurred on June 30, 2006 and December 29, 2006 (the Purchase Dates) with a purchase of an aggregate 997,577 shares of Common Stock at a purchase price of \$55.45 per share on June 30, 2006 and 695,074 shares of Common Stock at a purchase price of \$55.92 per share on December 29, 2006. Such purchase prices reflect the lesser of 85% of either the closing price of the Common Stock on the applicable Purchase Date or the closing price of the Common Stock on the start date of the applicable employee's participation in the plan.

(2) These plans were assumed pursuant to the terms of the merger agreement between Amgen and Immunex Corporation which was approved by our stockholders in May 2002. Both plans were previously approved by Immunex Corporation'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.



## **Table of Contents**

- (3) This plan was assumed by Amgen in connection with the merger of Tularik Inc. with and into Amgen SF, LLC, a wholly owned subsidiary of Amgen, on August 13, 2004. This plan was previously approved by Tularik Inc.'s shareholders.
- (4) The Tularik Inc. 1991 Stock Plan (the "Tularik 1991 Plan") was terminated on March 14, 1997 by Tularik Inc. Although there are options still outstanding under the Tularik 1991 Plan, no shares are available for issuance under these plans for future grants.
- (5) These plans were assumed by Amgen in connection with the merger of Abgenix, Inc. 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, Inc.'s shareholders. The 1996 Plan terminated on July 16, 2006. Although there are options still outstanding under the 1996 Plan, 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 although there are options still outstanding under this plan, 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 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.

### **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, 2006 and were adopted or assumed by the Board 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 Corporation which was approved by the Company's stockholders in May 2002. The plan was previously approved by Immunex Corporation'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.

*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.

*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.



## **Table of Contents**

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, (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.

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 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 acceleration of the vesting of options if the optionee voluntarily retires at or after age 60 after having been an employee of Amgen or its affiliate for at least fifteen 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 vesting date for those 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 for those with five or more years, or to December 31 of the year following the year in which the termination occurs for those with less than five years, of employment or relationship with Amgen of such employee, director or consultant. In the case of Voluntary Retirement or death, Discretionary Options terminate the earlier of the termination date set forth in the applicable grant agreement or eighteen months, or in the case of disability the earlier of the termination date set forth in the applicable grant agreement or twelve months.

The Board 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 (1) a cash payment upon exercise, (2) by authorizing Amgen to withhold a portion of the stock otherwise issuable to the optionee, (3) by delivering already-owned stock of Amgen or (4) by a combination of these means.

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

## **Table of Contents**

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 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 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 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 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. 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; or (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; or (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 (a) exercised with respect to stock options or, if the surviving or acquiring corporation agrees to assume the Stock Awards or substitute similar awards, (b) assumed or (c) 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 may suspend or terminate the 1999 Plan without stockholder approval or ratification at any time or from time to time. No incentive stock options may be granted under

## **Table of Contents**

the 1999 Plan after February 22, 2009. 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.

### *Amgen Inc. Amended and Restated 1997 Equity Incentive Plan*

The Amgen Inc. Amended and Restated 1997 Equity Incentive Plan (formerly known as the Tularik Inc. 1997 Equity Incentive Plan, as amended) (the "Acquired 1997 Plan") was assumed by Amgen in connection with the merger of Tularik Inc. with and into Amgen SF, LLC, a wholly owned subsidiary of Amgen on August 13, 2004. The Acquired 1997 Plan was previously approved by Tularik Inc.'s shareholders. The Acquired 1997 Plan consists of two articles: Article I which governs awards granted prior to August 13, 2004 (the "Restatement Date") and Article II which governs awards granted on or after the Restatement Date. As the terms of options grants made pursuant to the Acquired 1997 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 1997 Plan. This description is qualified in its entirety by reference to the Acquired 1997 Plan itself, which was filed as an exhibit to the Company's Form S-8 dated August 16, 2004. Except as described below, the material provisions of Article II of the Acquired 1997 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 1997 Plan, as applicable):

The Acquired 1997 Plan will terminate on March 2, 2007;

Subject to adjustments upon certain changes in the common stock, the number of shares authorized for issuance under Article II of the Acquired 1997 Plan is 1,153,152;

No Stock Award may be granted to any person under Article II of the Acquired 1997 Plan who is an employee or director of or consultant to the Company or its affiliates (other than Tularik Inc.) on the Restatement Date;

Under Article II of the Acquired 1997 Plan, no person may receive Stock Awards for more than 451,000 shares of common stock in any calendar year;

Subject to adjustments upon certain changes in the common stock, under Article II of the Acquired 1997 Plan no more than 902,006 of the shares eligible for issuance under the plan in any calendar year may be issued upon exercise of Incentive Stock Options under the plan;

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 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 1997 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.

*Terms of Restricted Stock Units (RSUs).* The following is a description of the permissible terms of RSUs granted under the Acquired 1997 Plan after the Restatement Date. Individual grants of RSUs may be more restrictive as to any or all of the permissible terms described below.



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

RSUs granted under the Acquired 1997 Plan shall constitute stock bonuses and shall be in such form and contain such terms and conditions as the Board shall deem appropriate. RSUs vest in cumulative increments or vest fully after a specified holding period. RSUs granted from the Restatement Date under the Acquired 1997

## **Table of Contents**

Plan typically vest at the rate of 25% per year during the grantee's employment or service as a consultant. Absent death, disability or Voluntary Retirement, in certain circumstances, unvested RSUs shall automatically expire and terminate on the date of termination of employment. The Board also has the power to accelerate the vesting period for RSUs or suspend vesting during leaves of absences.

Upon a grantee's Voluntary Retirement, the RSUs scheduled to vest between and including the date of such retirement and December 31 of the second year following the year in which the retirement occurs shall accelerate to vest immediately. If the grantee terminates his or her employment or relationship as a consultant with Amgen or an affiliate due to death or disability and has been employed for less than five full years, the RSUs scheduled to vest between and including the date of such death or disability and December 31 in the first year following such termination, shall accelerate to vest immediately. If the grantee terminates his or her employment or relationship as a consultant with Amgen or an affiliate due to death or disability and has been employed for five or more years, the RSUs scheduled to vest between and including the date of such death or disability and December 31 in the second year following such termination, shall accelerate to vest immediately.

To the extent provided by the terms of the RSUs, the grantee may satisfy any federal, state or local tax withholding obligations by (1) authorizing Amgen to withhold a portion of the stock otherwise issuable to grantee, (2) deducting such obligations from compensation, (3) a cash payment upon vesting or (4) by a combination of these means.

### *Amended and Restated 1997 Special Non-Officer Equity Incentive Plan*

The Amended and Restated 1997 Special Non-Officer Equity Incentive Plan (the "1997 Plan") was adopted by the Company on December 8, 1997. This description is qualified in its entirety by reference to the 1997 Plan itself, which was filed as an exhibit to the Company's Form 10-Q for the quarter ended September 30, 2002. Except as described below, the material provisions of the 1997 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 1997 Plan, as applicable):

The 1997 Plan terminates on December 9, 2007;

Officers who are appointed by the Board are excluded from the 1997 Plan;

The 1997 Plan does not provide for non-discretionary grants to Directors of the Company;

Subject to adjustments upon certain changes in the common stock, the number of shares authorized for issuance under the 1997 Plan is 101,000,000; and

Under the 1997 Plan, no person may receive Stock Awards for more than 2,000,000 shares of common stock in any calendar year.

### *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, Inc. 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 options 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;

## **Table of Contents**

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, Inc.) 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 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, 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 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 1997 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.

**Table of Contents**

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

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

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

Information about certain relationships and transactions with related parties is incorporated by reference from the section entitled CERTAIN  
RELATIONSHIPS AND RELATED TRANSACTIONS in our Proxy Statement.

**Item 14. PRINCIPAL ACCOUNTANT 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, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K***(a)1. Index to Financial Statements*

The following Consolidated Financial Statements are included herein:

	<b>Page</b>
	<b>number</b>
<u>Report of Independent Registered Public Accounting Firm on the Financial Statements</u>	F-1
<u>Consolidated Statements of Operations for each of the three years in the period ended December 31, 2006</u>	F-2
<u>Consolidated Balance Sheets at December 31, 2006 and 2005</u>	F-3
<u>Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2006</u>	F-4
<u>Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2006</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6 - F-31

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

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

	<b>Page</b>
	<b>number</b>
<u>II. Valuation Accounts</u>	F-32

All other schedules are omitted because they are not applicable, or 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	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.)
4.1	Form of stock certificate for the common stock, par value \$.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 13, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992, between Amgen Inc. and Citibank N.A. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	6.50% Notes Due December 1, 2007. (Filed as an exhibit to Form 8-K filed on December 5, 1997 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997, between Amgen Inc. and Citibank, N.A. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	Officers' Certificate, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of February 26, 1997, each between Amgen Inc. and Citibank, N.A., establishing a series of securities entitled 6.50% Notes Due December 1, 2007 (Filed as an exhibit to Form 8-K filed on December 5, 1997 and incorporated herein by reference.)
4.6	8 <sup>1</sup> / <sub>8</sub> % Debentures due April 1, 2007. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)



## **Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
4.7	Officers' Certificate, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of February 26, 1997, each between Amgen Inc. and Citibank, N.A., 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, between Amgen Inc. and LaSalle Bank National Association. (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, between Amgen Inc. and LaSalle Bank National Association. (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, between Amgen Inc. and JPMorgan Chase Bank. (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	Registration Rights Agreement, dated as of November 18, 2004, among Amgen Inc. and Morgan Stanley & Co. Incorporated and Merrill Lynch, Pierce, Fenner & Smith Incorporated. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.16	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.)
4.17	Indenture, dated as of May 6, 2005, between Amgen Inc. and LaSalle Bank National Association. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
4.18	Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006, between Amgen Inc. and JPMorgan Chase Bank, N.A., as trustee (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.)
4.19	Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006 between Amgen Inc. and JPMorgan Chase Bank, N.A., as trustee (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.)
4.20	Registration Rights Agreement, dated as of February 17, 2006, among Amgen Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Morgan Stanley & Co. Incorporated, Citigroup Global Markets Inc., JPMorgan Securities Inc., Lehman Brothers Inc., Bear, Stearns & Co. Inc., Credit Suisse Securities (USA) LLC. (Filed as an exhibit to Form 8-K on February 21, 2006 and incorporated herein by reference.)
4.21	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.)



**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
4.22	The instruments defining the rights of holders of the long-term debt securities of Abgenix, Inc. and its subsidiaries are omitted pursuant to section (b)(4)(iii)(A) of Item 601 of Regulation S-K. Amgen Inc. hereby agrees to furnish copies of these instruments to the Securities and Exchange Commission upon request.
10.1+	Amended and Restated 1991 Equity Incentive Plan (As Amended and Restated December 5, 2005) and Forms of Stock Option Grant Agreements and Restricted Stock Unit Agreements. (Filed as exhibits to Form 8-K on December 8, 2005 and incorporated herein by reference.)
10.2+	Amgen Inc. Director Equity Incentive Program (As Amended and Restated December 6, 2005) and Forms of Stock Option Grant Agreements and Restricted Stock Unit Agreements. (Filed as exhibits to Form 8-K on December 8, 2005 and incorporated herein by reference.)
10.3+	Amgen Inc. Amended and Restated 1997 Equity Incentive Plan (As Amended and Restated December 5, 2005) and Forms of Stock Option Grant Agreements and Restricted Stock Unit Agreements. (Filed as exhibits to Form 8-K on December 8, 2005 and incorporated herein by reference.)
10.4+	Amended and Restated 1999 Equity Incentive Plan (As Amended and Restated of December 5, 2005) and Forms of Stock Option Grant Agreements. (Filed as exhibits to Form 8-K on December 8, 2005 and incorporated herein by reference.)
10.5+	Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (As Amended and Restated April 1, 2006). (Filed as an exhibit to Form S-8 on April 3, 2006 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 (As Amended and Restated July 12, 2005). (Filed as an exhibit to Form 8-K on July 14, 2005 and incorporated herein by reference.)
10.8+	Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 8-K on October 12, 2004 and incorporated herein by reference.)
10.9+	First Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 8-K on October 20, 2005 and incorporated herein by reference.)
10.10+	Second Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated July 1, 2006). (Filed as an exhibit to Form 8-K on May 16, 2006 and incorporated herein by reference.)
10.11+*	Third Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2007).
10.12+	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.)
10.13+	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.)
10.14+	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.)
10.15+	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.)

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.16+	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.)
10.17+	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.)
10.18+	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.)
10.19+	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.)
10.20+*	Eight Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended December 15, 2006).
10.21+	Amgen Inc. Executive Incentive Plan. (Filed as Annex G to Amendment No. 1 to Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
10.22+	First Amendment to the Amgen Inc. Executive Incentive Plan (As Amended December 6, 2004). (Filed as an exhibit to Form 8-K on December 9, 2004 and incorporated herein by reference.)
10.23+	Amgen Inc. Executive Nonqualified Retirement Plan. (Filed as an exhibit to Form 10-K for the year ended December 31, 2001 on February 26, 2002 and incorporated herein by reference.)
10.24+	Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2005). (Filed as an exhibit to Form 8-K on October 12, 2004 and incorporated herein by reference.)
10.25+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 8-K on October 20, 2005 and incorporated herein by reference.)
10.26+	Second Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 8-K on November 22, 2005 and incorporated herein by reference.)
10.27+*	Third Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated January 1, 2005).
10.28+	Amended and Restated Amgen Inc. Performance Award Program (As Amended and Restated December 5, 2005). (Filed as an exhibit to Form 8-K on December 8, 2005 and incorporated herein by reference.)
10.29+	Form of Performance Unit Agreement to the Amended and Restated Amgen Inc. Performance Award Program (As Amended and Restated December 5, 2005). (Filed as an exhibit to Form 8-K on December 8, 2005 and incorporated herein by reference.)
10.30+	Amgen Inc. Amended and Restated 1987 Directors' Stock Option Plan. (Filed as an exhibit to Form 10-K for the year ended December 31, 1996 on March 24, 1997 and incorporated herein by reference.)
10.31+	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.)
10.32+	Agreement, dated March 2, 2001, between Amgen Inc. and Mr. George J. Morrow. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2001 on May 14, 2001 and incorporated herein by reference.)
10.33+	Agreement, dated March 2, 2001 between Amgen Inc. and Dr. Roger M. Perlmutter, M.D., Ph.D. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2001 on May 14, 2001 and incorporated herein by reference.)

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.34+	Agreement, dated May 2, 2001, between Amgen Inc. and Mr. Brian McNamee. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2001 on July 27, 2001 and incorporated herein by reference.)
10.35+	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.)
10.36+	Agreement, dated May 14, 2001, between Amgen Inc. and Mr. Richard Nanula. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2001 on July 27, 2001 and incorporated herein by reference.)
10.37+	Promissory Note, dated June 27, 2001, of Mr. Richard Nanula. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2001 on July 27, 2001 and incorporated herein by reference.)
10.38+	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.)
10.39+	Restricted Stock Purchase Agreement, dated December 6, 2004, between Amgen Inc. and Dennis M. Fenton. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.40	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.)
10.41	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.)
10.42	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.)
10.43	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.)
10.44	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.)
10.45	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.)
10.46	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.)

## **Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.47	Amendment Agreement, dated June 30, 1988, to Research, Development, Technology Disclosure and License Agreement: GM-CSF dated March 31, 1987, between Kirin Brewery Company, Limited and Amgen Inc. (Filed as an exhibit to Form 8 amending the Quarterly Report on Form 10-Q for the quarter ended June 30, 1988 on August 25, 1988 and incorporated herein by reference.)
10.48	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.)
10.49	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.)
10.50	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.)
10.51	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.)
10.52	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.)
10.53	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.)
10.54	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.)
10.55	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.)
10.56	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.)

## **Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.57	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.)
10.58	Asset Purchase Agreement dated May 2, 2002, by and between Immunex Corporation and Schering Aktiengesellschaft (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.)
10.59	Amendment No. 1 dated as of June 25, 2002 and Amendment No. 2 dated as of July 17, 2002 to the Asset Purchase Agreement dated as of September 25, 2002, by and between Immunex Corporation and Schering Aktiengesellschaft. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2002 on August 13, 2002 and incorporated herein by reference.)
10.60	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.)
10.61	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.)
10.62	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.)
10.63	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.)
10.64	Credit Agreement, dated as of July 16, 2004, among Amgen Inc., the Banks therein named, Citibank N.A., as Issuing Bank, Citicorp USA, Inc., as Administrative Agent, and Barclays Bank PLC, as Syndication Agent. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2004 on August 6, 2004 and incorporated herein by reference.)
10.65	First Amendment dated as of December 6, 2005, to the Credit Agreement dated as of July 16, 2004, among Amgen Inc., the Banks therein named, Citibank N.A., as Issuing Bank, Citicorp USA, Inc. as Administrative Agent, and Barclays Bank PLC, as Syndication Agent. (Filed as an exhibit to Form 8-K dated and filed on December 8, 2005 and incorporated herein by reference.)
10.66	Purchase Agreement, dated as of November 15, 2004, among Amgen Inc. and Morgan Stanley & Co. Incorporated and Merrill Lynch, Pierce, Fenner & Smith Incorporated, as representatives of the several initial purchasers. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
10.67	Purchase Agreement, dated as of February 14, 2006, among Amgen Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Morgan Stanley & Co. Incorporated, Citigroup Global Markets Inc., JPMorgan Securities, Inc., Lehman Brothers Inc, Bear, Stearns & Co. Inc., Credit Suisse Securities (USA) LLC. (Filed as an exhibit to Form 8-K on February 21, 2006 and incorporated herein by reference.)

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.68	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.)
10.69	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.)
10.70	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.)
10.71	Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International for warrants expiring in 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.72	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.)
10.73	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.)
10.74	Purchase Agreement, dated February 16, 2006, between Amgen Inc. and Citigroup Global Markets Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
21*	Subsidiaries of the Company.
23	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. The consent set forth on page 103 is incorporated herein by reference.
24	Power of Attorney. The Power of Attorney set forth on page 102 is incorporated herein by reference.
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.)

**Table of Contents**

**SIGNATURES**

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

AMGEN INC.  
(Registrant)

Date: 02/28/07

By:

/s/ RICHARD D. NANULA  
**Richard D. Nanula**  
**Executive Vice President**

**and Chief Financial Officer**

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

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Richard D. Nanula 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	Chairman of the Board,	02/28/07
<b>Kevin W. Sharer</b>	Chief Executive Officer and President, and Director (Principal Executive Officer)	
/s/ RICHARD D. NANULA	Executive Vice President and	02/28/07
<b>Richard D. Nanula</b>	Chief Financial Officer  (Principal Financial Officer)	
/s/ MICHAEL A. KELLY	Vice President Corporate Planning and Control and Chief Accounting Officer (Principal Accounting Officer)	02/28/07
<b>Michael A. Kelly</b>		
/s/ DAVID BALTIMORE	Director	02/28/07
<b>David Baltimore</b>		
/s/ FRANK J. BIONDI, JR.	Director	02/28/07
<b>Frank J. Biondi, Jr.</b>		
/s/ JERRY D. CHOATE	Director	02/28/07
<b>Jerry D. Choate</b>		
/s/ FREDERICK W. GLUCK	Director	02/28/07
<b>Frederick W. Gluck</b>		
/s/ FRANK C. HERRINGER	Director	02/28/07
<b>Frank C. Herringer</b>		
/s/ GILBERT S. OMENN	Director	02/28/07
<b>Gilbert S. Omenn</b>		



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

/s/ JUDITH C. PELHAM	Director	02/28/07
<b>Judith C. Pelham</b>		
/s/ J. PAUL REASON	Director	02/28/07
<b>J. Paul Reason</b>		
/s/ LEONARD D. SCHAEFFER	Director	02/28/07
<b>Leonard D. Schaeffer</b>		

**Table of Contents****EXHIBIT 23****CONSENT OF ERNST & YOUNG LLP,****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, and 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, and 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, and 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

**Table of Contents**

restated), and in the Registration Statement (Form S-8 No. 333-133002) 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), and 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), of our reports dated February 22, 2007, with respect to the consolidated financial statements and schedule of Amgen Inc., Amgen Inc. management's assessment of the effectiveness of internal control over financial reporting, 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, 2006.

/s/ Ernst & Young LLP

Los Angeles, California

February 22, 2007

**Table of Contents**

**Report of Independent Registered Public Accounting Firm  
on the Financial Statements**

**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, 2006 and 2005, and the related Consolidated Statements of Operations, Stockholders' Equity, and Cash Flows for each of the three years in the period ended December 31, 2006. 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, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, 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), the effectiveness of Amgen Inc.'s internal control over financial reporting as of December 31, 2006, 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 22, 2007 expressed an unqualified opinion thereon.

As discussed in Note 2 to the Consolidated Financial Statements, the Company changed its method of accounting for stock-based compensation in 2006 upon adoption of Statement of Financial Standards No. 123 (R), Share-Based Payments.

/s/ Ernst & Young LLP

Los Angeles, California

February 22, 2007

**Table of Contents****AMGEN INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****Years ended December 31, 2006, 2005, and 2004****(In millions, except per share data)**

	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Revenues:</b>			
Product sales	\$ 13,858	\$ 12,022	\$ 9,977
Other revenues	410	408	573
 Total revenues	 14,268	 12,430	 10,550
<b>Operating expenses:</b>			
Cost of sales (excludes amortization of acquired intangible assets presented below)	2,095	2,082	1,731
Research and development	3,366	2,314	2,028
Write-off of acquired in-process research and development	1,231		554
Selling, general and administrative	3,366	2,790	2,556
Amortization of acquired intangible assets	370	347	333
Other		49	
 Total operating expenses	 10,428	 7,582	 7,202
 Operating income	 3,840	 4,848	 3,348
<b>Other income (expense):</b>			
Interest and other income, net	309	119	85
Interest expense, net	(129)	(99)	(38)
 Total other income	 180	 20	 47
 Income before income taxes	 4,020	 4,868	 3,395
Provision for income taxes	1,070	1,194	1,032
 Net income	 \$ 2,950	 \$ 3,674	 \$ 2,363
<b>Earnings per share:</b>			
Basic	\$ 2.51	\$ 2.97	\$ 1.86
Diluted	\$ 2.48	\$ 2.93	\$ 1.81
<b>Shares used in calculation of earnings per share:</b>			
Basic	1,176	1,236	1,271
Diluted	1,190	1,258	1,320

See accompanying notes.

**Table of Contents****AMGEN INC.****CONSOLIDATED BALANCE SHEETS****December 31, 2006 and 2005****(In millions, except per share data)**

	<b>2006</b>	<b>2005</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,283	\$ 1,840
Marketable securities	4,994	3,415
Trade receivables, net	2,124	1,769
Inventories	1,903	1,258
Other current assets	1,408	953
Total current assets	11,712	9,235
Property, plant and equipment, net	5,921	5,038
Intangible assets, net	3,747	3,742
Goodwill	11,302	10,495
Other assets	1,106	787
	<b>\$ 33,788</b>	<b>\$ 29,297</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 555	\$ 596
Accrued liabilities	4,589	2,999
Convertible notes	1,778	
Other long-term debt	100	
Total current liabilities	7,022	3,595
Deferred tax liabilities	367	1,163
Convertible notes	5,000	1,759
Other long-term debt	2,134	2,198
Other non-current liabilities	301	131
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$0.0001 par value; 5 shares authorized; none issued or outstanding		
Common stock and additional paid-in capital; \$0.0001 par value; 2,750 shares authorized; outstanding 1,166 shares in 2006 and 1,224 shares in 2005	24,155	23,561
Accumulated deficit	(5,203)	(3,132)
Accumulated other comprehensive income	12	22
Total stockholders' equity	<b>18,964</b>	<b>20,451</b>
	<b>\$ 33,788</b>	<b>\$ 29,297</b>

See accompanying notes.



**Table of Contents****AMGEN INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY****Years ended December 31, 2006, 2005, and 2004****(In millions)**

	<b>Number of shares</b>	<b>Common stock and additional paid-in capital</b>	<b>Accumulated deficit</b>	<b>Accumulated other comprehensive income</b>	<b>Total</b>
Balance at December 31, 2003	1,284	\$ 19,995	\$ (667)	\$ 61	\$ 19,389
Comprehensive income:					
Net income			2,363		2,363
Other comprehensive loss, net of tax:					
Unrealized losses on securities, net of reclassification adjustments				(82)	(82)
Foreign currency translation adjustments				24	24
Total other comprehensive loss					(58)
Comprehensive income					2,305
Issuance of common stock for the acquisition of Tularik Inc.	24	1,332			1,332
Fair value of options assumed from Tularik Inc.		71			71
Issuance of common stock upon the exercise of employee stock options and in connection with an employee stock purchase plan	21	453			453
Stock-based awards		60			60
Tax benefits related to employee stock options		167			167
Repurchases of common stock	(69)		(4,072)		(4,072)
Balance at December 31, 2004	1,260	22,078	(2,376)	3	19,705
Comprehensive income:					
Net income			3,674		3,674
Other comprehensive income, net of tax:					
Unrealized gains on securities, net of reclassification adjustments				65	65
Foreign currency translation adjustments				(46)	(46)
Total other comprehensive income					19
Comprehensive income					3,693
Issuance of common stock upon the exercise of employee stock options and in connection with an employee stock purchase plan	27	1,087			1,087
Stock-based awards		120			120
Tax benefits related to employee stock options		276			276
Repurchases of common stock	(63)		(4,430)		(4,430)
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, net of reclassification adjustments				(49)	(49)
Foreign currency translation adjustments				39	39
Total other comprehensive loss					(10)
Comprehensive income					2,940
	12	528			528



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

Issuance of common stock upon the exercise of employee stock options and in connection with an employee stock purchase plan

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)

Balance at December 31, 2006	1,166	\$ 24,155	\$ (5,203)	\$ 12	\$ 18,964
------------------------------	-------	-----------	------------	-------	-----------

See accompanying notes.

F-4

**Table of Contents****AMGEN INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****Years ended December 31, 2006, 2005, and 2004****(In millions)**

	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Cash flows from operating activities:</b>			
Net income	\$ 2,950	\$ 3,674	\$ 2,363
Depreciation and amortization	963	841	734
Write-off of acquired in-process research and development	1,231		554
Stock-based compensation expense	403	106	45
Tax benefits related to employee stock-based compensation		315	203
Deferred income taxes	(540)	(95)	57
Other items, net	(81)	60	116
<b>Cash provided by (used in) changes in operating assets and liabilities, net of acquisitions:</b>			
Trade receivables, net	(355)	(308)	(453)
Inventories	(561)	(370)	(175)
Other current assets	(6)	(47)	(85)
Accounts payable	(24)	72	179
Accrued income taxes	581	81	(318)
Other accrued liabilities	828	582	477
<b>Net cash provided by operating activities</b>	<b>5,389</b>	<b>4,911</b>	<b>3,697</b>
<b>Cash flows from investing activities:</b>			
Cash paid for acquisitions, net of cash acquired	(2,167)		115
Purchases of property, plant and equipment	(1,218)	(867)	(1,336)
Purchases of marketable securities	(5,386)	(9,597)	(6,869)
Proceeds from sales of marketable securities	3,065	9,835	6,606
Proceeds from maturities of marketable securities	785	603	208
Other	(210)	(33)	(123)
<b>Net cash used in investing activities</b>	<b>(5,131)</b>	<b>(59)</b>	<b>(1,399)</b>
<b>Cash flows from financing activities:</b>			
Repurchases of common stock	(2,000)	(4,430)	(4,072)
Repayment of debt	(653)	(1,175)	
Proceeds from issuance of convertible notes and related transactions, net	439		1,989
Proceeds from issuance of warrants	774		
Net proceeds from issuance of common stock upon the exercise of employee stock options and in connection with an employee stock purchase plan	528	1,087	453
Other	97	(20)	21
<b>Net cash used in financing activities</b>	<b>(815)</b>	<b>(4,538)</b>	<b>(1,609)</b>
<b>(Decrease) increase in cash and cash equivalents</b>	<b>(557)</b>	<b>314</b>	<b>689</b>
Cash and cash equivalents at beginning of year	1,840	1,526	837
<b>Cash and cash equivalents at end of year</b>	<b>\$ 1,283</b>	<b>\$ 1,840</b>	<b>\$ 1,526</b>

See accompanying notes.

F-5

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****December 31, 2006****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 financial statements and accompanying notes. Actual results may differ from those estimates.

*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 Statement of Financial Accounting Standards ( SFAS ) No. 115, Accounting for Certain Investments in Debt and Equity Securities. Accordingly, these investments are recorded at fair value, which is based on quoted market prices. For the years ended December 31, 2006, 2005 and 2004, realized gains totaled \$23 million, \$25 million and \$23 million, respectively, and realized losses totaled \$25 million, \$20 million and \$27 million, respectively. The cost of securities sold is based on the specific identification method. 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):

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
<b>December 31, 2006</b>				
Type of security:				
Corporate debt securities	\$ 2,578	\$ 5	\$ (10)	\$ 2,573
U.S. Treasury securities and obligations of U.S. government agencies	2,451	3	(11)	2,443
Other interest bearing securities	1,044			1,044
<b>Total debt securities</b>	<b>6,073</b>	<b>8</b>	<b>(21)</b>	<b>6,060</b>
Equity securities	99	2	(2)	99
	<b>\$ 6,172</b>	<b>\$ 10</b>	<b>\$ (23)</b>	<b>\$ 6,159</b>

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

<b>December 31, 2005</b>	<b>Amortized cost</b>	<b>Gross unrealized gains</b>	<b>Gross unrealized losses</b>	<b>Estimated fair value</b>
Type of security:				
Corporate debt securities	\$ 1,492	\$ 1	\$ (15)	\$ 1,478
U.S. Treasury securities and obligations of U.S. government agencies	2,684		(16)	2,668
Other interest bearing securities	903			903
Total debt securities	5,079	1	(31)	5,049
Equity securities	66	8	(1)	73
	\$ 5,145	\$ 9	\$ (32)	\$ 5,122

	<b>December 31,</b>	
<b>Contractual maturity:</b>	<b>2006</b>	<b>2005</b>
Maturing in one year or less	\$ 1,962	\$ 2,913
Maturing after one year through four years	3,196	1,351
Maturing after four years	902	785
Total debt securities	6,060	5,049
Equity securities	99	73
	\$ 6,159	\$ 5,122

	<b>December 31,</b>	
<b>Classification in balance sheets:</b>	<b>2006</b>	<b>2005</b>
Cash and cash equivalents	\$ 1,283	\$ 1,840
Marketable securities	4,994	3,415
Other assets noncurrent	56	44
	6,333	5,299
Less cash	(174)	(177)
	\$ 6,159	\$ 5,122

The primary objectives for our investment portfolio are liquidity and safety of principal. Investments are made with the objective of achieving the highest rate of return consistent with these two objectives. Our investment policy limits investments to certain types of 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.

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

Inventories are stated at the lower of cost or market. Cost, which include amounts related to materials, labor and overhead, is determined in a manner which approximates the first-in, first-out (FIFO) method. Inventories consisted of the following (in millions):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Raw materials	\$ 205	\$ 145
Work in process	1,090	758
Finished goods	608	355
	\$ 1,903	\$ 1,258

*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 equipment	3	15

*Property, plant and equipment*

Property, plant and equipment are recorded at historical cost and consisted of the following (in millions):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Land	\$ 398	\$ 294
Buildings and improvements	2,776	2,485
Manufacturing equipment	1,081	923
Laboratory equipment	761	618
Furniture, fixtures and other equipment	2,401	2,043
Construction in progress	1,271	958
	8,688	7,321
Less accumulated depreciation and amortization	(2,767)	(2,283)
	\$ 5,921	\$ 5,038

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

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.

F-8

**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 amortization period of 14 years at December 31, 2006). As of December 31, 2006, intangible assets consisted of the following (dollars in millions):

<b>Intangible assets subject to amortization</b>	<b>Weighted average amortization period</b>	<b>December 31,</b>	
		<b>2006</b>	<b>2005</b>
Acquired product technology rights:			
Developed product technology	15 years	\$ 2,877	\$ 3,077
Core technology	15 years	1,348	1,348
Trade name	15 years	190	190
Acquired R&D technology rights	5 years	350	
Other intangible assets	11 years	454	335
		5,219	4,950
Less accumulated amortization		(1,472)	(1,208)
		\$ 3,747	\$ 3,742

Acquired product technology rights relate to the identifiable intangible assets acquired in connection with the Immunex Corporation ( Immunex ) acquisition in July 2002. Amortization of acquired product technology rights is included in Amortization of acquired intangible assets in the Consolidated Statements of Operations. 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 includes the XenoMouse® technology acquired in the Abgenix Inc. ( Abgenix ) acquisition (see Note 7, Acquisitions Abgenix, Inc. ). Amortization of acquired R&D technology rights is included in Research and development expense in the Consolidated Statements of Operations. Amortization of other intangible assets is principally included in Cost of sales and Selling, general and administrative expense in the Consolidated Statements of Operations. The total estimated amortization for each of the next five years for our intangible assets subject to amortization is \$412 million, \$412 million, \$412 million, \$405 million and \$355 million in 2007, 2008, 2009, 2010 and 2011, 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 three months ended September 30, 2006, we recognized a \$49 million impairment charge 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 Operations.

We had \$11,302 million and \$10,495 million of goodwill at December 31, 2006 and 2005, respectively, which primarily relates to the acquisition of Immunex. The increase in goodwill in 2006 is due to the goodwill associated with the Abgenix and Avidia, Inc. ( Avidia ) acquisitions (see Note 7, Acquisitions ) net of the reduction due primarily to tax benefits realized upon exercise of stock options during the year ended December 31, 2006, which were assumed in various business combinations. We perform an impairment test annually and whenever events or changes in circumstances indicate that the carrying amount of goodwill may not be recoverable.

*Product sales*

Product sales primarily consist of sales of Aranesp®, Neulasta®/NEUPOGEN®, EPOGEN® and ENBREL.

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.





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

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.), a subsidiary of Johnson & Johnson ( "Johnson & Johnson" ), 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 Johnson & Johnson and do recognize the product sales made by Johnson & Johnson 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 Johnson & Johnson, noted above, we earn a 10% royalty on net sales, as defined, of Epoetin alfa by Johnson & Johnson 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 3, "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 development period or agreement term. 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, which are expensed as incurred, are primarily comprised of costs for salaries and benefits associated with R&D personnel, overhead and occupancy, clinical trial and related clinical manufacturing, including contract services and other outside costs, process development, quality assurance, information systems and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include such costs related to activities performed on behalf of corporate partners.

*Acquired in-process research and development*

The fair value of acquired in-process R&D ( "IPR&D" ) projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are immediately expensed. In 2006, we expensed \$1,101 million and \$130 million of acquired IPR&D related to the Abgenix and Avidia acquisitions (see Note 7, "Acquisitions"), respectively. In 2004, we expensed \$554 million of acquired IPR&D associated with the Tularik Inc. ( "Tularik" ) acquisition (see Note 7, "Acquisitions"). Acquired IPR&D is considered part of total R&D expense.

*Selling, general and administrative costs*

Selling, general and administrative expenses are primarily comprised of salaries and benefits associated with sales and marketing, finance, legal and other administrative personnel; outside marketing expenses including advertising; overhead and occupancy costs; outside legal costs; and other general and administrative costs.

**Table of Contents**

**AMGEN INC.**

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

We have a co-promotion agreement with Wyeth. Under the terms of this agreement, Amgen and Wyeth market and sell Enbrel® (etanercept) in the United States and Canada and develop certain future indications of ENBREL for use in these geographic territories. The rights to detail and promote ENBREL in the United States and Canada for oncology indications are reserved for us. Wyeth is paid a share of the resulting profits on sales of ENBREL, after deducting the applicable costs of sales, including manufacturing costs and royalties paid to third parties, and expenses associated with R&D and sales and marketing. Such amounts paid to Wyeth are included in Selling, general and administrative expense in the Consolidated Statements of Operations. 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, inventory and allocation of bulk supplies of ENBREL.

Advertising costs are expensed as incurred. For the years ended December 31, 2006, 2005 and 2004, advertising costs were \$134 million, \$109 million and \$73 million, respectively.

*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, 2006, 2005 and 2004 was \$129 million, \$99 million and \$38 million, respectively. Interest costs capitalized for the years ended December 31, 2006, 2005 and 2004, were \$43 million, \$30 million and \$20 million, respectively. Interest paid, net of interest rate swap settlement activity, during the years ended December 31, 2006, 2005 and 2004, totaled \$122 million, \$84 million and \$13 million, respectively.

*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 2032 Modified Convertible Notes, 2011 Convertible Notes, 2013 Convertible Notes and upon the assumed exercise of our warrants using the treasury stock method (collectively Dilutive Securities ). Potential common shares also include common stock to be issued upon the assumed conversion of our 2032 Convertible Notes under the if-converted method. 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 5, Financing arrangements ).

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

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

	<b>Years ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Income (Numerator):</b>			
Net income for basic EPS	\$ 2,950	\$ 3,674	\$ 2,363
Adjustment for interest expense on 2032 Convertible Notes, net of tax		6	21
Income for diluted EPS, after assumed conversion	\$ 2,950	\$ 3,680	\$ 2,384
<b>Shares (Denominator):</b>			
Weighted-average shares for basic EPS	1,176	1,236	1,271
Effect of dilutive securities, primarily stock options	14	12	14
Effect of 2032 Convertible Notes, after assumed conversion		10	35
Weighted-average shares for diluted EPS	1,190	1,258	1,320
Basic earnings per share	\$ 2.51	\$ 2.97	\$ 1.86
Diluted earnings per share	\$ 2.48	\$ 2.93	\$ 1.81

For the years ended December 31, 2006, 2005 and 2004, there were employee stock options, calculated on a weighted average basis, to purchase 13 million, 16 million and 45 million shares, respectively, with exercise prices greater than the average market prices of common stock that are not included in the computation of 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 the warrants are not included above as their impact on EPS would have been anti-dilutive. Shares which may be issued under our 2006 and 2005 performance award programs were not included because conditions under the programs were not met.

*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 based on quoted market prices. The accounting for changes in the fair value (i.e., unrealized gains or losses) 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 also 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 in Europe. These contracts are designated as cash flow hedges and accordingly, the gains and losses on these forward and option contracts are reported as a component of other comprehensive income and reclassified to earnings in the same periods during which the hedged transactions affect earnings. During the years ended December 31, 2006, 2005 and 2004, gains and losses on these foreign currency forward and option contracts were not material. No

portions of these foreign currency forward and option contracts are

F-12

**Table of Contents**

**AMGEN INC.**

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

excluded from the assessment of hedge effectiveness, and there are no material ineffective portions of these hedging instruments. At December 31, 2006 and 2005, 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, gains and losses on these foreign currency forward contracts are recognized in interest and other income, net in the current period. During the years ended December 31, 2006, 2005 and 2004, 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 protect against possible increases in value of certain debt instruments. 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, 2006, 2005 and 2004, 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.

*Reclassifications*

Certain prior period amounts have been reclassified to conform to the current period presentation.

*Recent Accounting Pronouncements*

In June 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. ( FIN ) 48, Accounting for Uncertainty in Income Taxes, effective for fiscal years beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing rules for recognition, measurement, classification and disclosure in our financial statements of uncertain tax positions taken or expected to be taken in a tax return. Based on our evaluations, we currently believe that the only impact to us of adopting this new standard is to reclassify certain liabilities for uncertain tax positions from current to non-current liabilities in our Consolidated Balance Sheet. We adopted this new standard effective January 1, 2007.

**2. 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, 2006, these plans provide for future grants and/or issuances of up to approximately 41 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.

Prior to January 1, 2006, we accounted for our employee stock-based compensation under the recognition and measurement principles of Accounting Principles Board Opinion ( APB ) No. 25, Accounting for Stock Issued to Employees, and related interpretations, as permitted by SFAS No. 123, Accounting for Stock-Based Compensation. Under the recognition principles of APB No. 25, compensation expense related to restricted stock and performance units was recognized in our financial statements. However, APB No. 25 generally did not require the recognition of compensation expense for our stock options because the exercise price of these instruments was generally equal to the market value of the underlying common stock on the date of grant, and the related number of shares granted were fixed at that point in time.

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123(R), Share-Based Payment. In addition to recognizing compensation expense related to restricted stock and performance units, SFAS No. 123(R) also requires us to recognize compensation expense related to the estimated fair value of stock options. We adopted SFAS No. 123(R) using the modified-prospective-transition method. Under that transition method, compensation expense recognized subsequent to adoption includes:

(a) compensation cost for all

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

share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the values estimated in accordance with the original provisions of SFAS No. 123 and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair values estimated in accordance with the provisions of SFAS No. 123(R). Consistent with the modified-prospective-transition method, our results of operations for prior periods have not been adjusted to reflect the adoption of SFAS 123(R).

As a result of recognizing compensation expense for stock options pursuant to the provisions of SFAS No. 123(R), our income before income taxes for the year ended December 31, 2006, was \$233 million lower and our net income was \$152 million lower, than if we had continued to account for stock options under APB No. 25. In addition, both basic and diluted earnings per share for the year ended December 31, 2006 were \$0.14 lower, than if we had continued to account for stock options under APB No. 25.

The following table reflects the components of stock-based compensation expense recognized in our Consolidated Statements of Operations for the years ended December 31, 2006, 2005 and 2004 (in millions):

	2006	2005	2004
Stock options	\$ 233	\$	\$
Restricted stock	58	36	11
Performance units	112	70	34
Total stock-based compensation expense, pre-tax	403	106	45
Tax benefit from stock-based compensation expense	(117)	(32)	(15)
Total stock-based compensation expense, net of tax	\$ 286	\$ 74	\$ 30

The above table does not reflect any stock option compensation for the years ended December 31, 2005 and 2004 as we generally did not record stock option expense under APB No. 25, as previously discussed. The following table illustrates the effect on net income and earnings per share for the years ended December 31, 2005 and 2004 if we had applied the fair value recognition provisions to our stock options as provided under SFAS No. 123 (in millions, except per share information):

	2005	2004
Net income	\$ 3,674	\$ 2,363
Stock-based compensation, net of tax	(233)	(292)
Pro forma net income	\$ 3,441	\$ 2,071
Earnings per share:		
Basic	\$ 2.97	\$ 1.86
Impact of stock option expense	(0.19)	(0.23)
Basic pro forma	\$ 2.78	\$ 1.63
Diluted	\$ 2.93	\$ 1.81
Impact of stock option expense	(0.19)	(0.23)
Diluted pro forma	\$ 2.74	\$ 1.58

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

For purposes of this pro forma disclosure, the fair values of stock options were estimated using the Black-Scholes option valuation model and amortized to expense over the options' vesting periods.

F-14



**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Employee stock option and restricted stock grants*

Several of 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 a stock option grant upon commencement of employment. These stock-based plans provide for accelerated vesting/lapse of restrictions in certain circumstances due to retirement, death or disability, or if there is a change in control as defined in the plans.

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 common stock during the period the option is 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. Upon the adoption of SFAS No. 123(R) the expected life of the option is estimated using the simplified method as provided in Securities and Exchange Commission (SEC) Staff Accounting Bulletin No. 107. Under this method, the expected life equals the arithmetic average of the vesting term and the original contractual term of the option. Prior to adoption of SFAS No. 123(R), we used 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. Upon adoption of SFAS No. 123(R), we began using historical data to estimate forfeiture rates applied to the gross amount of expense determined using the option valuation model. Prior to adoption of SFAS No. 123(R), we recognized forfeitures as they occurred. There was no material impact upon adoption of SFAS No. 123(R) between these methods of accounting for forfeitures. The 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, 2006, 2005 and 2004:

	<b>2006</b>	<b>2005</b>	<b>2004</b>
Fair value of common stock	\$ 71.16	\$ 63.47	\$ 59.32
Fair value of stock options granted	\$ 21.70	\$ 18.46	\$ 22.90
Risk-free interest rate	4.8%	4.0%	2.6%
Expected life (in years)	4.8	5.0	4.3
Expected volatility	24.1%	23.4%	44.0%
Expected dividend yield	0%	0%	0%

During the quarter ended March 31, 2005, we revised our method of estimating expected volatility used in the Black-Scholes option valuation model to reflect the consideration of implied volatility in our publicly traded equity instruments.

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

Stock option information with respect to our stock-based compensation plans during the three years ended December 31, 2006 is as follows (options and dollars in millions, except per share amounts):

	<b>Options</b>	<b>Weighted- average exercise price</b>	<b>Weighted- average remaining contractual life (Yrs)</b>	<b>Aggregate intrinsic value</b>
Balance unexercised at December 31, 2003	94.6	\$ 44.68		
Granted	16.2	\$ 59.32		
Assumed from acquisitions (including 1.7 vested)	3.5	\$ 23.15		
Exercised	(19.5)	\$ 20.42		
Forfeited/expired	(5.8)	\$ 59.93		
Balance unexercised at December 31, 2004	89.0	\$ 50.82		
Granted	9.7	\$ 63.47		
Exercised	(25.5)	\$ 39.73		
Forfeited/expired	(5.6)	\$ 59.83		
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	3.8	\$ 622
Vested or expected to vest at December 31, 2006	64.5	\$ 59.79	3.7	\$ 604
Exercisable at December 31, 2006	40.3	\$ 56.97	2.8	\$ 468

The total intrinsic value of options exercised during the year ended December 31, 2006 was \$315 million.

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 year ended December 31, 2006 is as follows (shares in millions):

<b>Nonvested shares</b>	<b>Shares</b>	<b>Weighted- average grant date fair value</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

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

The total fair value of shares of restricted stock that vested during the year ended December 31, 2006 was \$56 million.

As of December 31, 2006, there was \$526 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 1.5 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.

F-16

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

Beginning in 2004, certain management-level employees receive annual grants of performance units. A performance unit gives the recipient the right to receive common stock that is contingent upon achievement of specified pre-established performance goals over a three-year performance period. The performance goals are based upon both Amgen's standalone performance and its performance compared to other benchmark companies, in each case with respect to compound annual growth rates for revenue and earnings per share, as defined in the program. Performance units are assigned a unit value based on the fair market value of Amgen common stock on the grant date. The ultimate level of attainment of performance goals is determined at the end of the performance period and expressed as a percentage (within a range of 0% to 225%). This percentage is multiplied by the number of performance units initially granted and by the initial value per unit to determine the aggregate dollar value of the award. The aggregate dollar value is then divided by the average closing price of Amgen common stock during a specified period following the performance period to determine the number of shares of common stock payable to the recipient. This performance award program provides for partial vesting/lapse of restrictions in certain circumstances due to death or disability, or if there is a change in control as defined in the plans.

The performance period for those instruments granted in 2004 (the 2004 grant) ended on December 31, 2006. Total compensation recognized over the three years ended December 31, 2006 associated with the 2004 grant was \$107 million. This amount will be paid by issuance of shares of our common stock to the recipients in March 2007. The exact number of shares to be issued will be based on the then average closing price of our stock as discussed above.

The performance periods for the remaining outstanding instruments under this program have not yet ended at December 31, 2006 and, accordingly, the related performance units are unvested and no related shares of common stock has been issued to any recipient.

As of December 31, 2006, there was \$107 million of total estimated unrecognized compensation cost related to the 2005 and 2006 performance unit periods that is expected to be recognized over a weighted-average period of 1 year.

Under APB No. 25, the estimated amounts owed for grants of performance units were classified in stockholders' equity, but upon adoption of SFAS No. 123(R), these amounts are classified as liabilities. Accordingly, on January 1, 2006, a reclassification was made from stockholders' equity to liabilities (current and non-current) totaling \$104 million.

**3. Related party transactions**

We own a 50% interest in KA, a corporation formed in 1984 with Kirin Brewery Company, Limited (Kirin) for the development and commercialization of certain products based on advanced biotechnology. We account for our interest in KA under the equity method and include our share of KA's profits or losses in Selling, general and administrative expense in the Consolidated Statements of Operations. For the years ended December 31, 2006, 2005 and 2004, our share of KA's profits were \$61 million, \$58 million, and \$25 million, respectively. At December 31, 2006 and 2005, the carrying value of our equity method investment in KA was \$241 million and \$180 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 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. We currently market certain of these products under the brand names Aranesp®, Neulasta®, NEUPOGEN® and EPOGEN®, respectively. KA receives royalty income from us, as well as Kirin, Johnson & Johnson and F. Hoffman-La Roche Ltd. (Roche) under separate product license agreements for certain geographic areas outside of the United States. During the years ended December 31, 2006, 2005, and 2004, KA earned royalties from

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

us of \$324 million, \$288 million, and \$266 million, respectively. These amounts are included in Cost of sales (excludes amortization of acquired intangible assets) in the Consolidated Statements of Operations.

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, 2006, 2005 and 2004, we earned revenues from KA of \$131 million, \$113 million, and \$187 million, respectively, for certain R&D activities performed on KA's behalf. These amounts are included in Other revenues in the Consolidated Statements of Operations.

**4. Income taxes**

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

	Years ended December 31,		
	2006	2005	2004
Current provision:			
Federal	\$ 1,392	\$ 1,079	\$ 809
State	73	82	88
Foreign	138	128	78
Total current provision	1,603	1,289	975
Deferred (benefit) provision:			
Federal	(481)	(90)	52
State	(49)	(7)	14
Foreign	(3)	2	(9)
Total deferred (benefit) provision	(533)	(95)	57
Total provision	\$ 1,070	\$ 1,194	\$ 1,032

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):

	December 31,	
	2006	2005
Deferred tax assets:		
Intercompany inventory related items	\$ 668	\$ 454
Expense accruals	346	205
Acquired net operating loss and credit carryforwards	532	189
Expense capitalized for tax	136	76
Convertible debt	362	
Other	166	75
Total deferred tax assets	2,210	999

Edgar Filing: AMGEN INC - Form 10-K

Valuation allowance	(102)	(102)
Net deferred tax assets	2,108	897
Deferred tax liabilities:		
Acquired intangibles	(1,320)	(1,356)
Financing debt instrument	(54)	(30)
Fixed assets	(108)	(85)
Other	(3)	(44)
Total deferred tax liabilities	(1,485)	(1,515)
Total deferred taxes	\$ 623	\$ (618)

F-18

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

At December 31, 2006, we had net current deferred tax assets of \$990 million, primarily composed of temporary differences related to inventory, accrued liabilities and financing debt instruments, as well as acquired net operating losses and credits. At December 31, 2005, our net current deferred tax assets were \$543 million.

At December 31, 2006, we had operating loss carryforwards of \$952 million available to reduce future federal taxable income, which begin expiring in 2007. In addition, we had operating loss carryforwards of \$576 million available to reduce future taxable income in various state taxing jurisdictions. We have provided a valuation allowance against \$310 million of the state operating loss carryforwards. The state operating loss carryforwards will begin expiring in 2007.

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

	Tax rate for the		
	years ended December 31,		
	2006	2005	2004
Federal statutory rate applied to income before income taxes	35.0%	35.0%	35.0%
Foreign earnings including earnings invested indefinitely	(18.3)%	(10.3)%	(12.8)%
State taxes	1.6%	1.5%	3.0%
Acquired IPR&D	10.7%		5.7%
Audit settlements	(2.2)%		
Utilization of tax credits, primarily research and experimentation	(1.0)%	(0.7)%	(0.5)%
Other, net	0.8%	(1.0)%	
Effective tax rate	26.6%	24.5%	30.4%

We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be invested indefinitely outside the United States. At December 31, 2006, these earnings amounted to approximately \$5,883 million. If these earnings were repatriated to the United States, we would be required to accrue and pay approximately \$2,159 million of additional taxes based on the current tax rates in effect. For the years ended December 31, 2006, 2005 and 2004, our total foreign profits before income taxes were approximately \$2,329 million, \$1,830 million and \$1,443 million, respectively. These earnings include income from manufacturing operations in Puerto Rico under tax incentive grants that expire in 2020.

On October 22, 2004, the President of the United States signed the American Jobs Creation Act of 2004, which provided a temporary incentive to repatriate undistributed foreign earnings. One provision of the American Jobs Creation Act reduced the effective tax rate by providing an 85% dividend-received deduction for certain dividends from controlled foreign corporations. In the fourth quarter of 2005, we repatriated \$500 million of foreign earnings, which was the maximum amount of foreign earnings qualifying for the reduced tax rate. The tax expense incurred on the repatriation was approximately \$43 million.

Our income tax returns are routinely audited by the Internal Revenue Service 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. We periodically evaluate our exposures associated with tax filing positions. While we believe our positions comply with applicable laws, we record liabilities based upon estimates of the ultimate outcomes of these matters.

Income taxes paid during the years ended December 31, 2006, 2005, and 2004, totaled \$987 million, \$840 million and \$1,138 million, respectively.





**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****5. Financing arrangements**

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements as of December 31, 2006 and 2005 (in millions):

	2006	2005
0.125% convertible notes due 2011 (2011 Convertible Notes)	\$ 2,500	\$
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,500	
Zero coupon 30 year modified convertible notes due in 2032 (2032 Modified Convertible Notes)	1,778	1,759
4.85% notes due 2014 (2014 Notes)	1,000	1,000
4.00% notes due 2009 (2009 Notes)	999	998
Other	235	200
<b>Total borrowings</b>	<b>9,012</b>	<b>3,957</b>
Less current portion	1,878	
<b>Total non-current debt</b>	<b>\$ 7,134</b>	<b>\$ 3,957</b>

*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) in a private placement. 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 the 2013 Convertible Notes may be convertible 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 the 2013 Convertible Notes may only be converted: 1) 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, 2) if we make specified distributions to holders of our common stock or specified corporate transactions occur or 3) 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: 1) cash equal to the lesser of the principal amount of the note or the conversion value, as defined, and 2) 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 and unpaid interest, if any. Debt issuance costs totaled approximately \$89 million and are being amortized over the life of the notes using the effective interest method.

In connection with 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 the 2013 Convertible Notes, we purchased convertible note hedges in private transactions. 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 the 2013 Convertible Notes upon conversion. These transactions will terminate at the earlier of the maturity dates of the related notes or the first day none of the related notes remain outstanding due to conversion or otherwise. The cost of the convertible note hedges aggregated approximately \$1.5 billion. The net proceeds received from the issuance of the 2011 and 2013 Convertible Notes, the repurchase of our common stock and the purchase of the convertible note hedges was \$439 million.



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

Also concurrent with the issuance of the 2011 Convertible Notes and the 2013 Convertible Notes, we sold warrants to acquire shares of our common stock at an exercise price of \$107.90 per share in a private placement. 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 Emerging Issues Task Force (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 in stockholders' equity in the Consolidated Balance Sheet as of December 31, 2006. 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 No. 133, Accounting for Derivative Instruments and Hedging Activities.

*2032 Modified Convertible Notes*

In 2002, we issued zero coupon, 30 year convertible notes (2032 Convertible Notes) with an aggregate face amount of \$3.95 billion (\$1,000 face amount per note) and yield to maturity of 1.125%. The original issue discount of \$1.13 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 \$1.59 billion aggregate principal amount of 2032 Convertible Notes for their then-accreted value of \$1,175 million in cash, or approximately 40% of our then outstanding 2032 Convertible Notes. Upon the repurchase of such 2032 Convertible Notes, a pro rata portion, \$20 million, of the related debt issuance costs were immediately charged to interest expense in the quarter ended March 31, 2005. We made an aggregate cash payment of \$22 million to the holders of the 2032 Convertible Notes who did not exercise the March 1, 2005 put option. This payment was approximately equal to 1.25% of the 2032 Convertible Notes' then-accreted value and will be amortized to interest expense over the life of the remaining outstanding 2032 Convertible Notes (or the 2032 Modified Convertible Notes, as discussed below) using the effective interest method. 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 2032 Convertible Notes on March 1, 2006 at the then-accreted value. Because the holders of substantially all of the convertible notes did not require us to repurchase such notes on the March 1, 2006 put date, the convertible notes were classified as non-current in the Consolidated Balance Sheet as of December 31, 2006.

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 are being accounted for as a debt modification. Accordingly, all cash paid to the holders of the 2032 Modified Convertible Notes and 2032 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.

**Table of Contents**

**AMGEN INC.**

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

The significant terms of the 2032 Modified Convertible Notes are as follows:

Holders of 2032 Modified Convertible Notes may convert each of their notes based on a conversion rate of 8.8601 shares of common stock of Amgen as defined below. 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 \$85.07 as of December 31, 2006. The conversion price per share at issuance of the Convertible Notes was \$80.61. The 2032 Modified Convertible Notes can only be converted if: 1) the closing price of our common stock exceeds the conversion price per share during a defined period at the end of the previous calendar quarter, 2) we call the 2032 Modified Convertible Notes for redemption or 3) we make certain significant distributions to common stockholders or enter into specified types of corporate transactions. (The 2032 Convertible Notes were convertible into common stock at any time based on the conversion rate, discussed above.)

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, 2006) multiplied by the average closing price of our common stock during a specified period following the conversion date. The conversion value is paid in: 1) cash equal to the lesser of the accreted value of the 2032 Modified Convertible Notes at the conversion date or the conversion value and 2) shares of common stock, if any, to the extent the conversion value exceeds the accreted value.

The conversion rate of the 2032 Modified Convertible Notes will be adjusted for any cash dividend paid by an amount equal to the dividend divided by the average closing price of common stock during a specified period immediately prior to the ex-dividend date.

The holders of the 2032 Modified Convertible Notes may require us to purchase for cash all or a portion of their notes on March 1, 2007, March 1, 2012 and March 1, 2017 at a price equal to the original issuance price plus the accrued original issue discount to the purchase dates. Accordingly, the notes are classified as current liabilities in the Consolidated Balance Sheet as of December 31, 2006.

If certain conditions are met, we are required to pay contingent interest on the 2032 Modified Convertible Notes in an amount equal to a specified percentage of the market price of the 2032 Modified Convertible Notes, as defined, without regard to the amount of cash dividends paid, if any.

We may redeem all or a portion of the 2032 Modified Convertible Notes for cash at any time on or after March 1, 2007 at the original issuance price plus accrued original issue discount as of the redemption date.

*2009 Notes and 2014 Notes*

At December 31, 2006 and 2005, we had \$1.0 billion aggregate principal amount of 4.00% notes due 2009 (the 2009 Notes ) and \$1.0 billion aggregate principal amount of 4.85% notes due 2014 (the 2014 Notes ) outstanding, originally issued in November 2004. The net proceeds of these two issuances totaled \$1,989 million.

*Other*

We had \$100 million of debt securities outstanding at December 31, 2006 and 2005 with a fixed rate of 6.5% that mature in 2007 (the 2007 Notes ). These debt securities were issued under our \$500 million debt shelf registration statement (the \$500 Million Shelf ) which was

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

established in 1997. See below for additional information on the \$500 Million Shelf.

We had \$100 million of debt securities outstanding at December 31, 2006 and 2005 with a fixed interest rate of 8.1% that mature in 2097 (the Century Notes ). These securities may be redeemed in whole or in part at our option at any time for a redemption price equal to the greater of the principal amount to be redeemed or the sum

F-22

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

of the present values of the principal and remaining interest payments discounted at a determined rate plus, in each case, accrued interest.

We had notes payable with an accreted value of \$35 million and an effective rate of 5.35% due in 2013, outstanding at December 31, 2006.

*Shelf registration statements and other facilities*

In 2004, we established a \$1.0 billion unsecured revolving credit facility to be used for general corporate purposes, including commercial paper support, which matures in November 2010. At December 31, 2006, we also had commercial paper authorization of \$1.2 billion. No amounts were outstanding under the credit facility or commercial paper program as of December 31, 2006.

In 2003, we established a \$1.0 billion shelf registration statement (the "\$1 Billion Shelf") to provide for financial flexibility. The \$1 Billion Shelf allows us to issue debt securities, common stock and associated preferred share purchase rights, preferred stock, warrants to purchase debt securities, common stock or preferred stock, securities purchase contracts, securities purchase units and depositary shares. Under the \$1 Billion Shelf, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. As of December 31, 2006, no securities had been issued under the \$1 Billion Shelf.

In 1997, pursuant to the \$500 Million Shelf, 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, 2006, no securities were outstanding under the \$400 million medium-term note program. At December 31, 2006 and 2005, we had \$100 million of long-term debt securities outstanding under the \$500 million shelf, as discussed above.

To protect against the potential increase in the fair value of our non-convertible, fixed interest rate notes due to a decline in interest rates, we entered into interest rate swap agreements that effectively convert the payment of our fixed rate notes to LIBOR-based variable interest payments over the life of the respective notes. These interest rate swap agreements qualify and are designated as fair value hedges. As of December 31, 2006 and 2005, \$2.2 billion and \$1.7 billion, respectively, aggregate face amount of our outstanding non-convertible, fixed interest rate debt was covered by these interest rate swap agreements.

Certain of our financing arrangements contain non-financial covenants and as of December 31, 2006, we are in compliance with all applicable covenants.

*Contractual maturities of long-term debt obligations*

The aggregate contractual maturities of all long-term debt obligations due subsequent to December 31, 2006, are as follows (in millions):

<b>Maturity date</b>	<b>Amount</b>
2007(1)	\$ 1,881
2008	
2009	1,000
2010	
2011	2,500
After 2011	3,635
<b>Total</b>	<b>\$ 9,016</b>

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

- (1) Included in this amount is the 2032 Modified Convertible Notes' accreted value on March 1, 2007, the next put date (see discussion of the 2032 Modified Convertible Notes above).

F-23

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. Stockholders' equity***Stockholder Rights Agreement*

We had an amended and restated preferred stock rights plan pursuant to which each share of common stock outstanding and each subsequently issued share had attached to them one whole preferred share purchase right (a "Right"). The Right represented the right to purchase one four-thousandth (1/4000) of a share of Series A Junior Participating Preferred Stock of Amgen at \$350.00. On July 11, 2006, Amgen's Board of Directors (the "Board") voted unanimously to terminate our preferred stock rights plan and accelerated the expiration date from December 2010 to July 31, 2006.

*Stock repurchase program*

A summary activity under our stock repurchase program for the years ended December 31, 2006, 2005 and 2004 is as follows (in millions):

	<b>2006</b>		<b>2005</b>		<b>2004</b>	
	<b>Shares</b>	<b>Dollars</b>	<b>Shares</b>	<b>Dollars</b>	<b>Shares</b>	<b>Dollars</b>
First quarter	46.6	\$ 3,374	26.8	\$ 1,675	10.1	\$ 650
Second quarter	13.0	876	12.1	750	17.4	1,000
Third quarter	7.3	505	9.5	769	24.0	1,398
Fourth quarter	3.3	245	14.8	1,236	17.6	1,024
<b>Total</b>	<b>70.2</b>	<b>\$ 5,000</b>	<b>63.2</b>	<b>\$ 4,430</b>	<b>69.1</b>	<b>\$ 4,072</b>

As of December 31, 2006, \$6.5 billion was available for stock repurchases under the \$5.0 billion repurchase authorization received from the Board in December 2006 and amounts remaining from the Board's previous authorization in December 2005. 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 and blackout periods in which we are restricted from repurchasing shares, and may include private block purchases as well as market transactions.

*Accumulated other comprehensive income*

Information regarding the components of accumulated other comprehensive income/(loss), net of tax, are as follows (in millions):

	<b>Net foreign currency translation</b>	<b>Other</b>	<b>Accumulated other comprehensive income</b>
Balance at December 31, 2005	\$ 6	\$ 16	\$ 22
Period change	39	(49)	(10)
<b>Balance at December 31, 2006</b>	<b>\$ 45</b>	<b>\$ (33)</b>	<b>\$ 12</b>

*Other*

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, \$0.0001 par value, of which 0.7 million shares have been reserved and designated Series A Preferred Stock. At December 31, 2006 and 2005, no shares of preferred stock were issued or



outstanding.

At December 31, 2006, we had reserved 267 million shares of our common stock, which may be issued through our option and stock purchase plans, through conversion of our convertible notes and through our warrants.

F-24

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Acquisitions***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 \$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. The purchase price, including cash paid to the former shareholders, the fair value of stock options assumed and transaction costs, was preliminarily allocated to IPR&D of \$130 million and other net assets acquired of \$30 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 \$125 million was assigned to goodwill. The estimated fair values of the 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 IPR&D was immediately expensed in the Consolidated Statement of Operations during the three months ended December 31, 2006 (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 25, 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.

*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 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):

In-process research and development	\$ 1,101
Identifiable intangible asset	320
Cash	252
Deferred tax assets, net	266
Property, plant and equipment	220
Other assets	75
Liabilities, principally debt	(738)
Goodwill	703
<b>Net assets acquired</b>	<b>\$ 2,199</b>

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

The estimated fair values of IPR&D, the identifiable intangible asset and property, plant and equipment were determined with the assistance of an independent valuation firm. The estimated fair values of the IPR&D

F-25

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

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 Abgenix's XenoMouse® technology that has alternative future uses in our R&D activities and will be amortized over its 5-year estimated useful life. The amount allocated to IPR&D was immediately expensed in the Consolidated Statement of Operations during the three months ended June 30, 2006 (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.

*Tularik Inc.*

On August 13, 2004, we acquired all of the outstanding common stock of Tularik in a transaction accounted for as a business combination. Tularik was a company engaged in drug discovery related to cell signaling and the control of gene expression. We issued 24 million shares of our common stock in the acquisition. Additionally, we issued 4 million stock options in exchange for Tularik stock options assumed in the acquisition. The purchase price of \$1.5 billion, which included the carrying value of our existing ownership interest in Tularik of approximately 21% or \$82 million, was allocated to IPR&D of \$554 million, other net assets acquired of \$188 million and goodwill of \$755 million. The amount allocated to IPR&D was immediately expensed in the Consolidated Statement of Operations during the three months ended September 30, 2004 (see Note 1, Summary of significant accounting policies—Acquired in-process research and development). The estimated fair value of these R&D projects was determined with the assistance of an independent valuation firm and was based on discounted after-tax cash flows adjusted for the probabilities of successful development and commercialization. The results of Tularik's operations have been included in our consolidated financial statements commencing August 14, 2004. Pro forma results of operations for the year ended December 31, 2004 assuming the acquisition of Tularik had taken place at the beginning of 2004 would not differ significantly from actual reported results.

**8. Commitments and contingencies***Commitments*

We lease certain administrative and laboratory facilities under non-cancelable operating leases that expire through December 2021. The following table summarizes the minimum future rental commitments under non-cancelable operating leases at December 31, 2006 (in millions):

<b>Year ended December 31,</b>	<b>Lease payments</b>
2007	\$ 96
2008	95
2009	102
2010	98
2011	87
Thereafter	752
<b>Total</b>	<b>1,230</b>
Less income from subleases	23
<b>Net minimum operating lease payments</b>	<b>\$ 1,207</b>

Rental expense on operating leases, net of sublease rental income, for the years ended December 31, 2006, 2005 and 2004 was \$69 million, \$48 million and \$45 million, respectively. Sublease income for the years ended December 31, 2006, 2005 and 2004 was not material.



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

We have supply agreements with various third-party contract manufacturers for the production, vialing and packaging of ENBREL and certain of our other products and product candidates. The following table summarizes the minimum contractual commitments to all third-party contract manufacturers at December 31, 2006 (in millions):

<b>Year ended December 31,</b>	<b>Commitments</b>
2007	\$ 230
2008	181
2009	182
2010	166
2011	169
Thereafter	157
<b>Total contractual purchases</b>	<b>\$ 1,085</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, 2006, 2005 and 2004 were \$333 million, \$386 million and \$268 million, respectively.

*Contingencies*

In the ordinary course of business, we are involved in various legal proceedings and other matters, including those that are tax-related. While it is not possible to accurately predict or determine the eventual outcome of these items, we do not believe any such items currently pending will have a material adverse effect on our consolidated financial position or liquidity, although an adverse resolution in any quarterly or annual reporting period of one or more of these items could have a material impact on the consolidated results of our operations for that period.

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. 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. 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>2006</b>	<b>2005</b>	<b>2004</b>
Product sales:			
Aranesp® U.S.	\$ 2,790	\$ 2,104	\$ 1,533
Aranesp® International	1,331	1,169	940
Neulasta® U.S.	2,217	1,900	1,476
NEUPOGEN® U.S.	830	805	778
Neulasta® International	493	388	264
NEUPOGEN® International	383	411	397
EPOGEN® U.S.	2,511	2,455	2,601
ENBREL® U.S.	2,736	2,470	1,827
ENBREL® International	143	103	73
Sensipar® U.S.	238	122	36
Sensipar® International	83	35	1
Vectibix® U.S.	39		
Other	64	60	51
<b>Total product sales</b>	<b>13,858</b>	<b>12,022</b>	<b>9,977</b>
Other revenues	410	408	573
<b>Total revenues</b>	<b>\$ 14,268</b>	<b>\$ 12,430</b>	<b>\$ 10,550</b>

**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 and Canada. 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. Information is as follows (in millions):

	<b>Years ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Revenues:</b>			
United States	\$ 11,782	\$ 10,298	\$ 8,847
Foreign countries	2,486	2,132	1,703
<b>Total revenues</b>	<b>\$ 14,268</b>	<b>\$ 12,430</b>	<b>\$ 10,550</b>

	<b>December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Long-lived assets:</b>			
United States	\$ 4,213	\$ 3,780	\$ 3,647
Foreign countries	1,708	1,258	1,065
<b>Total long-lived assets</b>	<b>\$ 5,921</b>	<b>\$ 5,038</b>	<b>\$ 4,712</b>

*Major customers*

In the United States, we sell primarily to wholesale distributors of pharmaceutical products. With the exception of ENBREL, we utilize these wholesale distributors as the principal means of distributing our products to healthcare providers such as clinics, dialysis centers, hospitals, and pharmacies. For wholesaler orders of ENBREL, we primarily drop-ship directly to pharmacies. Outside the United States, Aranesp®, Neulasta®, and NEUPOGEN® are principally distributed to hospitals and 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 appropriate credit limits, requiring collateral and obtaining credit insurance, where appropriate. We had three large wholesaler customers each accounting for more than 10% of total revenues for the years ended December 31, 2006, 2005 and 2004. On a combined basis, these distributors accounted for 61% and 73% of total gross revenues and U.S. gross product sales, respectively, for 2006, as noted in the following table (in millions):

	<b>Years ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>AmerisourceBergen Corporation</b>			
Gross product sales	\$ 6,523	\$ 5,593	\$ 3,519
% of total gross revenues	35%	34%	26%
% of U.S. gross product sales	42%	41%	32%
<b>Cardinal Health, Inc.</b>			
Gross product sales	\$ 2,490	\$ 2,752	\$ 1,909
% of total gross revenues	13%	17%	14%



# Edgar Filing: AMGEN INC - Form 10-K

% of U.S. gross product sales	16%	20%	18%
McKesson Corporation			
Gross product sales	\$ 2,427	\$ 2,534	\$ 2,094
% of total gross revenues	13%	15%	16%
% of U.S. gross product sales	15%	19%	19%

F-29

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

At December 31, 2006 and 2005, amounts due from these three large wholesalers each exceeded 10% of gross trade receivables, and accounted for 50% and 62%, respectively, of net trade receivables on a combined basis. At December 31, 2006 and 2005, 31% and 30%, 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, 2006 and 2005 was not material.

**10. Accrued liabilities**

Accrued liabilities consisted of the following (in millions):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Sales incentives	\$ 1,079	\$ 864
Employee compensation and benefits	1,068	737
Income taxes	1,057	476
Accrued royalties	189	230
Other	1,196	692
	<b>\$ 4,589</b>	<b>\$ 2,999</b>

**11. Fair values of financial instruments***Short-term assets and liabilities*

The fair value of available-for-sale investments is based on quoted market prices. The fair values of cash equivalents, accounts receivable and accounts payable approximate their carrying value due to the short-term nature of these financial instruments.

*2011 and 2013 Convertible Notes*

The 2011 and 2013 Convertible Notes are registered with the SEC and traded on the open market. The fair values of these convertible notes at December 31, 2006 were approximately \$2,465 million and \$2,488 million, respectively, and are based on quoted market prices.

*2032 Modified Convertible Notes*

The 2032 Modified Convertible Notes are registered with the SEC and traded on the open market. The fair value of these convertible notes at December 31, 2006 and 2005 were approximately \$1,769 million and \$1,837 million, respectively, and are based on quoted market prices.

*Medium and long-term notes*

The fair value of the 2009 Notes and the 2014 Notes at December 31, 2006 and 2005 was \$1,948 million and \$1,952 million, respectively. The fair values of the 2007 Notes and Century Notes at December 31, 2006 and 2005 were approximately \$236 million and \$249 million, respectively. The fair values for medium and long term notes were estimated based on quoted market rates for instruments with similar terms and remaining maturities.

*Derivative Financial Instruments*

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

The fair value of our derivative financial instruments, including our forward currency options and forward contracts and our interest rate swap agreements related to fixed-rate debt, was not material at December 31, 2006 or 2005.

F-30

**Table of Contents****AMGEN INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****12. Other**

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.

**13. Quarterly financial data (unaudited)**

	2006 Quarters ended(1)			
	Dec. 31(2)(3)	Sept. 30(4)(5)	June 30(6)	Mar. 31
	(In millions, except per share data)			
Product sales	\$ 3,737	\$ 3,503	\$ 3,491	\$ 3,127
Gross profit from product sales	3,176	3,014	2,998	2,575
Net income	833	1,102	14	1,001
Earnings per share(10):				
Basic	\$ 0.72	\$ 0.94	\$ 0.01	\$ 0.83
Diluted	\$ 0.71	\$ 0.94	\$ 0.01	\$ 0.82

  

	2005 Quarters ended			
	Dec. 31(7)	Sept. 30(8)	June 30(9)	Mar. 31
	(In millions, except per share data)			
Product sales	\$ 3,168	\$ 3,047	\$ 3,072	\$ 2,735
Gross profit from product sales	2,657	2,495	2,542	2,246
Net income	824	967	1,029	854
Earnings per share(10):				
Basic	\$ 0.67	\$ 0.78	\$ 0.83	\$ 0.68
Diluted	\$ 0.66	\$ 0.77	\$ 0.82	\$ 0.67

- (1) Beginning on January 1, 2006, we began recording expense associated with our stock options in accordance with SFAS No. 123R and elected not to apply this new accounting standard to our prior year financial statements. The amount of pre-tax expense recorded for each of the quarterly periods in 2006 was \$66 million, \$63 million, \$50 million and \$54 million for the quarter ended March 31, June 30, September 30 and December 31, 2006, respectively.
- (2) In the fourth quarter 2006, we recorded a charge of \$130 million related to the write-off of IPR&D related to the Avidia acquisition.
- (3) In the fourth quarter we recorded tax benefits for the retroactive extension of the R&D tax credit and from favorable audit settlements of \$35 million and \$27 million, respectively.
- (4) In the third quarter 2006, we recorded a charge of \$49 million related to the impairment of a non-ENBREL related intangible asset previously acquired in the Immunex acquisition.
- (5) In the third quarter 2006, we benefited \$60 million from favorable tax audit settlements.

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

- (6) In the second quarter 2006, we recorded a charge of \$1,101 million related to the write-off of IPR&D related to the Abgenix acquisition.
- (7) In the fourth quarter of 2005, we recorded a charge of \$43 million for the tax liability incurred as a result of repatriating certain foreign earnings under the American Jobs Act.
- (8) In the third quarter of 2005, we recorded a charge of \$47 million for writing off the cost of a semi-completed manufacturing asset that will not be used due to a change in manufacturing strategy.
- (9) In the second quarter of 2005, we recorded a charge of \$49 million for the impact of legal settlements incurred, net of amounts previously accrued, primarily related to settling a patent legal proceeding. Also in the second quarter of 2005, we benefited \$20 million from the termination of a manufacturing agreement with Genentech.
- (10) 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, 4, 7 and 12 for further discussion of the items described above.

F-31

**Table of Contents****SCHEDULE II****AMGEN INC.****VALUATION ACCOUNTS****Years ended December 31, 2006, 2005, and 2004****(In millions)**

	<b>Balance at beginning of period</b>	<b>Additions charged to costs and expenses</b>	<b>Other additions</b>	<b>Deductions</b>	<b>Balance at end of period</b>
<b>Year ended December 31, 2006:</b>					
Allowance for doubtful accounts	\$ 35	\$ 3	\$	\$	\$ 38
<b>Year ended December 31, 2005:</b>					
Allowance for doubtful accounts	\$ 29	\$ 7	\$	\$ 1	\$ 35
<b>Year ended December 31, 2004:</b>					
Allowance for doubtful accounts	\$ 27	\$ 2	\$	\$	\$ 29

F-32