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

May 22, 2007
Date of Report (Date of earliest event reported)

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

Delaware	**000-12477**	**95-3540776**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer of Identification Number)**

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA **91320-1799**
(Address of Principal Executive Offices) **(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))

Item 7.01 Regulation FD Disclosure.

The Company is filing recent developments, updated risk factors and updated legal proceedings with this Current Report on Form 8-K so that the recent developments, updated risk factors and updated legal proceedings will be disclosed pursuant to Regulation FD. A copy of the recent developments is attached hereto as Exhibit 99.1, risk factors is attached hereto as Exhibit 99.2 and legal proceedings is attached hereto as Exhibit 99.3, and are all incorporated herein by reference.

All statements included or incorporated by reference in this report, other than statements of historical facts, that address activities, events or developments that the Company intends, expects, projects, believes or anticipates will or may occur in the future are forward looking statements. This report contains forward looking statements that are based on current expectations, estimates, forecasts and projections about the Company and the Company's future performance, business, beliefs and management's assumptions. Words such as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume," or "continue," and variations of such words and similar expressions are intended to identify such forward looking statements. These statements are not guarantees of future performance and involve certain risks, uncertainties, and assumptions that are difficult to predict. The Company describes some of the risks, uncertainties, and assumptions that could affect the outcome or results of operations in "Risk Factors" in the Company's reports filed with the SEC, including the factors incorporated by reference herein. The Company has based the forward looking statements on management's beliefs and assumptions based on information available to management at the time the statements are made. Actual outcomes and results may differ materially from what is expressed, implied or forecast by the forward looking statements. Reference is made in particular to forward looking statements regarding product sales, reimbursement, expenses, earnings per share, liquidity and capital resources, and trends. Except as required under the federal securities laws and the rules and regulations of the SEC, the Company does not have any intention or obligation to update publicly any forward looking statements contained in this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Item 8.01 Other Events.

The disclosure set forth in 7.01 above is incorporated herein by reference.

Item 9.01 FinancialStatements and Exhibits.

Exhibit No.	Document Description
99.1	Recent Developments.
99.2	Risk Factors.
99.3	Legal Proceedings.

SIGNATURE

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

AMGEN INC.

Date: May 22, 2007

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

RECENT DEVELOPMENTS

We previously reported that the FDA had scheduled a meeting of its Oncologic Drugs Advisory Committee ("ODAC") and on May 10, 2007, the ODAC held a panel meeting to discuss the safety/efficacy profile of erythropoiesis-stimulating agents ("ESAs"), including Aranesp® and EPOGEN®. The ODAC is an advisory committee of external experts who advise the U.S. Food and Drug Administration ("FDA") about the safety and efficacy of drug products for use in treating cancer. This committee is advisory only and FDA officials are not bound or limited by its recommendations. However, the FDA commonly follows the recommendations of its advisory panels.

Responding to questions posed in advance by the FDA, the seventeen ODAC members voted on these questions and the results of these votes, as follows, could limit the use of our ESAs:

- Fifteen of the panel members voted to recommend additional restrictions on ESA labels;
- The panel voted unanimously to recommend additional clinical trials be conducted to more clearly define the benefits and risks associated with the use of ESAs;
- Twelve of the panel members voted to recommend additions to ESA labels to state that ESAs are not indicated for use in specific tumor types;
- Fifteen of the panel members voted to recommend a defined hemoglobin level in asymptomatic patients for initiation of treatment with ESAs; and
- Sixteen panel members voted to recommend changes to ESA labels recommending discontinuation of ESA therapy following the completion of a chemotherapy regimen and reevaluation of the degree of anemia with subsequent chemotherapy regimen.

However, eleven of the seventeen panel members voted against recommending lowering the upper limit of the hemoglobin range in the current ESA labels.

While the ODAC recommended that more restrictions be added to ESA labels and that additional clinical trials be conducted by companies with currently approved ESAs, including us, no specific restrictions or studies were recommended. Although not required, the FDA will likely take into consideration the recommendations by the ODAC and will decide what updates to the ESA labels are necessary and whether additional clinical trials for ESAs should be conducted and how those trials should be designed. The further restrictions to the prescribing information of the ESA labels may include i) limiting use of ESAs in certain tumor types, ii) establishment of a threshold hemoglobin level before therapy with ESAs may be initiated, and iii) limiting when and how long post-chemotherapy treatment ESAs should be used. The FDA has not publicly communicated a timeline to discuss the recommendations from the ODAC, although we expect the FDA will act in a timely manner. In addition, the FDA has stated that it intends to hold a meeting of the Cardio Renal Drugs Advisory Committee in the fall of 2007, to review the use of ESAs in the renal setting.

Further, on March 14, 2007, shortly after the label changes for all ESAs, the Centers for Medicare and Medicaid Services ("CMS") announced that the agency had begun reviewing all Medicare policies related to the administration of ESAs in non-renal disease applications as part of a national coverage analysis ("NCA") which is generally CMS' first step toward developing a national coverage determination ("NCD"). Generally, a NCD is a national policy statement granting, limiting or excluding Medicare coverage or reimbursement for a specific medical item or service. During the initial comment period which ended on April 13, 2007, we submitted comments to CMS which included a detailed and thorough review of the available clinical data, noted a series of important considerations and made a

number of specific recommendations for the agency to consider in developing a NCD. On May 14, 2007, CMS issued its Proposed National Coverage Decision Memorandum for Use of Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions (the "Proposed NCD"), which under the Medicare Prescription Drug Improvement and Modernization Act (the "MMA"), is subject to a 30-day public comment period ending June 13, 2007, before being finalized 60 days after the conclusion of the public comment period on August 12, 2007. In the Proposed NCD, CMS listed 13 oncology-related conditions for which CMS would deny Medicare coverage of Aranesp® and Johnson & Johnson's Procrit® for the treatment of anemia. CMS stated that it has proposed denying coverage because the agency believes that treatment with ESAs in these conditions is not reasonable and necessary either because of a deleterious or worse effect of the ESA on the underlying disease or because the underlying cancer increases the risk of adverse effects related to ESA use. The 13 conditions which CMS has proposed denying coverage are:

- any anemia in cancer or cancer treatment patients due to folate deficiency, deficiency, hemolysis, bleeding, or bone marrow fibrosis;
- the anemia of myelodysplasia;
- the anemia of myeloid cancers;
- the anemia associated with the treatment of myeloid cancers or erythroid cancers;
- the anemia of cancer not related to cancer treatment;
- any anemia associated with radiotherapy;
- prophylactic use to prevent chemotherapy-induced anemia;
- prophylactic use to reduce tumor hypoxia;
- patients with erythropoietin-type resistance due to neutralizing antibodies;
- patients with treatment regimens including anti-angiogenic drugs such as bevacizumab (Avastin®);
- patients with treatment regimens including monoclonal/polyclonal antibodies directed against the epidermal growth factor (EGF) receptor (Erbitux® and Vectibix™);
- anemia due to cancer treatment if patients have uncontrolled hypertension; and
- patients with thrombotic episodes related to malignancy.

In the Proposed NCD, CMS also proposed new limits on the permitted Medicare coverage of ESAs in certain types of cancers, including breast, lung, prostate and colorectal, which account for the most common solid tumor cancer cases in the United States. The cancer types other than the solid tumor cancers enumerated above include but are not necessarily limited to: bone (sarcoma), brain neurologic, cervical, gastric, head-and-neck (squamous cell), hepatic, lymphoma, melanoma, multiple myeloma, muscle including cardiac, ovarian, pancreatic (exocrine), retinal and uterine. CMS also proposed that use of ESAs in these cancers is only reasonable and necessary under conditions in which the presence of erythropoietin receptors on either normal tissue/cell lines or malignant tissue/cell lines has been reported in literature. As proposed, Medicare coverage of ESAs in these types of cancers would be limited under new dosing and treatment restrictions including:

- initial treatment with ESAs would be limited in patients with hemoglobin/hematocrit levels immediately prior to initiation of dosing for the month should be < 9 g/dL or 27 percent in patients without known cardiovascular disease and < 10 g/dL or 30 percent in patients with documented symptomatic ischemic disease that cannot be treated with blood transfusion;
- the maximum duration of covered treatment would be 12 weeks per year; and
- the maximum covered 4 week treatment dose would 126,000 units for erythropoietin and 630 mcg for darbepoetin.

CMS also stated in the Proposed NCD that:

- continued use of the drug (ESA) is not reasonable and necessary if there is evidence of poor drug response (hemoglobin/hematocrit rise < 1 g/dL or < 3%) after 4 weeks of treatment;
- continued administration of the drug (ESA) is not reasonable and necessary if there is an increase in fluid retention or weight (5 kg) after 2 weeks of treatment; and
- continued administration of the drug (ESA) is not reasonable and necessary if there is a rapid rise in hemoglobin/hematocrit > 1 g/dL or > 3% after 2 weeks of treatment.

Any Medicare reimbursement coverage decisions finalized by CMS in an NCD for treatment of anemia in cancer would likely be followed and implemented by private payers. Further, physicians may reduce use and dose of ESAs and private payers may accelerate reimbursement decisions in anticipation of the final NCD.

Additionally, CMS stated that, in light of the issues discussed in our review of the evidence and serious safety concerns voiced in the May 10, 2007 ODAC meeting, they were interested in public comment on whether coverage for ESA therapy for Medicare beneficiaries with cancer should occur only within appropriately designed clinical research studies where informed consent and safety monitoring can be assured. Lastly, in conjunction with CMS' announcement that it had begun reviewing all Medicare policies related to the administration of ESAs in non-renal disease applications on March 14, 2007, CMS also stated that the agency is currently reviewing the Claims Monitoring Policy: erythropoietin/darbepoetin alfa usage for beneficiaries with end stage renal disease ("EMP") for patients with End Stage Renal Disease ("ESRD") who are dialyzed in renal facilities although they have not yet announced further changes to the EMP.

These recent developments are likely to have a negative affect on use, reduce reimbursement and coverage and negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations. Future worldwide sales of Aranesp® and EPOGEN® will be dependent, in part, on the outcome and impact of these recent developments. However, management has begun taking actions to reduce operating expense growth to help minimize the impact of declines in revenue growth on our operating results. In addition, while we cannot accurately predict the impact of these recent developments on how, or under what circumstances, healthcare providers will prescribe or administer our products and we cannot estimate the full impact of the MMA on our business, we believe that it is likely to be significant to our business in 2007. Further, any changes to the EMP or an NCD for ESAs in the renal setting, which may include non-coverage and/or new dosing and treatment restrictions similar to those proposed in the Proposed NCD for treatment of anemia in oncology with ESAs, would negatively effect use, reduce reimbursement and coverage, negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations. (See Risk Factors *"—The results of the May 10, 2007 ODAC panel meeting on ESAs are likely to result in the FDA requiring us to perform additional clinical trials and/or change the labeling of ESAs." "—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 product." and "—Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or take other potentially limiting or costly actions if we or others identify side effects after our products are on the market.")*

As we have previously reported, F. Hoffman-La Roche Ltd. ("Roche") is developing a pegylated erythropoietin molecule ("peg-EPO") for which they have filed a biologic license application ("BLA") with the FDA and which Roche announced on May 18, 2007 that the FDA had issued an approvable letter for MIRCERA® for the treatment of anemia associated with chronic renal failure including patients on dialysis and patients not on dialysis. Roche stated that it has received a draft label from the FDA and expects the label to be finalized after the Cardiovascular and Renal Drugs Advisory Committee has issued its recommendations on the entire class of ESAs. The FDA stated that it intends to hold a meeting of the Cardio Renal Drugs Advisory Committee in the fall of 2007. According to Roche's public statements, they expect to launch the molecule in the U.S. nephrology segment in 2007, upon regulatory approval, despite our ongoing lawsuit and their acknowledgement of our U.S. erythropoietin patents. (See 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.")

We had previously announced that we had discontinued Vectibix™ treatment in our Panitumumab Advanced Colorectal Cancer Evaluation ("PACCE") trial, a non-registration-enabling trial evaluating the addition of Vectibix™ to standard chemotherapy and Avastin® (bevacizumab) for the treatment of first-line metastatic colorectal cancer. We are in discussions with the FDA with respect to the Vectibix™ label and expect that we will add the data from the PACCE trial to the label. The language is still in development, discussions with the FDA are on-going and any label change is subject to FDA approval. Further, we continue to be in discussions with European Medicines Agency (the "EMEA") and the Committee for Medicinal Products for Human Use ("CHMP") with respect to the approval of Vectibix™ in the European Union (the "EU") to treat patients with metastatic colorectal cancer whose disease has progressed on or following all standard chemotherapy regimens. We expect to hear from the CHMP on May 25, 2007, and in the event that we should not obtain an initial positive CHMP opinion, we can request re-examination of the CHMP opinion as part of the EU regulatory process. (See Risk Factors *"—Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or take other potentially limiting or costly actions if we or others identify side effects after our products are on the market.")*

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.

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. 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 or take other potentially limiting or costly actions 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.

We have substantially expanded our research and development ("R&D") 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. In the near term, 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. However, as a result of recent regulatory and reimbursement challenges related to Aranesp® and EPOGEN®, we have been and will continue to assess the optimal level of our R&D investment. To the extent future sales of Aranesp® and EPOGEN® are negatively impacted as a result of these recent events, we may defer or possibly cancel previously planned clinical trials in order to adjust our R&D investment plans. Such actions could delay obtaining approval or reduce the number of indications and market potential of our product candidates. In order to increase the number of patients available for enrollment for our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, China, India and some Central and South American countries utilizing third-party contract clinical trial providers. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to identify and understand the unique regulatory environments of individual countries. If we fail to adequately manage our increasingly larger, more complex and regulatory diverse clinical trials, our clinical trials and corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates altogether. If we are unable to market and sell our product candidates or are unable to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations would be materially adversely affected. Additional information on our clinical trials can be found on our website at (http://www.amgen.com). (This website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.)

Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or take other potentially limiting or costly actions 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 Centers for Medicare and Medicaid Services ("CMS"), as well as in foreign countries, such as the European Medicines Agency ("EMEA") in 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 U.S. Government Accountability Office ("GAO"), the United States Senate Committee on Finance, private health/science foundations and organizations, medical professionals, including physicians and investigators, and the general public are increasingly concerned about potential or perceived safety issues associated with pharmaceutical and biological products, whether under study for initial approval or already marketed. For example, we received a letter from Chairmen Dingell and Stupak of the House Subcommittee on Oversight and Investigation, Committee on Energy and Commerce posing questions around erythropoiesis-stimulating agent ("ESA") studies, promotions of ESAs, communications with the FDA and sales to physicians. We also received a letter from the United States Senate Committee on Finance requesting a briefing to discuss the issues and concerns reported in the media as to the marketing and safety of ESAs and our cooperation with the FDA. It has also been reported that Representative Pete Stark, who chairs the House Ways and Means Health Subcommittee, sent a Dear Colleague letter to other members of Congress requesting that they join his quest to overhaul Medicare reimbursement policy to curb ESA overuse due to safety concerns. As a result, safety signals from clinical trials or other sources are receiving greater scrutiny which may lead to fewer treatments being approved by the FDA or other regulatory bodies, termination of clinical trials before completion or 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 or from the marketed use of our drugs 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. (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.")* For example on March 9, 2007, based upon data from our Anemia of Cancer 103 study ("AoC 103 Study"), Johnson & Johnson's Correction of Hemoglobin and Outcomes In Renal Insufficiency ("CHOIR") study, and preliminary data from the third-party investigator Danish Head and Neck Cancer (DAHANCA) 10 Study, among others, the FDA approved updated safety information, including a boxed warning, in the prescribing information for the class of ESAs, including Aranesp® and EPOGEN®. The new boxed warning notes that ESAs, when administered to target a hemoglobin of greater than 12 g/dL: i) increased the risk for death and serious cardiovascular events; ii) shortened time to tumor progression in patients with advanced head and neck cancer receiving radiation therapy; and iii) shortened overall survival and increased deaths attributed to disease progression at four months in patients with metastatic breast cancer receiving chemotherapy. Physicians were advised in the boxed warning to use the lowest dose of ESAs that will gradually increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusions, and not to exceed 12 g/dL. The EMEA has also reported that it is reviewing the safety of ESAs, made by us, Johnson & Johnson, Shire Pharmaceuticals Group ("Shire") and F. Hoffman-La Roche Ltd. ("Roche"). Further, the FDA held a meeting of the Oncologic Drugs Advisory Committee ("ODAC") on May 10, 2007, at which the panel discussed the safety/efficacy profile of ESAs, including Aranesp® and EPOGEN®. (See *"—The results of the May 10, 2007 ODAC panel meeting on ESAs may result in the FDA requiring us to perform additional clinical trials and/or change the labeling of ESAs.")*

In addition, we recently announced that we had discontinued Vectibix™ treatment in our Panitumumab Advanced Colorectal Cancer Evaluation ("PACCE") trial, a non-registration-enabling trial evaluating the addition of Vectibix™ to standard chemotherapy and Avastin® (bevacizumab) for the

treatment of first-line metastatic colorectal cancer. The PACCE trial investigated a treatment regimen that used dual biologics combined with oxaliplatin- or irinotecan-based chemotherapy. The decision to discontinue Vectibix™ treatment in the trial was based on a preliminary review of data from a pre-planned interim efficacy analysis which revealed a statistically significant difference in progression-free survival in favor of the control arm. An unplanned analysis of overall survival also demonstrated a statistically significant difference favoring the control arm. We had previously informed investigators and regulatory authorities about safety information from a planned interim safety analysis of the PACCE trial which showed an increased incidence of grade 3 severe events of diarrhea, dehydration and infections in the Vectibix™-treated patients and additionally an increased incidence of pulmonary embolism was observed in patients who received Vectibix™ compared with those who did not. We are in discussions with the FDA with respect to the Vectibix™ label and expect that we will add the data from the PACCE trial to the label. The language is still in development, discussions with the FDA are on-going and any label change is subject to FDA approval. Further, we continue to be in discussions with EMEA and the Committee for Medicinal Products for Human Use ("CHMP") with respect to the approval of Vectibix™ in the European Union ("EU") to treat patients with metastatic colorectal cancer whose disease has progressed on or following all standard chemotherapy regimens. We expect to hear from the CHMP on May 25, 2007 and in the event that we should not obtain an initial positive CHMP opinion, we can request re-examination of the CHMP opinion as part of the EU regulatory process.

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™ pre-filled pen or with the reports of missing, detached or loose rubber caps with the needle less syringe packaged with the ENBREL vials, 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 or other safety concerns before or after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn, reformulation of our products may be required or other risk management activities may be imposed by regulators, additional clinical trials may be required, changes in labeling of our products, changes in guidelines and reimbursement 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. (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."*) Regulatory agencies such as the FDA could require us to engage in risk management activities which could modify or restrict our existing promotional activities, restrict or encumber the ability of healthcare providers to prescribe, dispense or use our products or limit patient access to our products. Certain specific labeling 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, subsequent concerns about the sufficiency of the data or studies underlying the label or changes to the underlying safety/efficacy analysis related to changes in clinical practice and options. 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-epidermal growth factor receptor ("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 has instituted a class label change for the three ESAs marketed in the United States to add information about pure red cell aplasia ("PRCA") to the adverse event profile section and for the boxed warning in the prescribing information of the label described above.

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 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, new indication or information to support a current indication, 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.

The results of the May 10, 2007 ODAC panel meeting on ESAs are likely to result in the FDA requiring us to perform additional clinical trials and/or change the labeling of our ESAs.

On May 10, 2007, the ODAC held a panel meeting to discuss the safety/efficacy profile of ESAs, including Aranesp® and EPOGEN®. The ODAC is an advisory committee of external experts who advise the FDA about the safety and efficacy of drug products for use in treating cancer. This committee is advisory only and FDA officials are not bound or limited by its recommendations. However, the FDA commonly follows the recommendations of its advisory panels.

Responding to questions posed in advance by the FDA, the seventeen ODAC members voted on these questions and the results of these votes, as follows, could limit the use of our ESAs:

- Fifteen of the panel members voted to recommend additional restrictions on ESA labels;
- The panel voted unanimously to recommend additional clinical trials be conducted to more clearly define the benefits and risks associated with the use of ESAs;
- Twelve of the panel members voted to recommend additions to ESA labels to state that ESAs are not indicated for use in specific tumor types;
- Fifteen of the panel members voted to recommend a defined hemoglobin level in asymptomatic patients for initiation of treatment with ESAs; and
- Sixteen panel members voted to recommend changes to ESA labels recommending discontinuation of ESA therapy following the completion of a chemotherapy regimen and reevaluation of the degree of anemia with subsequent chemotherapy regimen.

However, eleven of the seventeen panel members voted against recommending lowering the upper limit of the hemoglobin range in the current ESA labels.

While the ODAC recommended that more restrictions be added to ESA labels and that additional clinical trials be conducted by companies with currently approved ESAs, including us, no specific restrictions or studies were recommended. Although not required, the FDA will likely take into consideration the recommendations by the ODAC and will decide what updates to the ESA labels are necessary and whether additional clinical trials for ESAs should be conducted and how those trials should be designed. The further restrictions to the prescribing information of the ESA labels may include i) limiting use of ESAs in certain tumor types, ii) establishment of a threshold hemoglobin level before therapy with ESAs may be initiated, and iii) limiting when and how long post-chemotherapy treatment ESAs should be used. The FDA has not publicly communicated a timeline to discuss the recommendations from the ODAC, although we expect the FDA will act in a timely manner.

Although we cannot predict what action the FDA may take or the extent or impact of any such action, any restrictions to the labels of Aranesp® and EPOGEN® described above that may be required by the FDA are likely to negatively impact healthcare provider prescribing behavior, use of our ESA products, regulatory or private health organization medical guidelines, reimbursement and sales for our ESA products, which could have a material adverse effect on our business and results of operations. In addition, as the EMEA is currently reviewing the safety of ESAs made by us, Johnson & Johnson, Shire and Roche, if the EMEA were to add restrictions to the labels, it is likely to have a negative impact on the use, reimbursement and sales of Aranesp® in Europe. Further, the results of this ODAC meeting may result in oncologists exercising increasing caution with respect to the use of ESAs in certain therapeutic areas and the acceleration of further reimbursement constraints by payers in anticipation of regulatory action, both of which could have material adverse effect on the use and sales of Aranesp® and our business and the results of operations. Further, on May 14, 2007, CMS issued its Proposed National Coverage Decision Memorandum for Use of Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions following the close of its national coverage analysis ("NCA") and review of data and comments submitted as part of the NCA which if finalized in its proposed or similar form would have a material adverse effect on the use, reimbursement and sales of Aranesp®, and our business and results of operations. (S*ee "—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.")* The ODAC's recommendation for additional clinical trials of ESAs could result in substantial additional expense or additional label restrictions and may have a material adverse effect on our business and results of operations, and any negative results from such trials could materially effect the use, reimbursement and sales of our ESA products. (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.")* Further, the FDA has stated that it intends to hold a meeting of the Cardio Renal Drugs Advisory Committee in the fall of 2007, to review the use of ESAs in the renal setting. We cannot predict what action the FDA may take as a result of such committee meeting.

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.

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, in Europe and other countries outside the United States, 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 or to affect levels of use of our products. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to healthcare providers in response to ongoing initiatives to reduce

healthcare expenditures. Further, adverse events or results from clinical trials or studies performed by us or by others or from the marketed use of our drugs may expand safety labeling for our approved products and may negatively impact worldwide reimbursement for our products. On May 14, 2007, CMS issued its Proposed National Coverage Decision Memorandum for Use of Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions (the "Proposed NCD") following the close of its NCA and review of data and comments submitted as part of the NCA that, if put into effect as proposed or in a similar form, would have a material adverse effect on the use, reimbursement and sales of Aranesp® and our business and results of operations. A complete discussion of the NCA follows below. (See also *"—Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or take other potentially limiting or costly actions if we or others identify side effects after our products are on the market."* and *"—Guidelines and recommendations published by various organizations can reduce the use of our products.")* In addition, Senator Charles Grassley from the United States Senate Committee on Finance sent letters to the FDA, CMS and to us expressing interest in the use of ESAs in cancer and End Stage Renal Disease ("ESRD") patients and has requested meetings with each of the three. To the extent that there is resulting legislation or changes in CMS or FDA policy as a result of Senator Grassley's concerns, such changes could have a material or adverse effect on the use of our ESA products.

Most patients receiving Aranesp®, Neulasta® and NEUPOGEN® for approved indications are covered by both government and private payer healthcare programs. Government healthcare programs are governed by the Medicare Prescription Drug Improvement and Modernization Act (the "MMA") which was enacted into law in December 2003 and became effective January 1, 2005. Since January 1, 2005, in the physician clinic setting and since January 1, 2006, in the hospital outpatient setting, Aranesp®, Neulasta® and NEUPOGEN® have been 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 third quarter of 2007 will be based in part on certain historical sales and sales incentive data for Aranesp® from April 1, 2006 through March 30, 2007. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. 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. Prior to January 1, 2006, 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 the average wholesale price ("AWP") as the basis of Medicare Part B payment for covered outpatient drugs and biologics administered in the hospital outpatient setting. From 2003 to 2005, CMS applied an "equitable adjustment" such that the Aranesp® reimbursement rate was based on the AWP of PROCRIT®, Johnson & Johnson's recombinant human erythropoietin product marketed in the United States, using a dose conversion ratio. In 2006 and 2007, CMS did not apply an "equitable adjustment" to tie the reimbursement rate for Aranesp® to PROCRIT®. However, CMS has maintained that it reserves the right to apply an "equitable adjustment" to the payment rate for Aranesp® in future years.

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. 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. On May 18, 2007, CMS stated that it plans to make changes to the payment rates for EPOGEN® and Procrit® so that the same payment limit will be adopted for both products, commonly referred to as linkage. As a result of these changes, beginning in the third quarter of 2007, CMS will calculate payment rates for the products based on a weighted average of the ASPs for EPOGEN® and Procrit®, which could lead to a lower ASP reimbursement rate for EPOGEN®. Currently, EPOGEN® and Procrit® reimbursement is based upon the product's individual ASP and are not linked. Since April 1, 2006, the ESRD Program reimbursement has been subject to a revised 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. This policy, Claims Monitoring Policy: Erythropoietin/darbepoetin alfa usage for beneficiaries with end stage renal disease ("EMP") was further revised effective October 1, 2006. The revised EMP 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 the provider does not submit medical documentation to support maintaining a patient's hemoglobin above 13 grams per deciliter, reimbursement will be reduced to the level it would have been had the provider reduced dosage by twenty-five percent.

Changes resulting from the MMA, which beginning in 2005 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. While we cannot accurately predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products and we cannot estimate the full impact of the MMA on our business, we believe that it is 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 example, 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. However, recent developments around ESAs have been more rapid than previously anticipated. In addition, in the Medicare Physician Fee Schedule Proposed Rule for 2007, 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. Further, 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." 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.

In addition to private payers, since January 1, 2006, ENBREL and Sensipar® have been 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.

Other initiatives reviewing the coverage or reimbursement of our products, including those related to safety, could result in less extensive coverage or lower reimbursement and could negatively affect sales of some of our marketed products. For example, on March 14, 2007, shortly after the label changes for all ESAs, CMS announced that the agency had begun reviewing all Medicare policies related to the administration of ESAs in non-renal disease applications as part of a NCA which is generally CMS' first step toward developing a national coverage determination ("NCD"). Generally, a NCD is a national policy statement granting, limiting or excluding Medicare coverage or reimbursement for a specific medical item or service. During the initial comment period which ended on April 13, 2007, we submitted comments to CMS which included a detailed and thorough review of the available clinical data, noted a series of important considerations and made a number of specific recommendations for the agency to consider in developing a NCD. On May 14, 2007, CMS issued the Proposed NCD following a review of data and public comments submitted as part of the NCA, which under the MMA, is subject to a 30-day public comment period ending June 13, 2007, before being finalized 60 days after the conclusion of the public comment period on August 12, 2007. In the Proposed NCD, CMS listed 13 oncology-related conditions for which CMS would deny Medicare coverage of Aranesp® and Johnson & Johnson's Procrit® for the treatment of anemia. CMS stated that it has proposed denying coverage because the agency believes that treatment with ESAs in these conditions is not reasonable and necessary either because of a deleterious or worse effect of the ESA on the underlying disease or because the underlying cancer increases the risk of adverse effects related to ESA use. The 13 conditions which CMS has proposed denying coverage are:

- any anemia in cancer or cancer treatment patients due to folate deficiency, deficiency, hemolysis, bleeding, or bone marrow fibrosis;
- the anemia of myelodysplasia;
- the anemia of myeloid cancers;
- the anemia associated with the treatment of myeloid cancers or erythroid cancers;
- the anemia of cancer not related to cancer treatment;
- any anemia associated with radiotherapy;
- prophylactic use to prevent chemotherapy-induced anemia;
- prophylactic use to reduce tumor hypoxia;
- patients with erythropoietin-type resistance due to neutralizing antibodies;
- patients with treatment regimens including anti-angiogenic drugs such as bevacizumab (Avastin®);
- patients with treatment regimens including monoclonal/polyclonal antibodies directed against the EGFr (Erbitux® and Vectibix™);
- anemia due to cancer treatment if patients have uncontrolled hypertension; and
- patients with thrombotic episodes related to malignancy.

In the Proposed NCD, CMS also proposed new limits on the permitted Medicare coverage of ESAs in certain types of cancers, including breast, lung, prostate and colorectal, which account for the most common solid tumor cancer cases in the United States. The cancer types other than the solid tumor cancers enumerated above include but are not necessarily limited to: bone (sarcoma); brain neurologic; cervical, gastric, head-and-neck (squamous cell), hepatic, lymphoma, melanoma, multiple myeloma, muscle including cardiac, ovarian, pancreatic (exocrine), retinal and uterine. CMS also proposed that use of ESAs in these cancers is only reasonable and necessary under conditions in which the presence of erythropoietin receptors on either normal tissue/cell lines or malignant tissue/cell lines has been reported

in literature. As proposed, Medicare coverage of ESAs in these types of cancers would be limited under new dosing and treatment restrictions including:

- initial treatment with ESAs would be limited in patients with hemoglobin/hematocrit levels immediately prior to initiation of dosing for the month should be < 9 g/dL or 27 percent in patients without known cardiovascular disease and < 10 g/dL or 30 percent in patients with documented symptomatic ischemic disease that cannot be treated with blood transfusion;
- the maximum duration of covered treatment would be 12 weeks per year; and
- the maximum covered 4 week treatment dose would 126,000 units for erythropoietin and 630 mcg for darbepoetin.

CMS also stated in the Proposed NCD that:

- continued use of the drug (ESA) is not reasonable and necessary if there is evidence of poor drug response (hemoglobin/hematocrit rise < 1 g/dL or < 3%) after 4 weeks of treatment;
- continued administration of the drug (ESA) is not reasonable and necessary if there is an increase in fluid retention or weight (5 kg) after 2 weeks of treatment; and
- continued administration of the drug (ESA) is not reasonable and necessary if there is a rapid rise in hemoglobin/hematocrit > 1 g/dL or > 3% after 2 weeks of treatment.

Lastly, CMS stated that, in light of the issues discussed in our review of the evidence and serious safety concerns voiced in the May 10, 2007 ODAC meeting, they were interested in public comment on whether coverage for ESA therapy for Medicare beneficiaries with cancer should occur only within appropriately designed clinical research studies where informed consent and safety monitoring can be assured.

If the proposals in the Proposed NCD were finalized in its proposed or a similar form it would have a material adverse effect on the use, reimbursement and sales of Aranesp®, and our business and results of operations. In addition, any Medicare reimbursement coverage decisions finalized by CMS in an NCD for treatment of anemia in cancer would likely be followed and implemented by private payers. Further, physicians may reduce use and dose of ESAs and private payers may accelerate reimbursement decisions in anticipation of the final NCD.

Additionally, in conjunction with CMS' announcement that it had begun reviewing all Medicare policies related to the administration of ESAs in non-renal disease applications on March 14, 2007, CMS also stated that the agency is currently reviewing the EMP for patients with ESRD who are dialyzed in renal facilities although they have not yet announced further changes to the EMP. The FDA has stated that it intends to hold a meeting of the Cardio Renal Drugs Advisory Committee in the fall of 2007, to review the use of ESAs in the renal setting. We cannot predict what action the FDA may take as a result of such committee meeting. As a result of the current review of the EMP and the future meeting of the Cardio Renal Drugs Advisory Committee, we cannot predict the potential full impact any revisions to the EMP may have on our sales of our ESAs and on our business. However, any changes to the EMP or an NCD for ESAs in the renal setting, which may include non-coverage and/or new dosing and treatment restrictions similar to those proposed in the Proposed NCD for treatment of anemia in oncology with ESAs, would negatively effect use, reduce reimbursement and coverage, negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations.

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 are uncertain

as to 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 submitted a comment to CMS on the proposed rule which the DRA specifies that CMS issue a final rule no later than July 1, 2007. While we cannot predict the impact of the final rule prior to its issuance, changes reducing reimbursement could negatively affect 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, 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 and in 2007, following the update to the ESA labels, nearly all Medicare contractors dropped reimbursement for Aranesp® for anemia of cancer. (See *"—Guidelines and recommendations published by various organizations can reduce the use of our products.")* Also, we believe the increasing emphasis on cost-containment initiatives in the United States, Europe and other countries has and will continue to put pressure on the price and usage of our products, which may adversely impact product sales. 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.

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 a pegylated erythropoietin molecule ("peg-EPO") for which they have filed a biologic license application ("BLA") with the FDA and which Roche announced on May 18, 2007 that the FDA had issued an approvable letter for MIRCERA® for the treatment of anemia associated with chronic renal failure including patients on dialysis and patients not on dialysis. Roche stated that it has received a draft label from the FDA and expects the label to be finalized after the Cardiovascular and Renal Drugs Advisory Committee has issued its recommendations on the entire class of ESAs. The FDA stated that it intends to hold a meeting of the

Cardio Renal Drugs Advisory Committee in the fall of 2007. 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 Part I Item 3. "Legal Proceedings—Roche Matters" of our Form 10-K for the year ended December 31, 2006 and in Part II Item 1. "Legal Proceedings—Roche Matters" of our Form 10-Q for the quarter ended March 31, 2007. According to Roche's public statements, they expect to launch the molecule in the U.S. nephrology segment in 2007, upon regulatory approval, 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 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 granulocyte colony-stimulating factor ("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. In additional we have had one principal erythropoietin patent expiry in the EU and our principal European patent relating to G-CSF has expired.

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	U.S.	— Glycosylation analogs of erythropoietin proteins	5/15/2024
	Europe[1]	— Glycosylation analogs of erythropoietin proteins	10/12/2010
		— Glycosylation analogs of erythropoietin proteins	8/16/2014
Filgrastim	U.S.	— G-CSF polypeptides	12/3/2013
		— Methods of treatment using G-CSF polypeptides	12/10/2013
pegfilgrastim	U.S.	— Pegylated G-CSF	10/20/2015
	Europe[1]	— Pegylated G-CSF	2/8/2015
etanercept	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
panitumumab	U.S.	— Human monoclonal antibodies to EGFr	5/5/2017
cinacalcet HCl	U.S.[2]	— 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[1]	— Calcium receptor-active molecules	10/23/2015

(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.

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

We also have been granted or obtained rights to patents in Europe relating to erythropoietin; G-CSF; pegfilgrastim (pegylated G-CSF); etanercept; 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 or early 2008 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 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 expect that biosimilar erythropoietin products may be approved in the EU in 2007 and could be available in the EU shortly after approval. In the first quarter of 2007, Shire received approval in the EU for Dynepo™ (Epoetin delta), a competing erythropoietin product. 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 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. During this current Congressional session, several members of Congress expressed interest in the issue, a number of bills have been

introduced, and the House and Senate have held hearings. It is unknown what type of regulatory framework, what legal provisions, and what timeframes for guidance development any final legislation would contain. Until such legislation is created, we cannot predict when follow-on biologics could appear in the United States.

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 and organizational guidelines include:

- On April 12, 2007 the National Kidney Foundation ("NKF") distributed to the nephrology community the draft of the KDOQI (Kidney Disease Outcomes Quality Initiative) Clinical Practice Guideline and Clinical Practice Recommendations for Anemia Management in Chronic Kidney Disease. The draft guideline was open for comments from the community until April 30, 2007 prior to being finalized and published. The NKF's Anemia Working Group initiated a review of the existing guidelines following recent clinical developments, such as the publication of the results of the CHOIR and other trials. In the proposed guideline, the group recommends what factors should be considered in selecting a Hb target and states that the selected Hb target should generally be in the range 11.0 to 12.0 g/dL. Like others in the nephrology community, we are currently reviewing the new guideline and cannot predict what impact the revised guideline will have on our business but anticipate that CMS will likely consider the KDOQI guidelines as it undertakes its review of the EMP.
- 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.
- On February 2, 2007, following the reported results from our Anemia of Cancer ("AoC") 103 Study, the USP DI Drug Reference Guides removed Aranesp® in the treatment of AoC. Thereafter, nearly all Medicare contractors stopped reimbursing for Aranesp® use in AoC patients.

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 or new indications for existing products (collectively, "product candidates") that appear promising in the early phases of development, such as in early human clinical trials, may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results
- the product candidate was not effective or more effective than currently available therapies in treating a specified condition or illness
- the product candidate had harmful side effects in humans or animals
- the necessary regulatory bodies, such as the FDA, did not approve our product candidate for an intended use
- the product candidate was not economical for us to manufacture and commercialize
- other parties have or may have proprietary rights 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
- the regulatory pathway to approval for product candidates is uncertain or not well-defined

We recently announced that after discussions with the FDA we have decided not to file for approval of motesanib diphosphate in refractory thyroid cancer until there is more clarity on what would constitute an appropriate regulatory filing package for that indication.

Further, several of our product candidates have failed or been discontinued at various stages in the product development process, 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 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 or take other potentially limiting or costly actions 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.")

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 Part I Item 3. "Legal Proceedings" of our Form 10-K for the year ended December 31, 2006, in Part II Item 1. "Legal Proceedings" of our Form 10-Q for the quarter ended March 31, 2007 and in "Legal Proceedings" described elsewhere in this Form 8-K. 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 Part I Item 3. "Legal Proceedings—Average Wholesale Price Litigation" of our Form 10-K for the year ended December 31, 2006 and in Part II Item 1. "Legal Proceedings—Average Wholesale Price Litigation" of our Form 10-Q for the quarter ended March 31, 2007 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 revenues may fluctuate and our operating results are subject to fluctuations and these fluctuations could cause financial results to be below expectations and our stock price is volatile, which could adversely affect your investment.

Our operating results may fluctuate from period to period for a number of reasons. We have announced that we will be exploring expense reductions, however, some of our operating expenses are

fixed in the short term and cannot be reduced within a short period of time to offset unplanned or unexpected reductions in revenue. 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, as our ESAs and certain other principal products are facing a number of regulatory, reimbursement and competitive challenges, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Additionally, our stock price, like that of other biotechnology companies, is volatile. For example, in the fifty-two weeks prior to March 31, 2007, the trading price of our common stock has ranged from a high of $76.50 per share to a low of $55.72 per share.

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

- adverse developments regarding the safety or efficacy of our products
- changes in the government's or private payers' reimbursement policies or prescribing guidelines for our products
- inability to maintain regulatory approval of marketed products or manufacturing facilities
- actual or anticipated clinical trial results of ours or other companies and organizations
- actual or anticipated product supply constraints
- business development or licensing activities
- product development or other business announcements by us or our competitors
- regulatory matters or actions
- changes in our product pricing strategies
- lower than expected demand for our products
- changes in wholesaler buying patterns
- increased competition from new or existing products
- fluctuations in foreign currency exchange rates
- announcements in the scientific and research community
- intellectual property and legal matters
- 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

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

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 an avian or pandemic flu outbreak, or otherwise
- failure to comply with our quality standards which results in quality failures, product contamination and/or recall

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

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 or take other potentially limiting or costly actions 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
- labor disputes or shortages, including the effects of an avian or pandemic flu outbreak, or otherwise
- 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 Boehringer Ingelheim Pharma KG ("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 and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build and license a new manufacturing plant and it can take longer than three years to qualify a 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 state of regulatory compliance. Key manufacturing projects include: 1) construction, qualification and licensure of new formulation, fill and finish facilities at our Puerto Rico site; 2) expansion of existing bulk protein facilities at our Puerto Rico site including the licensure of our Puerto Rico plant for production of darbepoetin bulk drug substance and increased production of pegfilgrastim and Filgrastim bulk drug substance; 3) construction, qualification and licensure of our new process bulk and formulation, fill and finish plant in Ireland.

If regulatory authorities determine that we or our third-party contract manufacturers or third-party service providers have violated regulations or if they restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or our third-party contract manufacturers or third-party service providers comply, or indefinitely. Because our third-party contract manufacturers and third-party service providers are subject to FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and service providers may not be available on a timely basis or at all. 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 an avian or 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*.")

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, we 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 and continues to experience 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® faces competition in the EU from Dynepo™, a competing erythropoietin product marketed by Shire and may face competition from Roche's peg-EPO, which may receive approval in the EU and be launched later this year. Aranesp® and EPOGEN® may also face competition in the U.S. from Roche's peg-EPO for which they have filed a BLA with the FDA and which Roche announced on May 18, 2007 that the FDA had issued an approvable letter for MIRCERA® for the treatment of anemia associated with chronic renal failure including patients on dialysis and patients not on dialysis. Roche stated that it has received a draft label from the FDA and expects the label to be finalized after the Cardiovascular and Renal Drugs Advisory Committee has issued its recommendations on the entire class of ESAs. The FDA stated that it intends to hold a meeting of the Cardio Renal Drugs Advisory Committee in the fall of 2007. According to Roche's public statements, they expect to launch the molecule in the U.S. nephrology segment in 2007, upon regulatory approval, despite our ongoing lawsuit and 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.")* 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 in the U.S. to treat patients with metastatic colorectal cancer, competes with Imclone's Erbitux®. Further, if our currently marketed products are approved for new uses, or if we sell new products, or our competitors get new or expanded indications, we may face new, additional competition that we do not face today. Further, adverse clinical developments for our current products could limit our ability to compete. (See *"—Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or take other potentially limiting or costly actions if we or others identify side effects after our products are on the market.")* Our products may compete against products that have lower prices, equivalent or superior performance, are easier to administer or that are otherwise competitive with our products.

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 or early 2008 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. During this current Congressional session, several members of Congress expressed interest in the issue, a number of bills have been introduced, and the House and Senate have held hearings. It is unknown what type of regulatory framework, what legal provisions, and what timeframes for guidance development any final legislation would contain. 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.

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, however given the recent challenges around ESAs, our plan has a number of risks, some of which we cannot completely control. For example:

- we will need to monitor and make strategic expense management reduction decisions to help minimize the impact of declines in revenue growth on our operating results
- we will need to manage complexities associated with a larger and more geographically diverse organization
- we will need to manage and execute larger, more complex and increasingly global clinical trials
- we may need to significantly expand our sales and marketing resources to launch late-stage product candidates
- 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 certain of 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 effect on our business and results of operations.

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

The substantial majority of our U.S. product sales are made to three pharmaceutical product wholesaler distributors, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation. These distributors, in turn, sell our products to their customers, which include clinics, dialysis centers, hospitals and pharmacies. One of these products, EPOGEN®, is primarily sold to free-standing dialysis clinics, which have recently experienced significant consolidation. Two organizations, DaVita Inc. and Fresenius Medical Care North America, Inc. (“Fresenius”) own or manage a large number of the outpatient dialysis facilities located in the United States and account for a significant majority of all EPOGEN® sales in the free-standing dialysis clinic setting. In October 2006, we entered into a five-year sole sourcing and supply agreement with an affiliate of Fresenius, on its behalf and on behalf of certain of its affiliates, 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.

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 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 or take other potentially limiting or costly actions 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, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws or all potentially applicable foreign regulations and/or laws. If we 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.

The accounting method for our convertible debt securities may be subject to change.

A convertible debt security providing for net share settlement of the conversion value and meeting specified requirements under Emerging Issues Task Force ("EITF") Issue No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock," including our outstanding convertible debt securities, is accounted for by recognizing interest expense at its stated coupon rate. For purposes of computing diluted earnings per share, any shares issuable upon conversion of such a security is computed using the treasury stock method. The effect of the treasury stock method is that the shares potentially issuable upon conversion of our convertible debt securities that meet these specified requirements are not included in the calculation of our earnings per share except to the extent that the conversion value of such securities exceeds their principal amount, in which event they are treated for earnings per share purposes as us having issued the number of shares of our common stock necessary to settle the conversion.

The EITF is reviewing whether the accounting method for net share settled convertible securities should be changed. The EITF is considering a proposed method for accounting for net share settled convertible securities under which the debt and equity components of the security would be bifurcated and accounted for separately. The effect of this proposal is that the equity component would be included in the paid-in-capital section of stockholders' equity on an issuer's balance sheet and, accordingly, the initial carrying value of the convertible securities would be reduced. Net income for financial reporting purposes attributable to our common stockholders would be lower by recognizing accretion of the reduced carrying value of the convertible debt security to its face amount as additional interest expense. The diluted earnings per share calculation would continue to be calculated based on the treasury stock method.

We cannot predict the outcome of the EITF deliberations and whether the EITF will require that net share settled convertible securities, and their related impact on earnings per share, be accounted for under the existing method, the proposed method described above or some other method, and when any change would be implemented or whether it would be implemented retroactively or prospectively.

We also cannot predict any other changes in U.S. generally accepted accounting principles ("GAAP") that may be made affecting accounting for convertible debt securities. Any change in the accounting method for convertible debt securities could have an adverse impact on our past or future reported financial results. These impacts could adversely affect the trading price of our common stock and in turn negatively impact the trading price of the notes.

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.

LEGAL PROCEEDINGS

Certain of our legal proceedings are reported in our Annual Report on Form 10-K for the year ended December 31, 2006, our Form 10-Q for the quarter ended March 31, 2007 and below. 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.

Israel Bio-Engineering Project Litigation ("IBEP")

On May 18, 2007, IBEP filed a petition for a writ of certiorari with the U.S. Supreme Court.

Transkaryotic Therapies ("TKT") and Aventis Litigation

On May 14, 2007, the U.S. Supreme Court denied Amgen's petition for a writ of certiorari.

Elden v. Amgen Inc., et. al.

On May 11, 2007, a class action shareholder litigation suit was filed against Amgen Inc. Kevin W. Sharer, Willard H. Dere, Richard D. Nanula, Dennis M. Fenton, Roger M. Perlmutter, Brian M. McNamee, George J. Morrow, Edward V. Fritzky, Gilbert S. Omenn and Franklin P. Johnson, Jr., (the "Individual Defendants") in the United States District Court for the Central District of California (the "California Central District Court"). The complaint alleges that Amgen and the Individual Defendants made false statements that resulted in a fraudulent scheme and course of business operated as a fraud or deceit on purchasers of Amgen publicly traded securities in that: (i) they temporarily deceived the investing public regarding Amgen's prospects and business; (ii) they artificially inflated the prices of Amgen's publicly traded securities; and (iii) they caused plaintiffs and other members of the class to purchase Amgen publicly traded securities at inflated prices. The complaint also makes off-label marketing allegations and allegations as to a failure to disclose negative results of clinical studies. Amgen has not been served with the complaint. Plaintiffs seek class certification, compensatory damages, legal fees and other relief deemed proper.

Other

On May 10, 2007, Amgen received a subpoena from the Attorney General of the State of New York seeking documents related to Amgen's promotional activities, sales and marketing activities, medical education, clinical studies, pricing and contracting, license and distribution agreements and corporate communications. Amgen intends to fully cooperate in responding to the subpoena.

On May 14, 2007, Amgen was served with a shareholder demand on the Board of Directors ("Board") to establish a Special Litigation Committee to investigate potential breaches of fiduciary duties by current and/or former officers and directors of the Company (the "Individuals"). Shareholders allege that the Individuals violated core fiduciary duties, causing Amgen to suffer damages. Shareholders seek to recover from the Individuals i) damages resulting from their breach of fiduciary duties, ii) monies and benefits improperly granted to them, iii) insider trading proceeds, and iv) all costs associated with the inquiry by the Securities and Exchange Commission. Shareholders also demand that the Board make a claim under the Company's Errors and Omissions Policy in the amount of the damages and that the Board commence an action within 90 days.

On May 16, 2007, the United States Senate Committee on Finance issued a letter to Amgen requesting a briefing to discuss the issues and concerns reported in the media as to the marketing and

safety of erythropoiesis stimulating agents ("ESAs"). Senator Grassley requested documents and discussion around i) Amgen data requested by the FDA; ii) whether Amgen provided complete responses to FDA data requests; iii) whether Amgen has sponsored ESA trials that have been terminated, suspended, or otherwise not completed that showed evidence of serious adverse effects; iv) whether Amgen informed the FDA of studies related to the use of Aranesp® and EPOGEN® to improve a patient's quality of life; and v) what actions Amgen has taken to ensure that doctors and patients are informed of the new safety risks surrounding ESAs. Amgen intends to fully cooperate in responding to the subpoena.