AMGEN INC
Form 424B3
April 06, 2005

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Filed Pursuant to Rule 424(b)(3)
Registration No. 333-123300

PROSPECTUS

Offer to Exchange
4.00% Senior Notes Due 2009
Which Have Been Registered
Under the Securities Act of 1933
For Any And All Outstanding
4.00% Senior Notes Due 2009
&
Offer to Exchange
4.85% Senior Notes Due 2014
Which Have Been Registered
Under the Securities Act of 1933
For Any And All Outstanding
4.85% Senior Notes Due 2014

We are offering to exchange all of our outstanding unregistered 4.00% Senior Notes due 2009 for our registered 4.00% Senior Notes due 2009 and to exchange all of our outstanding unregistered 4.85% Senior Notes due 2014 for our registered 4.85% Senior Notes due 2014. The unregistered 4.00% Senior Notes due 2009 and the registered 4.00% Senior Notes due 2009 are sometimes collectively referred to as the 2009 Notes. The unregistered 4.85% Senior Notes due 2014 and the registered 4.85% Senior Notes due 2014 are sometimes collectively referred to as the 2014 Notes. The unregistered 4.00% Senior Notes due 2009 and the unregistered 4.85% Senior Notes due 2014 are sometimes collectively referred to as the Unregistered Notes. The registered 4.00% Senior Notes due 2009 and the registered 4.85% Senior Notes due 2014 are sometimes collectively referred to as the Registered Notes. The Unregistered Notes and the Registered Notes are sometimes collectively referred to as the Notes. The Unregistered Notes were issued on November 18, 2004 and as of the date of this prospectus, an aggregate principal amount of $1.0 billion of the 2009 Notes is outstanding and an aggregate principal amount of $1.0 billion of the 2014 Notes is outstanding. The terms of the registered 4.00% Senior Notes due 2009 are substantially identical to the outstanding unregistered 4.00% Senior Notes due 2009 and the terms of the registered 4.85% Senior Notes due 2014 are substantially identical to the outstanding unregistered 4.85% Senior Notes due 2014, except in each case, that the Registered Notes are registered under the Securities Act of 1933, as amended, and will not contain any legends restricting their transfer.

You should carefully review the risk factors beginning on page 6 of this prospectus before electing to exchange Unregistered Notes for Registered Notes.

Our offer to exchange Unregistered Notes for Registered Notes will be open until 5:00 p.m., New York City time, on May 4, 2005, unless we extend the offer.

You should carefully review the procedures for tendering the Unregistered Notes beginning on page 20 of this prospectus. If you do not follow these procedures, we may not exchange your Unregistered Notes for Registered Notes.

If you fail to tender your Unregistered Notes, you will continue to hold Unregistered Notes and your ability to transfer them could be adversely affected.

No public market currently exists for the Unregistered Notes. We do not intend to list the Registered Notes on any securities exchange and, therefore, no active public market is anticipated.

You may withdraw tenders of Unregistered Notes at any time before the exchange offer expires.

We will not receive any proceeds from this exchange offer.

Maturity: The 2009 Notes will mature on November 18, 2009.
The 2014 Notes will mature on November 18, 2014.

Interest Payments: We will pay interest on the Notes on May 18 and November 18 of each year. The first payment will be made on May 18, 2005.

Ranking: The Notes are senior unsecured obligations and rank equal in right of payment to all of our other existing and future senior unsecured indebtedness, including indebtedness under our senior credit facility, and senior in right of payment to all our existing and future subordinated indebtedness. The Notes are effectively subordinated in right of payment to all our subsidiaries obligations (including secured and unsecured obligations) and subordinated in right of payment to our secured obligations, to the extent of the assets securing such obligations.

Optional Redemption: We may redeem any or all of the Notes at any time at a redemption price equal to the principal amount of the Notes redeemed, plus accrued interest to, but not including, the redemption date plus an applicable premium.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OF THE NOTES OR DETERMINED THAT THIS PROSPECTUS IS ACCURATE OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

THE DATE OF THIS PROSPECTUS IS APRIL 6, 2005.

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Each broker-dealer that receives Registered Notes for its own account in the exchange offer must acknowledge that it will deliver a prospectus together with any resale of those Registered Notes. This prospectus, as it may be amended or supplemented from time to time, may be used by a broker-dealer in connection with resales of Registered Notes received in exchange for Unregistered Notes where those Unregistered Notes were acquired as a result of market-making activities or other trading activities. We have agreed that for a period of up to 90 days after the consummation of the exchange offer, we will make this prospectus, as amended or supplemented, available to any broker-dealer that requests it for use in these resales. For more information, see Plan of Distribution.

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by references in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus as if we had authorized it. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the registered securities to which it relates, nor does this prospectus constitute an offer to sell or a solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

The information contained in this prospectus is current only as of the date on the cover page of this prospectus, and may change after that date.

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WHERE YOU CAN FIND MORE INFORMATION

Available Information

We have filed and will file reports and other information with the Securities and Exchange Commission under the Securities and Exchange Act of 1934, as amended, which we refer to as the Exchange Act . You may read and copy this information at the SEC s Public Reference Room, 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549. You may also obtain copies of this information by mail from the Public Reference Section of the SEC at prescribed rates. Please call the SEC at 1-800-SEC-0330 for additional information about the Public Reference Room.

The SEC also maintains a website that contains reports, proxy statements and other information about issuers, including Amgen, who file electronically with the SEC. The address of that site is www.sec.gov.

You can also inspect reports and other information about us at the offices of the Nasdaq National Market, 1735 K Street, N.W., Washington, D.C. 20006-1005.

Incorporation of Certain Information by Reference

We are incorporating by reference into this prospectus certain information filed by us with the SEC, which means that we are disclosing important information to you by referring you to those documents. The information incorporated by reference is deemed to be part of this prospectus, except to the extent modified or superseded, as described below. This prospectus incorporates by reference the document set forth below that we have previously filed with the SEC. Those documents contain important information about us and our finances.

Our annual report on Form 10-K for the fiscal year ended December 31, 2004.

Our current reports on Form 8-K filed with the SEC on January 31, 2005, March 4, 2005 and March 11, 2005.

All documents that we file with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act, from the date of this prospectus to the end of the offering of the Registered Notes, shall also be deemed to be incorporated herein by reference and will automatically update information in this prospectus. However, notwithstanding the foregoing, we are not incorporating by reference any information furnished under either Item 2.02 or Item 7.01 of any Current Report on Form 8-K.

Any statements made in this prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other subsequently filed document that is also incorporated or deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request a copy of these filings, at no cost, by writing or calling us at the following address or telephone number:

Amgen Inc.
Investor Relations Department
One Amgen Center Drive
Thousand Oaks, California 91320-1799
Tel: 805-447-1000

Exhibits to the filings will not be sent, however, unless those exhibits have specifically been incorporated by reference into this prospectus.

We make available free of charge on or through our Internet website, www.amgen.com, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably

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practicable after we electronically file such material with, or furnish it to, the SEC. Information contained in our website does not constitute part of this prospectus unless otherwise specifically incorporated by reference herein.

IN ORDER FOR YOU TO RECEIVE TIMELY DELIVERY OF THE DOCUMENTS BEFORE THE EXPIRATION OF THE EXCHANGE OFFER, AMGEN SHOULD RECEIVE YOUR REQUEST NO LATER THAN APRIL 27, 2005.

FORWARD LOOKING INFORMATION

This prospectus and other documents we file with the SEC contain forward looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business or others on our behalf, our beliefs and our management s assumptions. In addition, we, or others on our behalf, may make forward looking statements in press releases or written statements, or in our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls, and conference calls. Words such as expect, anticipate, outlook, could, target, project, intend, plan, believe, seek, estimate, continue, 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. We describe our respective risks, uncertainties, and assumptions that could affect the outcome or results of operations in Risks Related to Our Business. We have based our forward looking statements on our management s beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied, or forecast by our forward looking statements. Reference is made in particular to forward looking statements regarding product sales, reimbursement, expenses, earnings per share, liquidity and capital resources, and trends. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward looking statements after the distribution of this prospectus, whether as a result of new information, future events, changes in assumptions, or otherwise.

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SUMMARY

The following summary is qualified in its entirety by the more detailed information included elsewhere or incorporated by reference in this prospectus. Because this is a summary, it may not contain all the information that may be important to you. You should read this entire prospectus, as well as the information incorporated by reference in this prospectus, before making an investment decision. Unless otherwise specified, the terms Amgen, we, our and us refer to Amgen Inc. and its consolidated subsidiaries when used in this prospectus.

Amgen Inc.

We are a global biotechnology company that discovers, develops, manufactures and markets human therapeutics based on advances in cellular and molecular biology.

We were incorporated in California in 1980 and merged into a Delaware corporation in 1987. Our principal executive offices are located at One Amgen Center Drive, Thousand Oaks, California 91320-1799 and our telephone number at that location is 805-447-1000.

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Summary of the Exchange Offer

The following is a brief summary of the terms of the exchange offer. For a more complete description, see The Exchange Offer.

Securities to be Exchanged	On November 18, 2004, we issued $1.0 billion in aggregate principal amount of unregistered 4.00% Senior Notes due 2009 and $1.0 billion in aggregate principal amount of unregistered 4.85% Senior Notes due 2014, collectively, the Unregistered Notes, in a transaction exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act). The terms of the Registered Notes and the Unregistered Notes are substantially identical in all material respects, except that the Registered Notes will be freely transferable by the holders of the Registered Notes except as otherwise provided in this prospectus. The Registered Notes will bear different CUSIP numbers from the Unregistered Notes. See Description of Notes.
The Exchange Offer	$1,000 principal amount of registered 4.00% Senior Notes due 2009 will be exchanged for each $1,000 principal amount of unregistered 4.00% Senior Notes due 2009. $1,000 principal amount of registered 4.85% Senior Notes due 2014 will be exchanged for each $1,000 principal amount of unregistered 4.85% Senior Notes due 2014. As of the date of this prospectus, unregistered 4.00% Senior Notes due 2009 representing $1.0 billion in aggregate principal amount are outstanding and unregistered 4.85% Senior Notes due 2014 representing $1.0 billion in aggregate principal amount are outstanding. Under existing SEC interpretations, the Registered Notes will in general be freely transferable after the exchange offer without further registration under the Securities Act; *provided* that, in the case of broker-dealers, a prospectus meeting the requirements of the Securities Act is delivered as required. By tendering Unregistered Notes in the exchange offer, you represent to us that, among other things: you, or the person or entity acquiring Registered Notes, are acquiring the Registered Notes in the ordinary course of business; neither you nor any person or entity receiving the related Registered Notes is engaging in or intends to engage in a distribution of the Registered Notes within the meaning of the federal securities laws; neither you nor any person or entity receiving the related Registered Notes has an arrangement or understanding with any person or entity to participate in any distribution of the Registered Notes;

neither you nor any person or entity receiving the related Registered Notes is an affiliate of Amgen Inc., as that term is defined under Rule 405 of the Securities Act; and

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	you are not acting on behalf of any person or entity who could not truthfully make these statements.
	Each broker-dealer that receives Registered Notes for its own account pursuant to the exchange offer must acknowledge that it will comply with the prospectus delivery requirements of the Securities Act in connection with any resale of the Registered Notes.
	See The Exchange Offer Procedures for Tendering and Plan of Distribution.
Registration Rights Agreement	We sold the Unregistered Notes on November 18, 2004 in a private placement in reliance on Rule 144A and Regulation S under the Securities Act. In connection with the sale, we entered into a registration rights agreement with the initial purchasers of the Unregistered Notes requiring us to make the exchange offer. The registration rights agreement also requires us to use our reasonable efforts to complete the exchange offer by September 26, 2005 or, if this fails, to cause to become effective a shelf registration statement for resales of the Notes.
	See The Exchange Offer Purpose of the Exchange Offer. If we do not do so, we will pay special interest on the Unregistered Notes at an initial rate of 0.25% per annum of the principal amount of Unregistered Notes, and 0.50% per annum after the first 90 days.
Expiration Date	The exchange offer will expire at 5:00 p.m., New York City time, on May 4 , 2005, or a later date and time if we extend it.
Withdrawal	The tender of the Unregistered Notes pursuant to the exchange offer may be withdrawn at any time prior to 5:00 p.m., New York City time, on the expiration date, or any later date and time to which we extend the offer.
Interest on the Registered Notes and the Unregistered Notes	Interest on the Registered Notes will accrue from the date of the original issuance of the Unregistered Notes or from the date of the last payment of interest on the Unregistered Notes, whichever is later. No additional interest will be paid on Unregistered Notes tendered and accepted for exchange.
Conditions to the Exchange Offer	The exchange offer is subject to customary conditions, some of which may be waived by us. See The Exchange Offer Conditions to the Exchange Offer.
Procedures for Tendering Unregistered Notes	A holder who wishes to tender Unregistered Notes in the exchange offer must transmit to the exchange agent an agent s message, transmitted by a book-entry transfer facility, which agent s message must be received by the exchange agent prior to 5:00 p.m., New York City time,

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	on the expiration date. In addition, the exchange agent must receive a timely confirmation of book-entry transfer of the Unregistered Notes into the exchange agent s account at The Depository Trust Company, or DTC, under the procedures for book-entry transfers described in The Exchange Offer Procedures for Tendering. Unregistered Notes must be tendered by electronic transmission of acceptance through DTC s, Automated Tender Offer Program, which we refer to as ATOP, procedures for transfer. A letter of transmittal need not accompany tenders effected through ATOP. Please carefully follow the instructions contained in this document on how to tender your securities. See The Exchange Offer Terms of the Exchange Offer.
Exchange Agent	JPMorgan Chase Bank, N.A., the trustee under the indenture governing the Notes, is serving as exchange agent in connection with the exchange offer.
United States Federal Income Tax Consequences	The exchange of Unregistered Notes for Registered Notes pursuant to the exchange offer should not constitute a sale or an exchange for federal income tax purposes. See United States Federal Income Tax Consequences.
Effect of Not Tendering	Unregistered Notes that are not tendered or that are tendered but not accepted will, following the completion of the exchange offer, continue to be subject to the existing restrictions on transfer. Except as noted above, we will have no further obligation to provide for the registration under the Securities Act of these Unregistered Notes.
Use of Proceeds	We will not receive any cash proceeds from the issuance of the Registered Notes pursuant to the exchange offer. See Use of Proceeds.
Risk Factors	See Risk Factors for a discussion of some factors you should carefully consider, including factors affecting forward-looking statements.

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Summary of the Terms of the Registered Notes

The form and terms of the Registered Notes are the same as the form and terms of the Unregistered Notes, except that the Registered Notes will be registered under the Securities Act and will not contain any legends restricting their transfer. However, the Registered Notes will bear different CUSIP numbers from the Unregistered Notes. The Registered Notes will evidence the same debt as the Unregistered Notes and both the Unregistered Notes and the Registered Notes, collectively, the Notes, are governed by the same indenture. The following summary of terms applies equally to the Registered Notes and the Unregistered Notes.

Issuer	Amgen Inc.
Total Amount of Registered Notes Offered	$1.0 billion aggregate principal amount of 4.00% Senior Notes due 2009. $1.0 billion aggregate principal amount of 4.85% Senior Notes due 2014.
Maturity	2009 Notes: November 18, 2009 2014 Notes: November 18, 2014
Interest	2009 Notes: 4.00% 2014 Notes: 4.85%
Interest Payment Dates	On May 18 and November 18, commencing May 18, 2005.
Ranking	The Registered Notes will be our senior unsecured obligations and will rank: equal in right of payment to all of our other existing and future senior unsecured indebtedness, including indebtedness under our senior credit facility; senior in right of payment to all of our existing and future subordinated indebtedness; and effectively subordinated in right of payment to all of our subsidiaries obligations (including secured and unsecured obligations) and subordinated in right of payment to our secured obligations, to the extent of the assets securing such obligations.
Optional Redemption	We may redeem any or all of the Registered Notes at any time at the redemption prices described in this prospectus, plus accrued interest.
Covenants	The Registered Notes and the related indenture do not contain any financial or other similar restrictive covenants. However, we will be subject to the covenants described under the caption Description of Notes.

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RISK FACTORS

Prospective investors should carefully consider the following information in addition to the other information contained in this prospectus and the documents incorporated by reference into this prospectus before exchanging Unregistered Notes for Registered Notes. You should carefully consider the following risk factors and all other information contained or incorporated by reference in this prospectus before making an investment decision. The occurrence of any one or more of the following could materially adversely affect your investment in the Notes or our business and operating results.

Risks Related to Our Business

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

In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payers such as state and federal governments, under programs such as Medicare and Medicaid in the United States, and private insurance plans. In certain foreign markets, the pricing and profitability of our products generally are subject to government controls. In the United States, there have been, there are, and we expect there will continue to be, a number of state and federal laws and/or regulations, or in some cases draft legislation or regulations that could limit the amount that state or federal governments will pay to reimburse the cost of pharmaceutical and biologic products. For example, the Medicare Prescription Drug, Improvement and Modernization Act (or the Medicare Modernization Act (MMA)) was enacted into law in December 2003. In addition, we believe that private insurers, such as managed care organizations, may adopt their own reimbursement reductions in response to legislation or regulation, including, without limitation, the MMA. However, we believe that private payers ability to fully implement reimbursement mechanisms in alignment with government legislation or regulation is limited. For example, we are aware of a few private payers who have adopted an average sales price methodology similar in structure to that of the MMA. However, the reimbursement rates based on such methodology are substantially greater than those under the current MMA reimbursement rates. We expect that, beginning in 2005, reimbursement changes resulting from the MMA are likely, to a degree, to negatively affect product sales of some of our marketed products. The main components of the MMA that affect our currently marketed products are as follows:

Through 2004 the Average Wholesale Price (AWP) mechanism was the basis of Medicare Part B payment for covered outpatient drugs and biologics. Effective January 1, 2005, in the physician clinic market segment, Aranesp®, Neulasta® and NEUPOGEN® will be reimbursed under a new Medicare Part B system that reimburses each product at 106% of its average sales price (ASP) (sometimes referred to as ASP + 6%). On November 3, 2004, The Centers for Medicare and Medicaid Services (CMS) released final rules for revisions to payment policies under the physician fee schedule for 2005. CMS then calculated each of Amgen s product s ASPs based on data submissions from us. ASPs will remain in effect for one quarter and will be updated quarterly thereafter. The 2005 reimbursement rates for Aranesp®, Neulasta®, and NEUPOGEN® (calculated at 106% of the ASPs and initially based on third quarter 2004 company data), are lower than our 2004 reimbursement rates as the ASP methodology incorporates sales incentives offered to healthcare providers. Per the MMA, effective January 1, 2006, physicians in this market segment will have the choice under the competitive acquisition program (CAP) between purchasing and billing for drugs under the ASP + 6% system or obtaining drugs from vendors selected by CMS via a competitive bidding process.

The Medicare hospital outpatient prospective payment system (OPPS), which determines payment rates for specified covered outpatient drugs and biologics in the hospital outpatient setting, will continue to utilize AWP as the basis for reimbursement in 2005. On November 3, 2004, CMS issued a final rule for the reimbursement of Aranesp® in 2005. Under this final rule, as in 2003 and 2004, CMS continued the application of an equitable

adjustment such that the Aranesp® reimbursement rate for 2005 is based on the AWP of PROCRIT®. For 2005 the reimbursement rate for Aranesp® is 83% of the AWP for PROCRIT®, down from 88% of the AWP for PROCRIT® in 2004, with a dose conversion ratio of 330 U PROCRIT® to 1 mcg Aranesp®, the same ratio as 2004. Effective January 1, 2006, the OPPS system will change from an AWP based reimbursement system to a system based on average acquisition cost . This change will affect Aranesp®, Neulasta® and NEUPOGEN® when administered in the hospital outpatient

setting. Although we do not know how CMS will define the OPPS average acquisition cost, it is possible that CMS could link acquisition cost to ASP, which could lower the reimbursement rate.

Pursuant to final rules issued by CMS on November 3, 2004, Medicare reimbursement for EPOGEN® used in the dialysis setting for calendar year 2005 has been changed from the previous rate of $10 per 1,000 Units to $9.76 per 1,000 Units, a rate based upon an average acquisition cost for 2003 determined by the Office of the Inspector General (OIG) and adjusted for price inflation based on the Producer Price Index for pharmaceutical products. Pursuant to the CMS final rules, the difference between the 2004 reimbursement rates for all drugs separately billed outside the dialysis composite rate (including EPOGEN®) and the 2005 reimbursement rates for such drugs will be added to the composite rate that dialysis providers receive for dialysis treatment. Again in 2006, the EPOGEN® rate may change, as the MMA provided for discretion in either continuing to pay for these separately reimbursed dialysis drugs at acquisition cost, or switching to an ASP based system. The payment rate for dialysis drugs not studied by the OIG, including Aranesp®, will be ASP+6%.

We believe these changes driven by the MMA are lowering the 2005 reimbursement rate for all areas in which CMS provides reimbursement for EPOGEN®, Aranesp®, Neulasta® and NEUPOGEN®. However, because we cannot predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products, as of the date of this prospectus, we cannot predict the full impact of the MMA on our business; however, it is likely to be, to a degree, negative.

In addition, on July 8, 2004, CMS released a proposed revision to the Hematocrit Measurement Audit Program Memorandum (HMA-PM), a Medicare payment review mechanism used by CMS to audit EPOGEN® utilization and appropriate hematocrit outcomes of dialysis patients. As of the date of this prospectus, the comment period for the proposed revision has expired and no final program memorandum has been issued. The proposed policy would not permit reimbursement for EPOGEN® in the following circumstances without medical justification: EPOGEN® doses greater than 40,000 Units per month in a patient with a hemoglobin greater than 13 grams per deciliter or doses greater than 20,000 Units per month in a patient with hemoglobin greater than 14 grams per deciliter. If the proposed revision, which has not yet been finalized, is adopted as the final form, it could result in a reduction in utilization of EPOGEN®. Although the proposed revision was scheduled to go into effect as early as January 1, 2005, it is unclear as to when it may be implemented. Amgen and the dialysis community have provided public comment based on data analysis suggesting that revision to the proposed policy is unwarranted. Given the importance of EPOGEN® utilization for maintaining the quality of care for dialysis patients, the precise impact of such a change on provider utilization remains unclear.

If, and when, reimbursement rates or availability for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales or revenues, which could have a material adverse effect on us and our results of operations. For example, in the United States the use of EPOGEN® in connection with treatment for end-stage renal disease is funded primarily by the U.S. federal government. In early 1997, CMS, formerly known as Healthcare Financing Administration (HCFA), instituted a reimbursement change for EPOGEN®, which materially and adversely affected our EPOGEN® sales until the policies were revised. Also, we believe the increasing emphasis on cost-containment initiatives in the United States has and will continue to put pressure on the price and usage of our products, which may adversely impact product sales. Further, when a new therapeutic product is approved, the governmental and/or private coverage and reimbursement for that product is uncertain. We cannot predict the availability or amount of reimbursement for our approved products or product candidates, including those at a late stage of development, and current reimbursement policies for marketed products may change at any time. Sales of all our products are and will be affected by government and private payer reimbursement policies. Reduction in reimbursement for our products could have a material adverse effect on our results of operations.

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Our current products and products in development cannot be sold if we do not maintain regulatory approval.

We and certain of our licensors and partners conduct research, preclinical testing, and clinical trials for our product candidates. In addition, we manufacture and contract manufacture and certain of our licensors and partners manufacture our product candidates. We also manufacture and contract manufacture, price, sell, distribute, and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, including Europe. 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 product), market and sell our products in those countries. In our experience, obtaining regulatory approval is costly and takes many years, and after it is obtained, it remains costly to maintain. The FDA and other U.S. and foreign regulatory agencies have substantial authority to terminate clinical trials, require additional testing, delay or withhold registration and marketing approval, require changes in labeling of our products, and mandate product withdrawals. Substantially all of our marketed products are currently approved in the United States and most are approved in Europe and in other foreign countries for specific uses. However, later discovery of unknown problems with our products could result in restrictions on the sale or use of such products, including potential withdrawal of the product from the market. If new medical data suggests an unacceptable safety risk or previously unidentified side-affects, we may voluntarily withdraw, or regulatory authorities may mandate the withdrawal of such product from the market for some period or permanently. We currently manufacture and market all our approved principal products, and we plan to manufacture and market many of our potential products. (See We may be required to perform additional clinical trials or change the labeling of our products if we or others identify side effects after our products are on the market.) Even though we have obtained regulatory approval for our marketed products, these products and our manufacturing processes are subject to continued review by the FDA and other regulatory authorities. In addition, ENBREL® is manufactured both by us at our Rhode Island manufacturing facility and by third-party contract manufacturers, Boehringer Ingelheim Pharma KG (BI Pharma) and Genentech, Inc. (Genentech). Fill and finish of bulk product produced both at our Rhode Island manufacturing facility and at Genentech is done by us and third-party service providers. BI Pharma, Genentech, and these third-party service providers are also subject to FDA regulatory authority. (See Limits on supply for ENBREL® may constrain ENBREL® sales.) In addition, later discovery of unknown problems with our products or manufacturing processes or those of our contract manufacturers or third-party service providers could result in restrictions on the sale, manufacture, or use of such products, including potential withdrawal of the products from the market. If regulatory authorities determine that we or our contract manufacturers or third-party service providers have violated regulations or if they restrict, suspend, or revoke our prior approvals, they could prohibit us from manufacturing or selling our marketed products until we or our contract manufacturers or third-party service providers comply, or indefinitely. In addition, if regulatory authorities determine that we or our licenser or partner conducting research and development activities on our behalf have not complied with regulations in the research and development of a product candidate, then they may not approve the product candidate and we will not be able to market and sell it. If we were unable to market and sell our products or product candidates, our business and results of operations would be materially and adversely affected.

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. For example, we are involved in an ongoing patent infringement lawsuit against Transkaryotic Therapies, Inc. (TKT) and Aventis with respect to our erythropoietin patents. If we lose or settle this or other litigations at certain stages or entirely, we could be: subject to competition and/or significant liabilities; required to enter into third-party licenses for the infringed product or technology; or

required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. We have filed applications for a number of patents and have been granted patents or obtained rights relating to erythropoietin, natural and recombinant G-CSF, darbepoetin alfa, pegfilgrastim, etanercept, and our other products and potential products. We market our erythropoietin, recombinant G-CSF, darbepoetin alfa, pegfilgrastim, and etanercept products as EPOGEN®, NEUPOGEN®, Aranesp®, Neulasta®, and ENBREL®, respectively. For additional information on our material patents see Patents and Trademarks in Item 1. Business.

We also have been granted or obtained rights to patents in Europe relating to: erythropoietin; G-CSF; pegfilgrastim (pegylated G-CSF); etanercept; two relating to darbepoetin alfa; and hyperglycosylated erythropoietic proteins. Our European patent relating to erythropoietin expired on December 12, 2004 and our European patent relating to G-CSF expires on August 22, 2006. We believe that after the expiration of each of these patents, other companies could receive approval for and market follow-on or biosimilar products to each of these products in Europe; presenting additional competition to our products. (See Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do.) While we do not market erythropoietin in Europe as this right belongs to Johnson & Johnson (through KA), we do market Aranesp® in the EU, which competes with Johnson & Johnson s and others erythropoietin products. We believe that the EU is currently in the process of developing regulatory requirements related to the development and approval of new competitive products. Until such requirements are finalized, we cannot predict when follow-on or biosimilar products could appear on the market in the EU or to what extent such additional competition would impact future Aranesp® and NEUPOGEN®/Neulasta® sales in the EU. However, based on the process and timing outlined by the EMEA, we believe product specific guidelines are not likely to be finalized until 2006.

Limits on supply for ENBREL® may constrain ENBREL® sales.

U.S. and Canadian supply of ENBREL® is impacted by many manufacturing variables, such as the timing and actual number of production runs, production success rate, bulk drug yield, and the timing and outcome of product quality testing. For example, in the second quarter of 2002, the prior co-marketer with respect to ENBREL®, experienced a brief period where no ENBREL® was available to fill patient prescriptions, primarily due to variation in the expected production yield from BI Pharma. If we are at any time unable to provide an uninterrupted supply of ENBREL® to patients, we may lose patients, physicians may elect to prescribe competing therapeutics instead of ENBREL®, and ENBREL® sales will be adversely affected, which could materially and adversely affect our results of operations. (See We are dependent on third parties for a significant portion of our supply and the fill and finish of ENBREL®; and our sources of supply are limited.)

We are dependent on third parties for a significant portion of our supply and the fill and finish of ENBREL®; and our sources of supply are limited.

We currently produce a substantial portion of annual ENBREL® supply at our Rhode Island manufacturing facility. However, we also depend on third parties for a significant portion of our ENBREL® supply as well as for the fill and finish of ENBREL® that we manufacture. BI Pharma is our primary third-party 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 manufacturers used for the 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, due to

regulatory requirements or action, or due to contamination of product lots or product recalls. This in turn could materially reduce our ability to satisfy demand for ENBREL®, which could materially and adversely affect our operating results. Factors that will affect our actual supply of ENBREL® at any time include, without limitation, the following:

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BI Pharma does not produce ENBREL® continuously; rather, it produces the bulk drug substance through a series of periodic campaigns throughout the year. Our Rhode Island manufacturing facility is currently dedicated to ENBREL® production. The amount of commercial inventory available to us at any time depends on a variety of factors, including the timing and actual number of BI Pharma s production runs, the actual number of runs at our Rhode Island manufacturing facility, and, for either the Rhode Island or BI Pharma facilities, the level of production yields and success rates, the timing and outcome of product quality testing, and the amount of filling and packaging capacity.

BI Pharma schedules the vialing production runs for ENBREL® in advance, based on the expected timing and yield of bulk drug production runs. Therefore, if BI Pharma realizes production yields beyond expected levels, or provides additional manufacturing capacity for ENBREL®, it may not have sufficient vialing capacity for all of the ENBREL® bulk drug that it produces. As a result, even if we are able to increase our supply of ENBREL® bulk drug, BI Pharma may not be able to fill and finish the extra bulk drug in time to prevent any supply interruptions.

We are dependent on third parties for some fill and finish and packaging of ENBREL® bulk drug substance manufactured at our Rhode Island facility. If third-party fill and finish and packaging manufacturers are unable to provide sufficient capacity or otherwise unable to provide services to us, then supply of ENBREL® could be adversely affected.

Our current plan to increase U.S. and Canadian supply of ENBREL® includes completion of an additional large-scale cell culture commercial manufacturing facility adjacent to the current Rhode Island manufacturing facility. We expect to submit this facility for FDA approval in 2005. Additionally, we have entered into a manufacturing agreement with Genentech to produce ENBREL® at Genentech s manufacturing facility in South San Francisco, California and the FDA approved this facility for ENBREL® production in October 2004. Under the terms of the agreement, Genentech is expected to produce ENBREL® through 2005, with an extension through 2006 by mutual agreement. ENBREL® bulk drug substance produced at the Genentech facility will be produced in campaigns similar to those conducted at BI Pharma. Consequently, supply from the Genentech facility is expected to also be dependent on the timing and number of production runs in addition to the other manufacturing, filling, and packaging risk discussed above. In addition, Wyeth is constructing a new manufacturing facility in Ireland, which is expected to increase the U.S. and Canadian supply of ENBREL®. If the additional ENBREL® manufacturing capacity at the Rhode Island site, or in Ireland are not completed on time, or if these manufacturing facilities do not receive FDA or the European Agency for the Evaluation of Medical Products (EMEA) approval before we encounter supply constraints, our ENBREL® sales would be restricted, which could have a material adverse effect on our results of operations. (See Limits on supply for ENBREL® may constrain ENBREL® sales.) If these third-party manufacturing facilities are completed and approved by the various regulatory authorities, our costs of acquiring bulk drug may fluctuate.

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®, NEUPOGEN® and Neulasta® and some formulation, fill and finish operations for ENBREL® at our manufacturing facility in Juncos, Puerto Rico. Our global supply of these products is dependent on the uninterrupted and efficient operation of this facility. Power failures, the breakdown, failure or substandard performance of equipment, the improper installation or operation of equipment, natural or other disasters, including hurricanes, or failures to comply with regulatory requirements, including those of the FDA, among others, could adversely affect our formulation, fill and finish operations. As a result, we may be unable to supply these products, which could adversely and materially affect our product sales. Although we have obtained limited insurance to protect against business interruption loss, 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 materially and adversely affecting our operating results.

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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 rheumatoid arthritis products marketed by Biogen IDEC Inc., Centocor, Inc., Johnson & Johnson, Abbott, Genentech, Pfizer, Novartis, and Sanofi-Aventis, as well as the generic drug methotrexate, and may face competition from other potential therapies being developed. Additionally, Aranesp® competes with Johnson & Johnson in the United States and the EU. Further, if our currently marketed products are approved for new uses, or if we sell new products, we may face new, additional competition that we do not face today. Additionally, some of our competitors, including biotechnology and pharmaceutical companies, market products or are actively engaged in research and development in areas where we have products or where we are developing product candidates or new indications for existing products. In the future, we expect that our products will compete with new drugs currently in development, drugs approved for other indications that may be approved for the same indications as those of our products, and off-label use of drugs approved for other indications. Our European patent relating to erythropoietin expired on December 12, 2004 and our European patent relating to G-CSF expires on August 22, 2006. We believe that after the expiration of each of these patents, other companies could receive approval for and market follow-on or biosimilar products to each of these products in Europe; presenting additional competition to our products. While we do not market erythropoietin in Europe as this right belongs to Johnson & Johnson (through KA), we do market Aranesp® in the EU, which competes with Johnson & Johnson s and others erythropoietin products. We believe that the EU is currently in the process of developing regulatory requirements related to the development and approval of follow-on or biosimilar products. Until such requirements are finalized, we cannot predict when follow-on or biosimilar products could appear on the market in the EU or to what extent such additional competition would impact future Aranesp® and NEUPOGEN®/Neulasta® sales in the EU. However, based on the process and timing outlined by the EMEA, we believe product specific guidelines are not likely to be finalized until 2006. Our products may compete against products that have lower prices, superior performance, are easier to administer, or that are otherwise competitive with our products. Our inability to compete effectively could adversely affect product sales.

Large pharmaceutical corporations may have greater clinical, research, regulatory, manufacturing, marketing, financial experience 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.

Certain of our raw materials, medical devices and components are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for commercial manufacturing and formulation of our products are provided by single-source unaffiliated third-party suppliers. Also, certain medical devices and components necessary for fill, finish, and packaging of our products are provided by single-source unaffiliated third-party suppliers. Certain of these raw materials, medical devices, and components are the proprietary products of these unaffiliated third-party suppliers and, in some cases, such proprietary products are specifically cited in our drug application with the FDA so that they must be obtained from that specific sole source and could not be obtained from another supplier unless and until the FDA approved that other supplier. We would be unable to obtain these raw materials, medical devices, or components for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This,

in turn, could materially and adversely affect our ability to satisfy demand for our products, which could materially and adversely affect our operating results.

Also, certain of the raw materials required in the commercial manufacturing and the formulation of our products are derived from biological sources, including mammalian tissues, bovine serum and human serum albumin, or HSA. We are investigating alternatives to certain biological sources. 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

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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 too, in turn, could adversely affect our ability to satisfy demand for our products, which could materially and adversely affect our operating results.

Our product development efforts may not result in commercial products.

We intend to continue an aggressive research and development program. Successful product development in the biotechnology industry is highly uncertain, and very few research and development projects produce a commercial product. Product candidates that appear promising in the early phases of development, such as in early human clinical trials, may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results;
- the product candidate was not effective in treating a specified condition or illness;
- the product candidate had harmful side effects in humans or animals;
- the necessary regulatory bodies, such as the FDA, did not approve our product candidate for an intended use;
- the product candidate was not economical for us to manufacture and commercialize;
- other companies or people have or may have proprietary rights to our product candidate, such as patent rights, and will not let us sell it on reasonable terms, or at all;
- the product candidate is not cost effective in light of existing therapeutics; or
- certain of our licensors or partners may fail to effectively conduct clinical development or clinical manufacturing activities.

Several of our product candidates have failed or been discontinued at various stages in the product development process, including, but not limited to, Brain Derived Neurotrophic Factor (BDNF), Megakaryocyte Growth and Development Factor (MGDF), and Glial Cell Lined-Derived Neurotrophic Factor (GDNF). For example, in 1997, we announced the failure of BDNF for the treatment of amyotrophic lateral sclerosis, or Lou Gehrig s Disease, because the product candidate, when administered by injection, did not produce acceptable clinical results for a specific use after a phase 3 trial, even though BDNF had progressed successfully through preclinical and earlier clinical trials. In addition, in 1998, we discontinued development of MGDF, a novel platelet growth factor, at the phase 3 trial stage after several people in platelet donation trials developed low platelet counts and neutralizing antibodies. Also, in June 2004, we announced that the phase 2 study of GDNF for the treatment of advanced Parkinson s disease did not meet the primary study endpoint upon completion of six 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 commercially successful products. Further, clinical trial results are frequently susceptible to varying interpretations by scientists, medical personnel, regulatory personnel, statisticians, and others, which may delay, limit, or prevent further clinical development or regulatory approvals of a product candidate. Also, the length of time that it takes for us to complete clinical trials and obtain regulatory

approval for product marketing has in the past varied by product and by the intended use of a product. We expect that this will likely be the case with future product candidates and we cannot predict the length of time to complete necessary clinical trials and obtain regulatory approval. (See Our current products and products in development cannot be sold if we do not maintain regulatory approval.)

We may be required to perform additional clinical trials or change the labeling of our products if we or others identify side effects after our products are on the market.

If we or others identify side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products, and changes to or re-approvals of our manufacturing facilities may be required, any of which could have a material adverse effect on sales of the affected products and on our business and results of operations.

After any of our products are approved for commercial use, we or regulatory bodies could decide that changes to our product labeling are required. Label changes may be necessary for a number of reasons, including: the identification of actual or theoretical safety or efficacy concerns by regulatory agencies or the discovery of significant problems with a similar product that implicates an entire class of products. Any significant concerns raised about the safety or efficacy of our products could also result in the need to reformulate those products, to conduct additional clinical trials, to make changes to our manufacturing processes, or to seek re-approval of our manufacturing facilities. Significant concerns about the safety and effectiveness of a product could ultimately lead to the revocation of its marketing approval. The revision of product labeling or the regulatory actions described above could be required even if there is no clearly established connection between the product and the safety or efficacy concerns that have been raised. The revision of product labeling or the regulatory actions described above could have a material adverse effect on sales of the affected products and on our business and results of operations. (See Our current products and products in development cannot be sold if we do not maintain regulatory approval.)

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, and other legal proceedings that arise from time to time in the ordinary course of our business. Matters required to be disclosed by us are set forth in Item 3. Legal Proceedings in our Form 10-K for the year ended December 31, 2004, which is incorporated by reference herein. Litigation is inherently unpredictable, and excessive verdicts can occur. Consequently, it is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages that could have a material adverse effect on our results of operations in the period in which such amounts 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, alleging that the reporting of prices for pharmaceutical products has resulted in false and overstated Average Wholesale Price (AWP), which in turn is alleged to have improperly inflated the reimbursement paid by Medicare beneficiaries, insurers, state Medicaid programs, medical plans and other payers to health care providers who prescribed and administered those products. As of the date of this prospectus, a number of these actions have been brought against us and/or Immunex, now a wholly owned subsidiary of ours. Additionally, a number of states have pending investigations regarding our Medicaid drug pricing practices and the U.S. Departments of Justice and Health and Human Services have requested that Immunex produce documents relating to pricing issues. Further, certain state government entity plaintiffs in some of these AWP cases are also alleging that companies, including ours, are not reporting their best price to the states under the Medicaid program. These cases and investigations are described in Item 3. Legal Proceedings Average Wholesale Price Litigation in our Form 10-K for the year ended December 31, 2004, which is incorporated by reference herein. 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 amounts are incurred.

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

Product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products that we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management s attention, and adversely affect our reputation and the demand for our products. Amgen and Immunex have been named as defendants in product liability actions for certain company products.

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

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

changes in the government s or private payers reimbursement policies for our products;

inability to maintain regulatory approval of marketed products;

changes in our product pricing strategies;

lower than expected demand for our products;

inability to provide adequate supply of our products;

changes in wholesaler buying patterns;

increased competition from new or existing products; or

fluctuations in foreign currency exchange rates.

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

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

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

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

we will need to assimilate new staff members;

we will need to manage complexities associated with a larger and faster growing organization;

we will need to accurately anticipate demand for the products we manufacture and maintain adequate manufacturing capacity, and our ability to do so may depend on factors that we do not control; and

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we will need to start up and operate a number of new manufacturing facilities, which may result in temporary inefficiencies and higher cost of goods.

Of course, there may be other risks and we cannot guarantee that we will be able to successfully manage these or other risks.

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable federal and state 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. (See Our current products and products in development cannot be sold if we do not maintain regulatory approval. and We may be required to perform additional clinical trials or change the labeling of our products if we or others identify side effects after our products are on the market.) While we have developed and instituted a corporate compliance program based on current best practices, we cannot assure you that we or our employees are or will be in compliance with all potentially applicable federal and state regulations and/or laws. If we fail to comply with any of these regulations and/or laws a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, including withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, or other sanctions or litigation.

Our 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, will prepare and implement 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.

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

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. However, professional societies, practice management groups, private health/science foundations, and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups/organizations may relate to such matters as usage, dosage, route of administration, and use of related therapies. Organizations like these have in the past made recommendations about our products. Recommendations or guidelines that are followed by patients and health care providers could result in decreased use of our products. In addition, the perception by the investment community or stockholders that recommendations or guidelines will result in decreased use of our products could adversely affect prevailing market prices for our common stock.

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

In connection with our ongoing process improvement activities associated with products we manufacture, we continually invest in our various manufacturing practices and related processes with the objective of increasing production yields and success rates to gain increased cost efficiencies and capacity utilization. Depending on the timing and outcomes of these efforts and our other estimates and assumptions regarding future product sales, the

carrying value of certain manufacturing facilities or other assets may not be fully recoverable and could result in the recognition of an impairment in the carrying value at the time that such effects are identified. The potential recognition of impairment in the carrying value, if any, could have a material and adverse affect on our results of operations.

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We may not realize all of the anticipated benefits of our merger with Tularik.

On August 13, 2004, we merged with Tularik Inc. The success of our merger with Tularik will depend, in part, on our ability to retain Tularik staff and to realize the anticipated synergies, cost savings, and growth opportunities from integrating the businesses of Tularik with the businesses of Amgen. Our success in realizing these benefits and the timing of this realization depend upon the successful integration of the operations and personnel of Tularik. The integration of two independent companies is a complex, costly, and time-consuming process. The difficulties of combining the operations of the companies include, among others:

retaining key staff members;

consolidating research and development operations;

consolidating corporate and administrative infrastructures;

preserving ours and Tularik s research and development, and other important relationships;

minimizing the diversion of management s attention from ongoing business concerns; and

coordinating geographically separate organizations.

In addition, even if we are able to integrate Tularik s operations successfully, this integration may not result in the realization of the full benefits of the synergies, cost savings, or sales and growth opportunities that we expect or that these benefits will be achieved within the anticipated time frame. For example, as of the date of this prospectus, we have discontinued a number of Tularik clinical development programs and may discontinue other or all such programs. Further, the elimination of significant duplicative costs may not be possible or may take longer than anticipated and the benefits from the merger may be offset by costs incurred in integrating the companies. We cannot assure you that the integration of Tularik with us will result in the realization of the full benefits anticipated by us to result from the merger. Our failure to achieve these benefits could have a material adverse effect on our results of operations.

Risks Relating to the Notes

Your failure to tender your Unregistered Notes in the exchange offer could limit the trading market and trading value of your Unregistered Notes.

We will only issue Registered Notes in exchange for Unregistered Notes that are timely received by the exchange agent. Therefore, you should allow sufficient time to ensure timely delivery of the Unregistered Notes and you should carefully follow the instructions on how to tender your Unregistered Notes. Neither we nor the exchange agent are required to tell you of any defects or irregularities with respect to your tender of the Unregistered Notes. If you do not tender your Unregistered Notes or if we do not accept your Unregistered Notes because you did not tender your Unregistered Notes properly, then, after we consummate the exchange offer, you may continue to hold Unregistered Notes that are subject to the existing transfer restrictions. In addition, if you tender your Unregistered Notes for the purpose of participating in a distribution of the Registered Notes, you will be required to comply with the registration and prospectus delivery requirements of the Securities Act in connection with any resale of the Registered Notes. If you are a broker-dealer that receives Registered Notes for your own account in exchange for