

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d) of**  
**The Securities Exchange Act of 1934**

February 13, 2006  
Date of Report (Date of earliest event reported)

**AMGEN INC.**  
(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-12477**  
(Commission  
File Number)

**95-3540776**  
(I.R.S. Employer of  
Identification Number)

**Amgen Inc.**  
**One Amgen Center Drive**  
**Thousand Oaks, CA**  
(Address of Principal Executive Offices)

**91320-1799**  
(Zip Code)

**805-447-1000**  
(Registrant's Telephone Number, Including Area Code)

**N/A**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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**Item 7.01. Regulation FD Disclosure.**

The Company is filing updated risk factors set forth in the private offering memorandum for the notes offering referred to in Item 8.01 below with this Current Report on Form 8-K so that the updated risk factors will be disclosed pursuant to Regulation FD. A copy of the risk factors is attached hereto as Exhibit 99.1, is incorporated herein by reference.

**Item 8.01. Other Events.**

In a press release issued on February 13, 2006, Amgen Inc. (the "Company"), announced that it intends to offer convertible senior notes in a private offering, subject to market conditions and other factors. A copy of the press release is attached hereto as Exhibit 99.2, is incorporated herein by reference, and is hereby filed.

**Item 9.01. Financial Statements and Exhibits.**

<u>Exhibit No.</u>	<u>Document Description</u>
99.1	Risk Factors.
99.2	Press release dated February 13, 2006.

**SIGNATURE**

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

AMGEN INC.

Date: February 13, 2006

By: /s/ Richard D. Nanula

Name: Richard D. Nanula

Title: Executive Vice President and Chief Financial Officer

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Document Description</u>
99.1	Risk Factors.
99.2	Press release dated February 13, 2006.

## FACTORS THAT MAY AFFECT AMGEN

The following items are representative of the risks, uncertainties, and assumptions that could affect the outcome of the forward looking statements.

***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 example, F. Hoffmann-La Roche Ltd ("Roche") is developing a pegylated erythropoietin molecule that, according to Roche's public statements, they expect to bring to the US market despite their acknowledgement of our U.S. erythropoietin patents. On November 8, 2005, we filed a lawsuit against Roche for patent infringement of six of our U.S. patents. This lawsuit is described in "Part II Item 1. Legal Proceedings—Amgen Inc. v. F. Hoffman-LaRoche Ltd., et al." in our Form 10-Q for the quarter ended September 30, 2005. 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. For example, we are currently involved in an ongoing patent infringement lawsuit against Transkaryotic Therapies, Inc. ("TKT") and Aventis with respect to our erythropoietin patents. If we lose or settle current or future litigations at certain stages or entirely, we could be: subject to competition and/or significant liabilities; required to enter into third-party licenses for the infringed product or technology; or required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. We have filed applications for a number of patents and have been granted patents or obtained rights relating to erythropoietin, natural and recombinant G-CSF, darbepoetin alfa, pegfilgrastim, etanercept, and our other products and potential products. We market our erythropoietin, recombinant G-CSF, darbepoetin alfa, pegfilgrastim, and etanercept products as EPOGEN<sup>®</sup>, NEUPOGEN<sup>®</sup>, Aranesp<sup>®</sup>, Neulasta<sup>®</sup>, and ENBREL<sup>®</sup>, respectively. Our material patents are set forth below. With respect to our material patents, we have had a number of G-CSF patent expiries in the U.S. and one erythropoietin patent expiry in the EU.

Product		General Subject Matter	Expiration
Epoetin alfa	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
darbepoetin alfa	Europe(1)	— Glycosylation analogs of erythropoietin proteins	10/12/2010
		— Glycosylation analogs of erythropoietin proteins	8/16/2014
Filgrastim	U.S.	— DNA, vectors, cells and processes relating to recombinant G-CSF	3/7/2006
		— G-CSF polypeptides	12/3/2013
		— Methods of treatment using G-CSF polypeptides	12/10/2013
	Europe(1)	— G-CSF DNA Vectors, cells, polypeptides, methods of use and production	8/22/2006
	pegfilgrastim	U.S.	— Pegylated G-CSF
Europe(1)		— Pegylated G-CSF	2/8/2015
Etanercept	U.S.	— Methods of treating TNF — dependent disease	9/5/2009
		— TNFR proteins and pharmaceutical compositions	9/5/2009
		— TNFR DNA vectors, cells and processes for making proteins	10/23/2012

(1) In some cases these European patents may also be entitled to Supplemental Protection in one or more countries in Europe and the length of any such extension will vary country by country.

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; and hyperglycosylated erythropoietic proteins. Our principal European patent relating to erythropoietin expired on December 12, 2004 and our principal European patent relating to G-CSF expires on August 22, 2006. We believe that after the expiration of each of these patents, 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 “—Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do.”) While we do not market erythropoietin in Europe as this right belongs to Johnson & Johnson (through Kirin Amgen, Inc. (“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 cannot predict with certainty when the first biosimilar products could appear on the market in the EU. However, we expect that the first competing Epoetin alfa product, manufactured by Shire Pharmaceuticals Group plc, may appear on the market in the EU in the third quarter of 2006. Also, we expect that biosimilar erythropoietin products will be approved in the EU beginning in late 2006 and will be available in the EU shortly after approval. We also expect that the first biosimilar G-CSF product may be approved as early as mid-2007 and that it would also compete with Neulasta® and NEUPOGEN®. We cannot predict whether or to what extent the entry of biosimilar products would impact future Aranesp®, Neulasta® or NEUPOGEN® sales in the EU. The EU is currently in the process of developing regulatory guidelines related to the development and approval of biosimilar products. In July 2005, the European Agency for the Evaluation of Medical Products (“EMA”), issued clinical trial guidance for certain biosimilar products including

erythropoietins and granulocyte-colony stimulating factors, which guidance recommends that applicants seeking approval of such biosimilar products conduct fairly extensive pharmacodynamic, toxicological, clinical safety studies and a pharmacovigilance program. In October 2005, the EMEA confirmed that biosimilar products will be approved under a different legal pathway than the one applicable to generics of small molecule drugs. Based on the process and timing outlined by the EMEA, we believe relevant product specific guidelines are likely to be finalized by the first quarter of 2006. However, we cannot predict what final EMEA product specific guidelines will be.

***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 U.S. Food and Drug Administration ("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. Further, the time within which we can complete our clinical trials depends in large part on the rate of patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, enrollment criteria, the proximity of the patients to the trial sites, 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 patient enrollment 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. 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.

In 2006, we are expecting a significant increase in the number, size, duration and complexity of our clinical trials, in particular with respect to denosumab, our late stage investigational product for osteoporosis, and we expect total research and development expenses to increase by 30-40%. For example, testing denosumab in the osteoporosis setting requires large clinical trials, substantial time and resources to recruit patients and significant expense to execute. We expect to start eleven "mega-trials" (involving 200 or more sites) in 2006 to support denosumab and our other our late-stage programs. To execute our clinical trial program, we need to accelerate the growth of our development organization, implement new management structures and approaches and increase dependence on third-party contract clinical trial providers. Further, to increase the number of patients available for enrollment for our clinical trials, we are planning to open clinical sites and enroll patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, China, India and some South American countries. We plan to conduct clinical trial activities in these new territories through third-party contract clinical trial providers.

If we fail to adequately manage the increasing number, size and complexity 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.

***Our product development efforts may not result in 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 research and development 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 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 companies or people 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 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 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 maintain regulatory approval and comply with manufacturing regulations.” 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.”)



***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<sup>®</sup> 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 Centers for Medicare & Medicaid Services (“CMS”). Most patients receiving Aranesp<sup>®</sup>, Neulasta<sup>®</sup>, and NEUPOGEN<sup>®</sup> for approved indications are covered by both government and private payer health care programs. Beginning in 2006, ENBREL<sup>®</sup> and Sensipar<sup>®</sup> are eligible for coverage from the U.S. government under Medicare Part D. 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. Generally, worldwide use of our products may be affected by cost containment pressures and cost shifting from governments and private insurers on health care providers in response to ongoing initiatives to reduce health care expenditures.

The Medicare Prescription Drug Improvement and Modernization Act (or the “Medicare Modernization Act” (“MMA”)) was enacted into law in December 2003 and became effective 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 in 2005, we believe that our product sales were not significantly impacted by the reimbursement changes resulting from the MMA. We believe this was, in part, due to the effects of CMS’s oncology demonstration project (the “2005 Demonstration Project”) on sales of our products used in supportive cancer care, especially Aranesp<sup>®</sup>. Furthermore, we believe this was also, in part, due to increased reimbursement rates to physicians from CMS for services associated with drug administration. The 2005 Demonstration Project, which provided financial incentives to physicians for collecting and reporting oncology patient survey data, expired on December 31, 2005. In November 2005, CMS announced a new demonstration project (the “2006 Demonstration Project”) that uses different criteria for how patients with cancer are evaluated and treated and that is targeted at approximately half of the funding originally targeted for the 2005 Demonstration Project. The final rule for the 2006 Medicare Physician Fee Schedule Payment Final Rule issued in November 2005 reduced payments for physician services in 2006 by approximately 4.4% on average. However, recently passed legislation will eliminate this reduction for 2006. 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. However, we believe that it is not likely to be significant to our business in 2006.

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. Effective January 1, 2005, in the physician clinic setting, Aranesp<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup> 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<sup>®</sup> that we submit for the second quarter of 2006 will be based on certain historical sales and sales incentive data for Aranesp<sup>®</sup> from January 1, 2005 through December 31, 2005. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. The 2005 reimbursement rates for Aranesp<sup>®</sup> and Neulasta<sup>®</sup> (calculated at 106% of the ASPs) were lower than their respective 2004 reimbursement rates.

Although the ASPs for Aranesp<sup>®</sup> and Neulasta<sup>®</sup> have trended downward during 2005, they began to stabilize during the fourth quarter of 2005.

- Per the MMA, physicians in the physician clinic setting will have the choice between purchasing and billing for drugs under the ASP+6% system or obtaining drugs from vendors selected by CMS under the “competitive acquisition program” (“CAP”) starting in 2006. Physicians who select to obtain drugs from CAP will no longer purchase or obtain reimbursement directly for such drugs. CMS issued a final rule related to CAP in November 2005. Based on this final rule, the election period for 2006 will occur between April 1 and May 15, 2006 for participation from July 1 through December 31, 2006; the first drug deliveries through the CAP will occur in July 2006. Based on the final rule for CAP, we do not anticipate widespread adoption of this program initially. Nevertheless, because we cannot fully predict how many physicians will select to obtain drugs from CAP, we cannot predict the full impact of the CAP on our business. However, pursuant to the final rule, discounts to CAP vendors are excluded from the calculation of ASPs and therefore do not have the potential to impact the ASPs for our products that would be available through the CAP.
- 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<sup>®</sup> reimbursement rate was based on the AWP of PROCRTIT<sup>®</sup>. For 2005, the reimbursement rate for Aranesp<sup>®</sup> was 83% of the AWP for PROCRTIT<sup>®</sup>, down from 88% of the AWP for PROCRTIT<sup>®</sup> in 2004, with a dose conversion ratio of 330 U PROCRTIT<sup>®</sup> to 1 mcg Aranesp<sup>®</sup>, 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 affects Aranesp<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup> when administered in the hospital outpatient setting. In November 2005, CMS released its final OPPS rule for 2006. This final rule bases reimbursement for non-pass through products such as Aranesp<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup> on an ASP+6% using the same payment amounts as used in the physician clinic setting and does not apply an “equitable adjustment” to tie the reimbursement rate for Aranesp<sup>®</sup> to PROCRTIT<sup>®</sup> using a dose conversion ratio. In the final rule, CMS noted that it reserves the right to apply “equitable adjustment” to the Aranesp<sup>®</sup> reimbursement rate calculation methodology in years after 2006.
- Pursuant to final rules issued by CMS on November 3, 2004, Medicare reimbursement for EPOGEN<sup>®</sup> 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<sup>®</sup>) and the 2005 reimbursement rates for such drugs was added to the composite rate that dialysis providers receive for dialysis treatment. In November 2005, CMS released the 2006 Medicare Physician Fee Schedule Payment Final Rule. In the final rule, CMS stated that EPOGEN<sup>®</sup> and separately billed ESRD drugs will be reimbursable at ASP+6% in both freestanding and hospital-based dialysis centers. This final rule establishes the payment mechanism for separately reimbursed dialysis drugs in both freestanding and hospital-based dialysis centers, including EPOGEN<sup>®</sup> and Aranesp<sup>®</sup>, 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. Based on this final rule, we expect that the reimbursement rate for EPOGEN<sup>®</sup> will decrease for 2006 compared to 2005. Because we cannot accurately predict the extent to which this reduced reimbursement will impact how, or under what circumstances, healthcare providers will prescribe or administer EPOGEN<sup>®</sup>, we cannot estimate the full impact of the reduced reimbursement rate on our EPOGEN<sup>®</sup> product sales. However, we believe that it is not likely to be significant in 2006.

In addition, on November 9, 2005, CMS released a final 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”), will be effective April 1, 2006. The final 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 by twenty-five percent. 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 new 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 new policy will substantially impact the utilization of EPOGEN® and Aranesp®. However, we are currently in the process of further evaluating the new Claims Monitoring Policy. As a result, we cannot predict the potential full impact of this final guidance on our business.

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, health care 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. 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.

***Certain of our raw materials, medical devices and components are single-sourced from third parties; third-party supply failures could adversely affect our ability 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 due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, and/or due to unexpected demand, labor shortages or disputes. We would also be unable to obtain these materials, devices and components for an indeterminate period of time if such supply was subsequently found to not be in compliance with our quality standards or resulted in quality failures or product contamination and/or recall when used to manufacture, formulate, fill, or finish our products. 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 the shortages in the future resulting in delayed shipments, supply constraints, stock-outs and/or recalls 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 human serum albumin, or HSA. We are investigating alternatives to certain biological sources 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.

***Our current products and products in development cannot be sold if we do not maintain regulatory approval and comply with manufacturing regulations.***

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. In our experience, obtaining regulatory approval is costly and takes many years, and after it is obtained, remains costly to maintain. (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.”)

The FDA and other U.S. and foreign regulatory agencies have substantial authority to terminate clinical trials, require additional testing, delay or withhold registration and marketing approval, require changes in labeling of our products, and mandate product withdrawals. 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. 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. We currently manufacture and market all our approved principal products, and we plan to manufacture and market many of our potential products. (See “—Difficulties, disruptions or delays in manufacturing may limit supply of our products and limit our product sales.” 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.”) Even though we have obtained regulatory approval for our marketed products, these products and our manufacturing processes are subject to continued review by the FDA and other regulatory authorities. In addition, ENBREL<sup>®</sup> is manufactured both by us at our Rhode Island manufacturing facilities and by third-party contract manufacturers, including Boehringer Ingelheim Pharma KG (“BI Pharma”). Formulation, fill, and finish of bulk product produced at our Rhode Island manufacturing facilities is performed by us and third-party service providers and formulation, fill, and finish of bulk product manufactured at our other facilities that is currently solely performed by us may also be performed

by us and third-party service providers in the future. The third-party contract manufacturers and third-party service providers are also subject to FDA regulatory authority. (See “—Difficulties, disruptions or delays in manufacturing may limit supply of our products and limit our product sales.”) In addition, later discovery of unknown problems with our products or manufacturing processes or those of our contract manufacturers or third-party service providers could result in restrictions on the sale, manufacture, or use of such products, including potential withdrawal of the products from the market. For example, we have conducted a voluntary wholesaler recall of a limited number of lots of ENBREL<sup>®</sup> 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<sup>®</sup>. Although there have been no observable adverse event trends associated 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. If regulatory authorities determine that we or our 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 contract manufacturers or third-party service providers comply, or indefinitely. In addition, if regulatory authorities determine that we or our licensor or partner conducting research and development activities on our behalf have not complied with regulations in the research and development 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.

***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<sup>®</sup>, Aranesp<sup>®</sup>, NEUPOGEN<sup>®</sup> and Neulasta<sup>®</sup> and some formulation, fill, and finish operations for ENBREL<sup>®</sup> 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. Power failures, the breakdown, failure or substandard performance of equipment, the improper installation or operation of equipment, natural or other disasters, including hurricanes, or failures to comply with regulatory requirements, including those of the FDA, contamination or shortages of components used in the formulation, fill and finish of our products, among others, could adversely affect our formulation, fill, and finish operations. 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 has 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.

***Difficulties, disruptions or delays in manufacturing 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 maintain regulatory approval and comply with manufacturing regulations.”) Our ability to adequately and timely manufacture and supply our products is impacted by many manufacturing variables, such as availability of raw materials and components used in the manufacturing process, particularly those for which we have no other

source or supplier, facility capacity, the timing and actual number of production runs, production success rates, bulk drug yields, and the 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<sup>®</sup> experienced a brief period where no ENBREL<sup>®</sup> was available to fill patient prescriptions, primarily due to variation in the expected production yield from BI Pharma, our primary third-party manufacturer of ENBREL<sup>®</sup>. 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 are dependent on third parties for a significant portion of our bulk supply and the formulation, fill, and finish of ENBREL<sup>®</sup>.***

We currently produce a substantial portion of annual ENBREL<sup>®</sup> supply at our Rhode Island manufacturing facilities. However, we also depend on third parties for a significant portion of our ENBREL<sup>®</sup> bulk supply as well as for the formulation, fill, and finish of ENBREL<sup>®</sup> that we manufacture. BI Pharma is our third-party manufacturer of ENBREL<sup>®</sup> bulk drug; accordingly, our U.S. and Canadian supply of ENBREL<sup>®</sup> is currently significantly dependent on BI Pharma's production schedule for ENBREL<sup>®</sup>. We would be unable to produce ENBREL<sup>®</sup> in sufficient quantities to substantially offset shortages in BI Pharma's scheduled production if BI Pharma or other third-party manufacturers used for the formulation, fill, and finish of ENBREL<sup>®</sup> 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. This in turn could materially reduce our ability to satisfy demand for ENBREL<sup>®</sup>, which could materially and adversely affect our operating results. Among the factors that could affect our actual supply of ENBREL<sup>®</sup> at any time include, without limitation, BI Pharma's and Rhode Island facilities' bulk drug production scheduling. For example: BI Pharma does not produce ENBREL<sup>®</sup> 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<sup>®</sup> 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 dependent on third parties for some formulation, fill, and finish of ENBREL<sup>®</sup> 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, then supply of ENBREL<sup>®</sup> could be adversely affected materially.

Under a collaboration and global supply agreement, we and Wyeth share the total worldwide supply of ENBREL<sup>®</sup> produced by Amgen's Rhode Island manufacturing facilities, BI Pharma's manufacturing facility in Germany and Wyeth's manufacturing facility in Ireland. Our ENBREL<sup>®</sup> supply forecasts rely on certain assumptions of how much ENBREL<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> could be adversely affected.

***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 hiring of approximately 1,000 new staff into our research and development organizations in 2006
- we will need to assimilate new staff members and we will need to manage complexities associated with a larger, faster growing and geographically diverse organization
- we will need to significantly expand our clinical development resources to manage and execute increasingly 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 and operate a number of new manufacturing facilities and enter into and manage new third-party contract manufacturing arrangements, which may result in temporary inefficiencies and higher cost of goods
- we are implementing an enterprise resource planning system to support our increasingly complex business and business processes and such implementation 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.

***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<sup>®</sup> competes in certain circumstances with products marketed by Centocor, Inc., Johnson & Johnson, Abbott Laboratories, Biogen IDEC Inc., Genentech, Inc., Pfizer Inc., Novartis Corp., and Sanofi-Aventis, as well as the generic drug methotrexate, and may face competition from other potential therapies being developed. Additionally, Aranesp<sup>®</sup> 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<sup>®</sup> may face competition in the EU from another Epoetin alfa product produced by Shire Pharmaceuticals Group plc in the third quarter of 2006. Aranesp<sup>®</sup> and EPOGEN<sup>®</sup> may also face competition from Roche's pegylated erythropoietin molecule that, according to Roche's public statements, they expect to bring to the U.S. market despite their acknowledgement of our U.S. erythropoietin patents. (See "—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.") 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 principal European patent relating to erythropoietin expired on December 12, 2004 and our principal European patent relating to G-CSF expires on August 22, 2006. We believe that after the expiration of each of these patents, other companies will receive approval for and market biosimilar products to compete with our products in the EU, presenting additional competition to our products. While we do not market erythropoietin in Europe as this right belongs to Johnson & Johnson (through KA), we do market Aranesp<sup>®</sup> in the EU, which competes with Johnson & Johnson's EPREX<sup>®</sup> product, Roche's Neorecormon<sup>®</sup> product and others' erythropoietin products. We cannot predict with certainty when the first biosimilar products could appear on the market in the EU. However, we believe that biosimilar erythropoietin products will be approved in the EU beginning in late 2006 and will be available in the EU shortly after approval. We also expect that the first biosimilar G-CSF product may be approved as early as mid-2007 and that it would also compete with Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup>. We cannot predict whether or to what extent the entry of biosimilar products would impact future Aranesp<sup>®</sup>, Neulasta<sup>®</sup> or NEUPOGEN<sup>®</sup> sales in the EU. Our products may compete against products that have lower prices, superior performance, are easier to administer, or that are otherwise competitive with our products. Our inability to compete effectively could adversely affect product sales materially. The EU is currently in the process of developing regulatory guidelines related to the development and approval of biosimilar products. In July 2005, the EMEA issued clinical trial guidance for certain biosimilar products including erythropoietins and granulocyte-colony stimulating factors, which guidance recommends that applicants seeking approval of such biosimilar products conduct fairly extensive pharmacodynamic, toxicological, clinical safety studies and a pharmacovigilance program. In October 2005, the EMEA confirmed that biosimilar products will be approved under a different legal pathway than the one applicable to generics of small molecule drugs. Based on the process and timing outlined by the EMEA, we believe relevant product specific guidelines are likely to be finalized by the first quarter of 2006. However, we cannot predict what the final EMEA product specific guidelines will be.

Certain of our competitors, including biotechnology and pharmaceutical companies, market products or are actively engaged in research and development 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.

***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.***

A significant portion of our product sales are made to three pharmaceutical product wholesaler distributors, AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation. Sales to these three customers aggregated approximately 94% of total U.S. product sales in 2005. 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 independent free-standing dialysis clinics, which have recently experienced significant consolidation. Three of these free-standing dialysis clinics, DaVita Inc., Fresenius Medical Care North America, Inc., and Renal Care Group, Inc., account for approximately 70% of all EPOGEN<sup>®</sup> sales in the free-standing dialysis clinic setting. 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.



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

Under a co-promotion agreement, we and Wyeth market and sell ENBREL® in the United States and Canada. A management committee comprised of an equal number of representatives from us and Wyeth is responsible for overseeing the marketing and sales of ENBREL® including strategic planning, the approval of an annual marketing plan, 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 we 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” in our Form 10-K for the year ended December 31, 2004 and are updated as required in subsequently filed Form 10-Qs. In addition, in February 2006, we were served with 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. 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 Corporation, 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 health care 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, are 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” in our Form 10-K for the year ended December 31, 2004, 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 company products.

***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.***

If we or others identify side effects 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.

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. 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. 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 product could ultimately lead to the revocation of its marketing approval. The 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. The revision of product labeling or the regulatory actions described above could have a material adverse effect on sales of the affected products and on our business and results of operations. (See “—Our current products and products in development cannot be sold if we do not maintain regulatory approval and comply with manufacturing regulations.”)

***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, private health/science foundations, and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care 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. Organizations like these have in the past made recommendations about our products. Recommendations or guidelines that are followed by patients and health care providers could result in decreased use of our products. For example, we understand that the Agency for Healthcare Research and Quality (“AHRQ”) is currently preparing a report on erythropoietic stimulating proteins used in cancer treatment. To the extent that the report makes recommendations on the use of Aranesp<sup>®</sup>, use of this product could be affected. In addition, the perception by the investment community or stockholders that recommendations or guidelines will result in decreased use of our products could adversely affect prevailing market prices for our common stock.

***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, 2005, the trading price of our common stock has ranged from a high of \$86.17 per share to a low of \$57.20 per share. Our stock price may be affected by a number of factors, such as:

- changes in reimbursement policies or medical practices
- adverse developments regarding the safety or efficacy of our products
- actual or anticipated clinical trial results
- 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
- failure to complete the Abgenix, Inc. (“Abgenix”) acquisition

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 U.S. and to extensive regulation in foreign countries. (See “—Our current products and products in development cannot be sold if we do not maintain regulatory approval and comply with manufacturing regulations.” and “—Difficulties, disruptions or delays in manufacturing may limit supply of our products and limit our product sales.” 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.”) 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:

- changes in the government’s or private payers’ reimbursement policies for 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
- 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.

***We may not realize all of the anticipated benefits of our merger with Abgenix, Inc.***

On December 14, 2005, we announced that we had signed a definitive merger agreement under which we would acquire Abgenix for approximately \$2.2 billion in cash plus the assumption of debt. The acquisition will provide us with full ownership of panitumumab and eliminate a tiered royalty on denosumab, two of our most important advanced pipeline products, as well as provide us with Abgenix's manufacturing plant. The success of the merger will depend, in part, on our ability to realize the anticipated growth opportunities from integrating the businesses. In particular, this will require the successful regulatory approval and commercial launch of panitumumab along with production of panitumumab at Abgenix's manufacturing plant. The integration of two independent companies is a complex, costly, and time-consuming process.

In addition, even if we are able to successfully integrate Abgenix's operations, this integration may not result in the realization of the full benefits of the growth opportunities that we expect to result from the merger, or we may not achieve the expected benefits within the anticipated time frame. Further, the benefits from the merger may be offset by costs incurred in integrating the two companies. We cannot assure you that the integration of Abgenix with us will result in the realization of the full post-merger benefits anticipated by us. Our failure to achieve these benefits could have a material and adverse effect on our results of operations.

***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. 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 effect on our results of operations.



News Release

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### **Amgen to Offer \$4.0 Billion Convertible Senior Notes; Company to Purchase Approximately \$3.0 Billion in Common Stock**

THOUSAND OAKS, Calif. – (Feb. 13, 2006) – Amgen (Nasdaq: AMGN), the world’s largest biotechnology company, today announced its intention to offer, subject to market and other conditions, approximately \$2.0 billion principal amount of Convertible Senior Notes due 2011 and approximately \$2.0 billion principal amount of Convertible Senior Notes due 2013 through offerings to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the “Securities Act”). In certain circumstances, the notes may be convertible into cash up to the principal amount. With respect to any excess conversion value, the notes may be convertible into cash, shares of Amgen common stock or a combination of cash and common stock, at Amgen’s option. The interest rate, conversion price and other terms are to be determined by negotiations between Amgen and the initial purchasers of the notes. Amgen also expects to grant the initial purchasers an option to purchase additional notes to cover overallocments.

Amgen expects to use the net proceeds from the offering and the proceeds of the warrant transactions referred to below to purchase approximately \$3.0 billion worth of shares of its common stock, some of which may be purchased contemporaneously with the closing of the sale of the notes, including through private block trades with one or more of the initial purchasers and/or their affiliates. In addition, proceeds from the transactions will be used to fund convertible note hedge transactions that Amgen expects to enter into with one or more of the initial purchasers of the notes and/or their affiliates. These convertible note hedge transactions are intended to offset the dilution to Amgen’s common stock upon potential future conversion of the notes. Amgen will enter into separate warrant transactions with one or more of the initial purchasers and/or their affiliates. Any remaining proceeds will be added to Amgen’s working capital and will be used for general corporate purposes.

This notice does not constitute an offer to sell or the solicitation of an offer to buy securities. Any offers of the securities will be made only by means of a private offering memorandum. The notes and the shares of Amgen common stock issuable upon conversion have not been, and will not be, registered under the Securities Act or the securities laws of any other jurisdiction and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

#### **About Amgen**

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the

new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a broad and deep pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit [www.amgen.com](http://www.amgen.com).

#### **Forward-Looking Statement**

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in our Form 10-K for the year ended December 31, 2004, and in our periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Amgen's results may be affected by our ability to successfully market both new and existing products domestically and internationally, sales growth of recently launched products, difficulties or delays in manufacturing our products, and regulatory developments (domestic or foreign) involving current and future products and manufacturing facilities. In addition, sales of our products are affected by reimbursement policies imposed by first party payors, including governments, private insurance plans and managed care providers, and may be affected by domestic and international trends toward managed care and healthcare cost containment as well as possible US legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of our products. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We, or others could identify side effects or manufacturing problems with our products after they are on the market. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. In addition, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors. Further, some raw materials, medical devices, and component parts for our products are supplied by sole third party suppliers.

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