

AMGEN INC  
Form 8-K  
July 16, 2002

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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

July 15, 2002

Date of Report (Date of earliest event reported)

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**AMGEN INC.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or other Jurisdiction  
of Incorporation)

000-12477  
(Commission File Number)

95-3540776  
(IRS Employer  
Identification Number)

Amgen Inc.  
One Amgen Center Drive  
Thousand Oaks, CA  
(Address of principal executive offices)

91320-1799  
(Zip Code)

805-447-1000  
(Registrant's telephone number, including area code)

N/A  
(Former Name or Former Address, if Changed Since Last Report)

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**Item 2. Acquisition or Disposition of Assets**

On July 15, 2002, Amgen Inc. ( "Amgen" ) announced the closing of its acquisition of Immunex Corporation ( "Immunex" ) pursuant to the Amended and Restated Agreement and Plan of Merger dated as of December 16, 2001 among Amgen, AMS Acquisition Inc., a wholly owned subsidiary of Amgen ( "Merger Sub" ), and Immunex, as amended by the First Amendment to Amended and Restated Agreement and Plan of Merger dated as of July 15, 2002 (the "Merger Agreement" ). Pursuant to the Merger Agreement, Immunex was merged with and into Merger Sub, with Merger Sub continuing as the surviving corporation and a wholly-owned subsidiary of Amgen, and each share of Immunex common stock outstanding at the effective time of the merger was converted into the right to receive 0.44 of a share of Amgen common stock and \$4.50 in cash.

A copy of Amgen's press release dated July 16, 2002 announcing the closing of the acquisition is attached hereto as Exhibits 99.1 and is incorporated herein by reference.

A description of certain factors that may affect Amgen's business, after giving effect to the acquisition, is attached to this Current Report as Exhibits 99.5 and is incorporated herein by reference.

**Item 5. Other Events.**

Set forth below is an update to the description of the business of Amgen Inc. and its consolidated subsidiaries (including Immunex Corporation, unless the context requires otherwise, "Amgen" or the "Company" ) set forth in Amgen's Annual Report on Form 10-K for the year ended December 31, 2001 to reflect Amgen's acquisition of Immunex on July 15, 2002. The updated business description is primarily based on filings made by Immunex with the Securities and Exchange Commission prior to Amgen's acquisition of Immunex. While we have no reason to believe this description is inaccurate, we can give you no assurance that this current description will conform with our operation of Immunex following the acquisition.

**BUSINESS**

**Products Acquired in Connection with Immunex Acquisition**

*Enbrel® (etanercept)*

Enbrel® (proper name - etanercept) is Immunex's trademark for its soluble tumor necrosis factor ( "TNF" ) receptor. Enbrel® blocks the biologic activity of TNF by competitively inhibiting TNF binding to the TNF cell surface receptors, which is expressed in a wide variety of tissues. TNF production is induced in response to inflammatory stimuli and mediates various physiologic responses including inflammatory and immunological responses.

In November 1998, Immunex received FDA approval and began marketing Enbrel® in the U.S. for the reduction of the signs and symptoms in patients with moderately to severely active rheumatoid arthritis ( "RA" ). In May 1999, Immunex received FDA approval of Enbrel® for treating moderately to severely active polyarticular-course juvenile RA ( "JRA" ), in patients who have had an inadequate response to one or more disease-modifying, anti-rheumatic drugs ( "DMARDs" ). In June 2000, the FDA approved Enbrel® for inhibiting the progression of structural damage in patients with moderately to severely active RA. In December 2000, the Canadian Health Protection Bureau approved Enbrel® in adults for reduction in signs and symptoms of moderately to severely active RA in patients who have had an inadequate response to one or more DMARDs. In January 2002, the FDA approved Enbrel® for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis ( "PsA" ). Because Enbrel® has been marketed only since 1998, its long-term effects are largely unknown. See "Factors that May

**Affect Amgen** 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.

Because demand for Enbrel® was projected to temporarily exceed supply, Immunex began an Enbrel® enrollment program in November 2000 to help ensure uninterrupted therapy for U.S. patients prescribed Enbrel® before January 1, 2001. The Enbrel® enrollment program called for these patients to register with Immunex and receive an enrollment number. As of January 1, 2001, patients considering therapy with Enbrel®, but not yet receiving treatment, were invited to enroll in the program and were placed on a waiting list. These patients receive Enbrel® on a first come, first served basis once additional supply of Enbrel® becomes available. In the second quarter of 2002, Immunex experienced a brief period where no Enbrel® was available to fill patient prescriptions, primarily due to variation in the production yield from BI Pharma. Once supply of Enbrel became available, Immunex resumed filling orders on a first come, first served basis. See **Factors that May Affect Amgen** Limits on our current source of supply for Enbrel® will constrain Enbrel® sales growth and Our sources of supply for Enbrel are limited.

Amgen owns the rights to Enbrel® in the U.S. and Canada, and Wyeth, formerly American Home Products Corporation, owns rights to Enbrel® in all other countries. Accordingly, Amgen does not receive royalties or a share of gross profits from sales of Enbrel® outside the U.S. and Canada. Amgen and Wyeth are marketing Enbrel® in the U.S. and Canada under a promotion agreement. See **Joint Ventures and Business Relationships** Wyeth.

Enbrel® sales for the years ended December 31, 2001, December 31, 2000 and December 31, 1999 were \$761.9 million, \$652.4 million, and \$366.9 million, respectively.

#### *Novantrone® (mitoxantrone)*

Novantrone® (proper name - mitoxantrone for injection concentrate) is Immunex's trademark for its compound similar to doxorubicin and idarubicin, two chemotherapeutic agents frequently used to treat some cancers, but with a molecular change that results in less damage to the heart. In December 1987, the FDA approved Novantrone® for initial therapy of acute nonlymphocytic leukemia in combination with other drug(s). In November 1996, Novantrone® was approved by the FDA for use in combination with corticosteroids for the treatment of pain in advanced hormone refractory prostate cancer. In October 2000, the FDA approved Novantrone® for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary progressive, progressive relapsing or worsening relapsing-remitting Multiple Sclerosis (MS). Novantrone® is not indicated for primary progressive MS.

Novantrone® sales for the years ended December 31, 2001, December 31, 2000 and December 31, 1999 were \$71.2 million, \$59.9 million and \$44.5 million, respectively.

#### *Leukine®*

In May 2002, Immunex announced that it had agreed to sell its Leukine® (proper name-sargramostim) business to Schering AG Germany for approximately \$380 million in cash plus the payment of additional cash consideration upon achievement of certain milestones. Immunex has agreed to sell its Leukine® business as a condition to obtaining regulatory approval of Amgen's acquisition of Immunex.

#### *Thioplex*

Thioplex® (proper name - thiotepa for injection) is Immunex's trademark for a powder formulation of thiotepa for injection. Thioplex® is approved for the palliative treatment of a wide variety of tumor types, which means that it alleviates symptoms without curing the underlying disease. The FDA has approved Thioplex® for a number of oncology indications. In 2001, Thioplex® began to face generic competition.

### **Acquired Product Candidates**

#### *Inflammation*

Poor regulation of TNF occurs in conditions such as psoriasis and ankylosing spondylitis. Psoriasis is a skin disorder that most commonly appears as inflamed swollen skin lesions, which can be extremely painful and disfiguring. Ankylosing spondylitis is a unique form of chronic inflammatory arthritis characterized by joint stiffness, pain and extra bone growth that can result in partial or complete fusion of the spine.

In August 2001, Immunex announced the results of a six-month randomized, placebo-controlled, double-blind Phase 2 clinical trial indicating that psoriasis patients treated with Enbrel® experienced significant improvement compared to patients who were treated with placebo. In the fourth quarter of 2001, Immunex commenced Phase 2/3 dose ranging clinical trial in psoriasis. In the second quarter of 2002, a second large, controlled trial was initiated. Immunex also collected data in its Phase 2 and 3 clinical trials in psoriatic arthritis that will assist Amgen in evaluating the safety and efficacy of Enbrel® in treating patients with psoriasis. Enbrel® is being studied in a large Phase 3 clinical trial in ankylosing spondylitis. Enbrel® is also being studied in a Phase 3 clinical trial for Wegner's Granulomatosis.

Amgen is developing IL-1 Receptor Type 2, a natural regulator of IL-1. IL-1 Receptor Type 2 is believed to work by competitively binding IL-1, which prevents IL-1 from binding to cell surface receptors, potentially preventing a signal to the cell that can lead to inflammatory disease. IL-1 Receptor Type 2 is in a Phase 1 clinical trial in RA to assess tolerability.

In May 1999, Immunex entered into an agreement with Genmab A/S, or Genmab, for HuMax-IL-15, a fully human antibody against interleukin-15, or IL-15. IL-15 is a cytokine that plays a role in the cascade of reactions that cause the inflammatory process involved in diseases such as RA, psoriasis and Crohn's disease. Under the terms of the agreement, Genmab is responsible for developing, at its cost, HuMax-IL-15 through Phase 2 clinical trials, but Amgen has an exclusive option to assume development responsibility of Phase 3 clinical trials, and then to market and sell HuMax-IL-15 should it receive FDA approval. In October 2001, Genmab announced the initiation of a Phase 1/2 clinical trial of HuMax-IL-15 in patients with RA.

#### *Cancer*

Certain tissue growth factors are believed to play a role in the development and growth of tumors. Immunex had entered into, and Amgen is continuing, a joint development and commercialization agreement with Abgenix, Inc. ( Abgenix ) for both parties to develop and commercialize human antibody ABX-EGF. See Joint Ventures and Business Relationships-Abgenix. It is believed that ABX-EGF targets the receptor for human epidermal growth factor, or EGFR, which is over expressed in some of the most prevalent human tumor types, including lung, prostate, pancreatic, colorectal, renal cell and esophageal. ABX-EGF is in a series of Phase 2 clinical trials to evaluate its tolerability and efficacy for the treatment of several types of cancers. These include clinical trials in patients with kidney, colorectal, prostate and non-small cell lung cancer.

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

##### *Wyeth*

*Background.* Prior to the acquisition of Immunex, Wyeth and Immunex were parties to several agreements relating to business and corporate governance matters. As a result of the closing of the acquisition of Immunex, some of these agreements were terminated, however, some agreements have survived the acquisition. In connection with the acquisition, Amgen entered into several agreements with Wyeth relating to these agreements to establish the framework for the ongoing relationship between Wyeth, Immunex and Amgen. In the following discussion, Wyeth refers to Wyeth, or its various divisions or affiliates.

*Amended and Restated Promotion Agreement.* In connection with the acquisition of Immunex, Amgen entered into an agreement with Wyeth to amend

and restate an existing long-term Enbrel® promotion agreement between Wyeth and Immunex. The principal operative terms of the amendment and restatement of the Enbrel® promotion agreement became effective at the closing of the acquisition of Immunex.

In 1997, Immunex entered into an Enbrel® promotion agreement with Wyeth. Under the terms of the Enbrel® promotion agreement, Enbrel® was promoted in the U.S. and Canada by the sales and marketing organization of Wyeth.

Under the amended and restated promotion agreement, Wyeth and Amgen will jointly market and sell Enbrel® to all appropriate customer segments in the U.S. and Canada for all approved indications other than oncology. The rights to promote Enbrel® in the U.S. and Canada for oncology indications are reserved to Amgen.

Under the amended and restated promotion agreement, an Enbrel® management committee comprised of an equal number of representatives from Wyeth and from Amgen will be responsible for overseeing the marketing and sales of Enbrel® including strategic planning, approval of an annual marketing plan, product pricing and establishing an Enbrel® brand team. The Enbrel® brand team, with equal representation from each party, will prepare and implement the annual marketing plan and will be responsible for all sales activities. The agreement provides that each of Wyeth and Amgen will:

- have primary tactical execution responsibility for specific activities identified within the agreement or as directed by the management committee;

- be required to maintain a minimum level of financial commitment to promotion and marketing and a minimum number of sales personnel for Enbrel® as established from time to time by the management committee; and

- pay a defined percentage of all marketing and sales expenses approved by the management committee.

The amended and restated promotion agreement further provides that Amgen will:

- pay Wyeth a percentage of the annual gross profits of Enbrel® in the U.S. and Canada attributable to all indications for Enbrel®, other than oncology indications, on a scale that increases as gross profits increase;

- be entitled to keep all of the gross profits attributable to any future U.S. or Canadian oncology indications for Enbrel®; and

- pay Wyeth specified residual royalties on a declining scale based on net sales of Enbrel® in the U.S. and Canada in the three years following the expiration or termination of Wyeth's detailing and promotion of Enbrel®.

If Wyeth sells or distributes a biologic product in the U.S. and Canada that is directly competitive with Enbrel®, as defined in this agreement, and subject to several exclusions, Wyeth will give Amgen prior written notice and, upon Amgen's request, the parties will attempt in good faith to either establish mutually acceptable terms under which Amgen will co-promote this competitive biologic product or establish other terms for a commercial relationship with Wyeth, or negotiate an adjustment to the gross profits allocated to Wyeth under this agreement. If Amgen is unable to establish acceptable terms with Wyeth within 90 days of its request, Amgen will have the option to reacquire from Wyeth all marketing rights to Enbrel® in the U.S. and Canada and terminate this agreement, subject to the payment by Amgen of a substantial amount to Wyeth over a defined period. If Wyeth obtains a biologic product that is directly competitive with Enbrel® through the acquisition of another company and Amgen reacquires the marketing rights to Enbrel® in the U.S. and Canada, Wyeth's primary field sales force that had detailed Enbrel® in the relevant territory within the U.S. and Canada for a specified period will not sell, detail or otherwise distribute the competitive biologic product for a specified period in the U.S. and Canada.

Wyeth has agreed to reimburse Amgen for a defined percentage of the clinical and regulatory expenses Amgen incurs in connection with the filing and approval of any new indications for Enbrel® in the U.S. and Canada, excluding oncology and rheumatoid arthritis indications. Wyeth's reimbursement of these clinical and

regulatory expenses is in addition to another existing cost-sharing arrangement between Amgen and Wyeth for development costs related to Enbrel®. The additional Wyeth reimbursement for clinical and regulatory expenses under this agreement, a portion of which is payable upon regulatory filing of any new indication and the remainder of which will be payable upon regulatory approval of any new indication, if any, applies for that part of the U.S. and Canadian clinical and regulatory expenses for Enbrel® for which Amgen would otherwise be financially responsible under the cost-sharing provisions in the other cost-sharing agreement. Wyeth will also provide reimbursement under this agreement for a defined percentage of specified patent expenses related to Enbrel®, including any up-front license fees and milestones, as well as patent litigation and interference expenses.

Subject to specified limitations, Wyeth will also be responsible for a defined percentage of the liabilities, costs and expenses associated with the manufacture, use or sale of Enbrel® in the U.S. or Canada.

*Agreement Regarding Governance and Commercial Matters.* In connection with the acquisition of Immunex, Amgen also entered into an agreement regarding governance and commercial matters with Wyeth. This agreement relates to, among other things:

the rights of Wyeth to complete the development of and sell identified products under development by Immunex and the rights to market and promote those products developed by Immunex under an existing products rights agreement (described below);

amending the product rights agreement as of the closing of the acquisition of Immunex to terminate the rights described above in exchange for a specified payment to Wyeth;

Amgen's agreement not to sue Wyeth under any of Amgen's patents or any patents that come under Amgen's control for infringement for developing, making, using, marketing, distributing, importing or selling Enbrel® anywhere in the world outside of the U.S. and Canada; and

Amgen's grant to Wyeth of an exclusive option to acquire, subject to the approval of a third party, an exclusive sublicense under a license agreement between a third party and Amgen. Wyeth may exercise this option at any time on or before December 31, 2002. If exercised, in addition to all upfront payments, milestone payments, and royalties payable under the sublicense agreement, Wyeth will reimburse Amgen in an amount not to exceed a defined cap for amounts paid to the third party in 2002 to maintain the license agreement.

*TNFR License and Development Agreement.* In July 1996, Immunex entered into a TNFR license and development agreement with Wyeth under which Immunex retained marketing rights to Enbrel® in the U.S. and Canada, and Wyeth retained marketing rights to Enbrel® outside of the U.S. and Canada. The TNFR agreement also addresses joint project management, cost sharing for development activities related to Enbrel®, manufacturing responsibilities, intellectual property protection and disposition of rights upon relinquishment or termination of product development.

*Agreements Related to the Manufacturing of Enbrel®.* Under the TNFR agreement, Immunex agreed with Wyeth to negotiate the terms of a supply agreement for

the commercial supply of Enbrel® to Wyeth outside the U.S. and Canada. In November 1998, Immunex and Wyeth entered into an Enbrel® Supply Agreement with Boehringer Ingelheim Pharma KG ( BI Pharma ), for the commercial supply of Enbrel® to Immunex in the U.S. and Canada, and to Wyeth outside of the U.S. and Canada. The Enbrel® Supply Agreement was amended in June 2000 to offer BI Pharma financial incentives to provide additional near-term production capacity for Enbrel®, to facilitate process improvements for Enbrel® and to extend the term of the agreement. The parties have agreed to further amend the Enbrel® Supply Agreement, to be effective June 2002, to reflect the transfer of production to a new BI Pharma manufacturing facility, to provide for the use of an improved manufacturing process, to extend the term of the agreement, and to offer BI Pharma additional financial incentives to provide additional near-term production capacity for Enbrel®.

On January 1, 2002, Immunex purchased from Wyeth a large-scale biopharmaceutical manufacturing facility in West Greenwich, Rhode Island. Immunex collaborated with Wyeth to retrofit this facility and it is intended for the production of Enbrel®. In connection with the signing of the purchase agreement for the Rhode Island manufacturing facility, Immunex and Wyeth entered into a collaboration and global supply agreement related to the manufacture, supply, inventory, and allocation of defined supplies of Enbrel® produced at the Rhode Island manufacturing facility, and a new Rhode Island manufacturing facility under construction as well as particular supplies of Enbrel® produced by either BI Pharma in Germany or Wyeth at a manufacturing facility Wyeth is constructing in Ireland. However, until the Rhode Island manufacturing facility receives regulatory approval, a preliminary August 2000 agreement among Immunex and Wyeth will continue to govern the allocation of supplies of Enbrel®. See Manufacturing and Raw Materials.

*Stockholders' Rights Agreement.* In connection with Amgen's acquisition of Immunex, Amgen entered into a stockholders' rights agreement with Wyeth.

*Standstill Provisions.* Under the stockholders' rights agreement, Wyeth agreed that until December 16, 2006, it may not:

acquire or propose to acquire any Amgen securities or securities of Amgen subsidiaries or any assets of Amgen or its subsidiaries or make any public announcement with respect to any of the foregoing;

participate in any way in any solicitation of proxies to vote, or seek to advise or influence any person with respect to the voting of, any of Amgen securities or make any public announcement with respect to any of the foregoing;

form or in any way participate in a group in connection with any of the foregoing;

otherwise act to seek to control or influence Amgen management, board of directors or policies;

request Amgen to amend or waive the standstill provisions of the stockholders' rights agreement or take any action which would reasonably be expected to require Amgen to make a public announcement regarding the possibility of a business combination or merger or make any public announcement with respect to any of the restrictions in this clause; or

advise, assist or encourage, or direct any person to advise, assist or encourage any other persons, in connection with any of the foregoing.

The above restrictions do not apply to:

purchases by Wyeth of Amgen common stock for employee benefit or other plans not to exceed 1% of the outstanding shares of Amgen common stock; or

securities held by a company that Wyeth acquires in the future, if the fair market value of the securities represents less than 20% of the assets of that company; however, Wyeth must use commercially reasonable efforts to divest those securities within 18 months of the consummation of the acquisition.

*Voting of Amgen Common Stock.* Under the stockholders' rights agreement, Wyeth agreed that, until

Wyeth beneficially owns in the aggregate less than 2% of the outstanding shares of Amgen common stock, Wyeth must cause all shares of Amgen common stock beneficially owned by it to be voted:

with respect to the election of directors, in favor of those individuals nominated by Amgen's board of directors or a nominating committee of Amgen's board of directors;

on all proposals of Amgen's other stockholders, in accordance with the recommendation of Amgen's board of directors; and

on all other matters that come before Amgen's stockholders for a vote, in proportion to the votes cast by the other Amgen stockholders.

*Lock-Up of Shares of Common Stock Acquired in the Acquisition.* Under the stockholders' rights agreement, Wyeth and Amgen agreed that, for 90 days following the closing of Amgen's acquisition of Immunex, Wyeth may not transfer any shares of Amgen's common stock other than transfers:

to a wholly-owned subsidiary of Wyeth;

pursuant to a third party tender offer or exchange offer which was not induced by Wyeth and (a) which is approved by Amgen's board of directors or (b) in circumstances in which it is reasonably likely that Wyeth would be, as a result of not tendering or exchanging, forced to receive consideration that is different than the consideration available to those stockholders who did tender or exchange;

arising as a result of a merger or similar transaction involving Amgen; or

in the form of a pledge in connection with bona fide financings (other than derivative transactions) with a financial institution, provided the pledgee agrees to the applicable restrictions set forth in stockholders' rights agreement.

*Volume Limitations on Sales of Common Stock.* Wyeth may not transfer more than 20 million shares of Amgen common stock (including common stock underlying derivative transactions) in any calendar quarter, excluding shares of Amgen common stock transferred pursuant to underwritten syndicated offerings.

In addition, the aggregate number of shares of Amgen common stock underlying derivative transactions effected in any calendar week by Wyeth may not exceed 20% of the aggregate trading volume of Amgen common stock on the Nasdaq National Market in the immediately preceding calendar week.

*Registration Rights.*

*Shelf Registration.* Under the stockholders' rights agreement, Amgen agreed that Amgen would prepare and file with the SEC immediately after the closing of the acquisition of Immunex a registration statement registering the resale of Amgen common stock from time to time by Wyeth or any other permitted holders of Amgen common stock received by Wyeth in the acquisition. Amgen further agreed to use commercially reasonable efforts to:

cause the shelf registration statement to be declared effective within 90 days after the closing of the acquisition of Immunex; and

keep the shelf registration statement continuously effective until the earlier of (a) the first anniversary of the closing of the acquisition of Immunex and (b) the sale of all of the securities included in the shelf registration statement.

Wyeth, or any other permitted holders of Amgen common stock received by Wyeth in the acquisition, may request Amgen to effect an underwritten syndicated offering by supplement or amendment to the shelf registration



statement. In this case, the requesting party or parties and Amgen will enter into an underwriting agreement in customary form with the underwriters for the offering which will be underwritten by two co-managing underwriters with the requesting holders selecting one co-managing underwriter and with Amgen selecting the second co-managing underwriter. In some circumstances, Amgen may delay an offering for a limited period of time.

Amgen is only obligated to effect two offerings under the shelf registration statement and each of these offerings must include at least 5 million shares of common stock. In addition, these underwritten offerings will be subject to cutback if either of the co-managing underwriters reasonably advises Amgen that the number of shares of Amgen common stock requested to be included in the offering exceeds the number that can be sold in the offering at a price reasonably related to the then current market value of Amgen common stock.

***Demand Registration Rights.*** Beginning on the first anniversary of the closing of the acquisition of Immunex, and until the fourth anniversary of the closing of the acquisition of Immunex, Wyeth, or any other permitted holders of Amgen common stock received by Wyeth in the acquisition, may request that Amgen file a registration statement covering the registration of a minimum of 5 million shares of Amgen common stock held by these holders in an underwritten offering. Amgen has agreed to use its commercially reasonable efforts to cause to be registered all the shares that the requesting party or parties have requested to be registered.

Amgen is obligated to effect up to four demand registrations, less the number of underwritten offerings effected under the shelf registration statement. In certain circumstances, Amgen may delay an offering for a limited period of time. Furthermore, Amgen's board of directors may delay the filing of a demand registration statement if the filing would likely materially interfere with a potential contemplated material financing, acquisition, corporation reorganization, corporate development or merger or other transaction involving Amgen. Other terms of the demand registration are comparable to those provided with respect to the shelf registration described above.

If Amgen files a demand registration statement registering an underwritten offering of Amgen common stock on behalf of Wyeth, or any other permitted holders of Amgen common stock received by Wyeth in the acquisition, Amgen may include in the registration statement shares of Amgen common stock for Amgen's own account. Amgen's right is subject to cutback if either of the co-managing underwriters reasonably advises Wyeth that the number of shares of common stock requested to be included in the offering exceeds the number that can be sold in the offering at a price reasonably related to the then current market value of Amgen common stock.

***Piggy Back Registration Rights.*** If Amgen files a registration statement registering an underwritten offering of Amgen common stock on Amgen's behalf or on behalf of other holders of Amgen common stock, Wyeth, or any other permitted holders of common stock received by Wyeth in the acquisition, have the right to request that Amgen include their shares in the registration statement. Their right to include shares is subject to customary cutbacks if the managing underwriter, to be selected by Amgen, advises Amgen that the number of shares of common stock requested to be included in the offering exceeds the number that can be sold in the offering at a price reasonably related to the then current market value of Amgen common stock. Furthermore, Amgen may decide for any reason not to proceed with the proposed registration and may, at Amgen's election, give written notice of the determination to the parties requesting inclusion in the registration, and, thereupon, Amgen will be relieved of its obligation to register any shares of Amgen common stock in connection with that registration statement.

***Termination.*** Except with respect to the standstill provisions and the voting provisions, which will terminate as described above, the stockholders' rights agreement and the obligations of the parties under it will terminate on the first date on which Wyeth beneficially owns less than 5 million shares of Amgen common stock.

***Terminated Agreements.*** Wyeth also entered into the following agreements with Immunex that were terminated upon the closing of the acquisition of Immunex.

***Product Rights Agreement.*** In July 1998, Immunex entered into a product rights agreement with Wyeth, under which Immunex granted Wyeth, among other things, an option to obtain royalty-bearing worldwide exclusive licenses to a limited number of Immunex products for all clinical indications. This option is referred to as a product

call. The product rights agreement also granted Wyeth a right of first refusal to Immunex covered products and technologies that may only be exercised if the Immunex board of directors decides that Immunex will not market a covered product or technology by itself in any part of the world where it has or acquires marketing rights. In accordance with the agreement regarding governance and commercial matters, the product rights agreement was amended at the closing of the acquisition of Immunex to terminate Wyeth's product call right and right of first refusal in exchange for a specified payment to Wyeth by Amgen. Under the terms of the agreement, termination of these rights also terminated the agreement.

*Governance Agreement.* Prior to the acquisition of Immunex, Immunex and Wyeth were parties to a governance agreement which related to, among other things:

corporate governance, including the composition of the Immunex board of directors (immediately prior to the closing of the acquisition of Immunex, Wyeth had the right to designate for election two directors of Immunex);

Wyeth's right to purchase additional shares of Immunex common stock from Immunex if specified events occur;

future purchases and sales of Immunex common stock by Wyeth;

the requirement that members of the Immunex board of directors designated by Wyeth approve specified corporate actions; and

the requirement that a supermajority of the members of the Immunex board of directors approve specified corporate actions.

Pursuant to the terms of the governance agreement and the agreement regarding governance and commercial matters, the governance agreement terminated as of the closing of the acquisition of Immunex.

#### *Abgenix*

Amgen and Abgenix have an agreement providing for the joint development and commercialization of ABX-EGF. Under the agreement, development and commercialization costs will be shared equally, as would any potential profits from sales of ABX-EGF. Abgenix has responsibility for completing the ongoing Phase 1 clinical trial. Amgen and Abgenix are responsible for the ongoing and future Phase 2 clinical trials and Amgen has primary responsibility for future Phase 3 clinical trials. If the clinical trials for ABX-EGF are successful and regulatory approval is received, Amgen would play the primary role in marketing ABX-EGF, while Abgenix would retain co-promotion rights.

#### **Marketing**

Amgen and Wyeth share commercialization responsibilities for Enbrel® under a co-promotion agreement. Under the Enbrel promotion agreement, Amgen and Wyeth jointly promote Enbrel in the U.S. and Wyeth promotes Enbrel in Canada to healthcare providers such as doctors and hospitals, pharmacy benefit managers and managed care organizations. In February 2002, Immunex began detailing Enbrel® in the U.S. through its own dedicated sales force. Immunex has focused its sales force on double covering certain key rheumatologists currently visited by Wyeth sales representatives and on promoting the new PsA indication for Enbrel to dermatologists. See *Joint Ventures and Business Relationships* Wyeth. Enbrel® is reimbursed by private payors, and changes in coverage and reimbursement policies of these payors could have a material adverse effect on sales of Enbrel®.

Amgen uses pharmaceutical wholesalers and specialty distributors for Enbrel® and Novantrone®. For Enbrel®, rather than stocking inventory of product at wholesalers, wholesaler orders for Enbrel® are primarily drop-shipped directly to pharmacies for end-users. Amgen receives and processes product orders through a centralized

customer service and sales support group. A third party provides Amgen with shipping, warehousing and data processing services on a fee basis.

Because demand for Enbrel® was projected to temporarily exceed supply, Immunex began an Enbrel® enrollment program in November 2000 to help ensure uninterrupted therapy for U.S. patients prescribed Enbrel® before January 1, 2001. The Enbrel® enrollment program called for these patients to register with Immunex and receive an enrollment number. As of January 1, 2001, patients considering therapy with Enbrel®, but not yet receiving treatment, were invited to enroll in the program and were placed on a waiting list. These patients receive Enbrel® on a first come, first served basis once additional supply of Enbrel® becomes available. In the second quarter of 2002, Immunex experienced a brief period where no Enbrel® was available to fill patient prescriptions, primarily due to variation in the production yield from BI Pharma. Once supply of Enbrel became available, Immunex resumed filling orders on a first come, first served basis. See Factors that May Affect Amgen Limits on our current source of supply for Enbrel® will constrain Enbrel® sales growth and Our sources of supply for Enbrel® are limited.

## Competition

Any products or technologies that are directly or indirectly successful in addressing RA could negatively impact the market for Enbrel®. A number of companies are marketing or developing biological or other products that compete or are expected to compete with Enbrel®. Companies marketing treatments include: Centocor/Johnson & Johnson, which currently markets Remicade® for use with methotrexate to treat RA; Aventis, which markets Arava®; Pharmacia Corporation, which markets Celebrex®; Merck, which markets Vioxx®; and other generic competitors which market methotrexate, gold, sulphazine and Plaquinil. The Company also markets Kineret for the reduction of the signs and symptoms of moderately to severely active RA in patients 18 years of age or older who have failed one or more DMARD. Companies developing treatments include: Abbott Laboratories/Knoll, which is developing D2E7; Pharmacia/Celltech Group plc, which is developing CDP870; Genentech/Hoffman-LaRoche Inc., which is studying Rituxan for use in treating RA; Ares-Serono, which is studying Rebif and TBP-1 in RA; Regeneron Pharmaceuticals Incorporated, which is developing IL-1 TRAP; various other companies, including Vertex and Scios, are developing programs against the P38 MAP target; Vertex Pharmaceuticals Incorporated/Aventis Pharmaceuticals, which is developing pralnacasan; Alexion Pharmaceuticals Inc., which is developing an antibody that inhibits the complement cascade; Immune Response Corporation, which is developing a proprietary immune-based vaccine therapy; and various other competitors, such as Celgene, working with Selective Cytokine Inhibitory Drugs, Glaxo SmithKline, Altana and ICOS Corporation, with respect to PDE-4. Because demand for Enbrel® was projected to temporarily exceed supply, Immunex began an Enbrel® enrollment program in November 2000 to help ensure uninterrupted therapy for U.S. patients prescribed Enbrel® before January 1, 2001. In the second quarter of 2002, Immunex experienced a brief period where no Enbrel® was available to fill patient prescriptions, primarily due to variation in the production yield from BI Pharma. Once supply of Enbrel® became available, Immunex resumed filling orders on a first come, first served basis. See Factors that May Affect Amgen Limits on our current source of supply for Enbrel® will constrain Enbrel® sales growth and Our sources of supply for Enbrel® are limited. Amgen believes that supply constraints being experienced by Amgen may make competitive products more attractive to patients and physicians.

A number of companies are marketing products that compete with Novantrone® for its oncology indications or may compete with Novantrone® for its new MS indication. The companies include Biogen, Berlex Laboratories (a subsidiary of Schering AG), Serone, Teva Pharmaceuticals Industries Limited, Pharmacia and Bedford Laboratories (a division of Ben Venue Laboratories, Inc.)

## Manufacturing and Raw Materials

Substantially all the raw materials used to manufacture Enbrel® are available from multiple sources. However, two of the raw materials used in the production of Enbrel are manufactured by single suppliers. A material shortage, contamination or recall could adversely impact or disrupt commercial manufacturing of Enbrel®.

Amgen is dependent on a third party contract manufacturer for commercial production of Enbrel®. Failure by these third parties to supply the quantities of Enbrel® for which Amgen has contracted could adversely affect Enbrel® sales. All finished dosage forms of Enbrel are currently manufactured by BI Pharma and packaged by a

third-party contract packager. All finished dosage forms for Novantrone® are manufactured by Wyeth subsidiaries or sourced by Wyeth from third-party manufacturers.

In November 1998, Immunex and Wyeth entered into a long-term supply agreement with BI Pharma to manufacture commercial quantities of Enbrel®. Until the retrofitted Rhode Island manufacturing facility receives FDA approval, Amgen's sales of Enbrel® are entirely dependent on BI Pharma manufacturing the product. Amgen has made significant purchase commitments to BI Pharma under the BI Pharma supply agreement to manufacture commercial inventory of Enbrel®. Under the BI Pharma supply agreement, BI Pharma has reserved a specified level of production capacity for Enbrel®, and Amgen's purchase commitments for Enbrel® are manufactured from that reserved production capacity. Amgen is required to submit a rolling three-year forecast for manufacturing the bulk drug for Enbrel®, and a rolling forecast for a shorter period for the number of finished vials of Enbrel® to be manufactured from the bulk drug. Amgen has submitted firm orders for the maximum production capacity that BI Pharma currently has reserved for Enbrel®. Amgen and Wyeth will be responsible for substantial payments to BI Pharma if Amgen and Wyeth fail to use a specified percentage of the production capacity that BI Pharma has reserved for Enbrel® each calendar year, or if the BI Pharma supply agreement is terminated prematurely under specified conditions. In June 2000, Immunex, Wyeth and BI Pharma amended the BI Pharma supply agreement to offer BI Pharma financial incentives to provide additional near-term production capacity for Enbrel®, to facilitate process improvements for Enbrel, and to extend the term of the agreement. The parties have agreed to further amend the Enbrel® Supply Agreement, to be effective June 2002, to reflect the transfer of production to a new BI Pharma manufacturing facility, to provide for the use of an improved manufacturing process, to extend the term of the agreement, and to offer BI Pharma additional financial incentives to provide additional near-term production capacity for Enbrel®.

On January 1, 2002, Immunex purchased from Wyeth a large-scale biopharmaceutical manufacturing facility in West Greenwich, Rhode Island (the RI Facility). Immunex and Wyeth have invested substantial sums and worked closely together to retrofit the Rhode Island manufacturing facility to accommodate the commercial production of Enbrel bulk drug. FDA approval is required for commercial production of Enbrel at this facility.

In November 2001, Immunex broke ground on the BioNext Project, a new manufacturing plant to be built adjacent to the RI Facility. When the facility is completed and approved by the FDA, it is scheduled to produce Enbrel® and possibly other products that may be developed.

In April 2002, Immunex announced that it had entered into a manufacturing agreement with Genentech, Inc. to produce Enbrel® at Genentech's manufacturing facility in South San Francisco, California. The manufacturing facility is subject to FDA approval, which the parties hope to obtain in 2004. Upon approval, the Genentech facility will become a licensed manufacturing site for commercial supply of Enbrel®. Under the terms of the agreement, Genentech will produce Enbrel® through 2005, with an extension through 2006 by mutual agreement.

Amgen is currently unable to supply enough Enbrel® to meet patient demand. BI Pharma's ability to provide additional production runs depends in part on factors beyond its control, including contractual commitments to other customers. There can be no assurances that Amgen will be able to supply sufficient quantities of Enbrel® in the future. Additionally, there can be no assurances that Amgen will be able to accurately anticipate future demand and have or retain adequate manufacturing capacity for either Enbrel® or Novantrone®. In the second quarter of 2002, Immunex experienced a brief period where no Enbrel® was available to fill patient prescriptions, primarily due to variation in the production yield from BI Pharma. Once supply of Enbrel became available, Immunex resumed filling orders on a first come, first served basis. See Factors that May Affect Amgen We depend on third party manufacturers for our supply of Enbrel®, Our sources of supply for Enbrel are limited and Limits on our current source of supply for Enbrel® will constrain Enbrel® sales growth.

## Patents and Trademarks

Enbrel® is a fusion protein consisting of a dimer of two subunits, each comprising a TNF receptor domain derived from a TNF receptor known as p80, fused to a segment derived from a human antibody molecule known as an Fc domain. Immunex believes that it was the first to isolate a recombinant DNA encoding p80 TNFR and also the first to express the protein using recombinant DNA technology. Immunex has been issued U.S. patents

covering p80 TNFR, DNAs encoding p80 TNFR, and methods of using TNFR:Fc, including for the treatment of arthritis. Immunex was granted a European patent in December 1995 covering p80 TNFR DNAs, proteins and related technology.

Two other companies, BASF and Yeda Research & Development Company, Ltd., filed patent applications disclosing partial amino acid sequence information of specified TNF-binding proteins, or TBPs, shortly prior to the time Immunex filed its patent applications claiming the full-length p80 TNFR DNAs and proteins corresponding in part to the TBPs disclosed by BASF and Yeda Research. BASF was issued a U.S. patent based on its TBP disclosure. Due to limitations in the claims of the BASF U.S. patent, Immunex has not entered into a license with BASF for its U.S. patent. This BASF U.S. patent lost an interference proceeding, which BASF is currently appealing through a U.S. district court action. In June 2000, Immunex entered into a royalty-bearing license agreement with respect to the BASF TBP patent family excepting the U.S. patent. If BASF were able to validly assert its U.S. TBP patent to cover TNFR:Fc in the U.S., Amgen's commercialization of Enbrel made in the U.S. could be impeded.

The Yeda Research TBP patents and patent applications are controlled by Ares-Serono International S.A. and its affiliate Inter-Lab Ltd. (collectively Serono). In January 1999, Immunex entered into a settlement agreement with Serono under which Immunex and Serono agreed to settle potential disputes concerning the patents and patent applications controlled by Serono that relate to TBPs. Under the settlement, Serono has agreed not to assert any of the foregoing patent rights against the manufacture, use or sale of Enbrel in any territory in consideration of the payment of fees and royalties by us to Serono for a specified term in respect of the net sales of Enbrel sold or manufactured in designated countries, including Germany and the U.S., where Yeda Research's patent rights have been filed.

After the effective dates on which Immunex filed its patent applications, Hoffmann-La Roche, or Roche, and Amgen, through Synergen Inc., also filed patent applications directed to p80 TNFR DNAs. No patents covering full-length TNFR or the intact extracellular domain of TNFR have been issued to Roche.

Immunex has also been granted a royalty-bearing worldwide exclusive license under patent rights jointly owned by Aventis SA (through its predecessor Hoechst AG) and Massachusetts General Hospital claiming cytokine receptor-Fc fusion proteins, including TNFR:Fc. Roche has filed patent applications with claims covering TNFR:Fc fusions, which were filed after the Aventis and Massachusetts General Hospital patent applications licensed to us. Roche has been granted a patent containing these claims in Japan. In September 1999, Immunex entered into a royalty-bearing worldwide co-exclusive license agreement with Roche under these Roche patents and patent applications.

ZymoGenetics, Inc. and Genentech have separately been issued U.S. patents having claims directed to specified fusion proteins comprising immunoglobulin constant region domains and specified processes for making these proteins, and have also filed corresponding European applications that have not yet been granted. On March 7, 2002, ZymoGenetics filed a patent infringement lawsuit against us in the U.S. District Court for the Western District of Washington. ZymoGenetics seeks a declaration of infringement and available remedies under the patent laws, including monetary damages and injunctive relief. In May 1999, Immunex entered into a royalty-bearing worldwide co-exclusive license agreement under the Genentech patents under which Immunex made an up-front payment to Genentech, a portion of which was reimbursed to us by Wyeth under the Enbrel® promotion agreement.

The Kennedy Institute of Rheumatology has been issued a patent having some claims directed to a method of treating arthritis by co-administering methotrexate and a soluble TNF receptor or a functional portion thereof. Immunex does not believe that the Kennedy Institute of Rheumatology patent would be successfully asserted against Enbrel®.

Immunex has been issued or obtained rights to U.S. patents relating to mitoxantrone that cover aspects of methods of using mitoxantrone to treat leukemia and solid tumors (expiring in 2006) and to treat neuroimmunologic diseases (expiring in 2005).

Immunex has obtained U.S. registration of its Enbrel® and Novantrone® trademarks.

### **Properties**

Amgen leases space in approximately 10 buildings in downtown Seattle and in two buildings in Bothell, Washington housing laboratory and office facilities. Amgen owns a manufacturing and development center in Bothell, Washington that includes a process development facility. Immunex has acquired approximately 20 acres of undeveloped land adjacent to the manufacturing and development center in Bothell, Washington.

On January 1, 2002, Immunex purchased from Wyeth a large-scale biopharmaceutical manufacturing facility in West Greenwich, Rhode Island. Amgen is in the process of preparing the Rhode Island manufacturing facility to accommodate the commercial production of Enbrel® bulk drug. FDA approval is required for commercial production of Enbrel® at this facility.

In November 2001, Immunex broke ground on the BioNext Project, a new manufacturing plant to be built adjacent to the RI Facility. When the facility is completed and approved by the FDA, it is scheduled to produce Enbrel® and possibly other products that may be developed.

Immunex also owns 29 acres of land in Seattle, Washington that is under construction as a research and technology center and that may allow Amgen to consolidate its non-manufacturing operations at this one site. The initial phase of the project is known as the Helix Project. Immunex also has additional acreage adjacent to this construction site for potential future expansion of this project.

In March 2001, Immunex entered into a seven and one-half year lease to finance construction of the Helix Project. The total amount committed by the lessor to fund the costs of the project, including financing costs, was \$750 million. Under the terms of the Helix Project lease, Immunex was permitted to acquire the lessor's interest in the Helix Project for the sum of the lessor's equity in the Helix Project improvements and the outstanding balance of the lease financing funded with commercial paper. As of July 1, 2002, the purchase option price of the Helix Project improvements based on such amounts was approximately \$250 million. The Helix Project lease financing was subject to acceleration upon a change of control of Immunex. In connection with the acquisition of Immunex by Amgen on July 15, 2002, Immunex exercised its purchase option to acquire the Helix Project improvements from the lessor. As part of the lease transaction, Immunex was required to restrict as collateral cash or investment securities worth \$765 million during the construction of the Helix Project. Immunex has elected to apply a portion of the liquidated collateral to the payment of the purchase option price, which payment and the resulting termination of the lease financing occurred immediately prior to the closing of Amgen's acquisition of Immunex. As a result, the Helix Project improvements were demised to Immunex, as the fee owner of the land associated with such improvements.

### **Legal Proceedings**

#### *ZymoGenetics litigation*

On March 7, 2002, ZymoGenetics filed a patent infringement lawsuit against Immunex in the U.S. District Court for the Western District of Washington, relating to U.S. patents having claims directed to specified fusion proteins comprising immunoglobulin constant region domains and specified processes for making these proteins. ZymoGenetics seeks a declaration of infringement and available remedies under the patent laws, including monetary damages and injunctive relief.

#### *Average Wholesale Price Litigation*

Immunex is also named in several putative class action, also naming Amgen, broadly alleging that it, together with a large number of other pharmaceutical manufacturers, reported prices for certain products that overstated the Average Wholesale Price ( AWP ), allegedly inflating reimbursements, including co-payments paid to providers who prescribe and administer the products. The complaints assert claims under the federal RICO statute and its state law corollaries, as well as state law claims for deceptive trade practices and common law fraud and seek

an undetermined amount of damages, as well as other relief, including declaratory and injunctive relief. The cases include: Citizens for Consumer Justice et. al. v. Abbott Laboratories, Inc. et. al. (United States District Court, District of Massachusetts); State of Nevada v. American Home Products Corporation et. al. (Second Judicial District Court, Washoe County, Nevada); and State of Montana ex rel. Mike McGrath, Attorney General v. Abbott Laboratories, Inc. et. al. (First Judicial District Court, Lewis and Clark County, Montana).

### Forward Looking Information

Except for the historical information contained in this Current Report, the matters discussed herein are by their nature forward-looking. Investors are cautioned that forward-looking statements or projections made by Amgen, including those made in this Current Report, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Amgen operates in a rapidly changing environment that involves a number of risks, some of which are beyond its control. Future operating results and Amgen's stock price may be affected by a number of factors, including, without limitation: (i) the results of preclinical and clinical trials; (ii) regulatory approvals of product candidates, new indications and manufacturing facilities; (iii) health care guidelines and policies relating to Amgen's products; (iv) reimbursement for Amgen's products by governments and private payors; (v) intellectual property matters (patents) and the results of litigation; (vi) competition; (vii) fluctuations in operating results; and (viii) rapid growth of Amgen. In addition, Amgen may not realize all of the anticipated benefits of its acquisition of Immunex, including the anticipated synergies, cost savings and growth opportunities from integrating the businesses of Immunex with the businesses of Amgen. These factors and others are discussed herein and in the sections appearing under the heading "Factors That May Affect Amgen" contained in Exhibit 99.5 attached hereto and in Amgen's other filings with the Securities and Exchange Commission, which sections are incorporated herein by reference.

### Item 7. Financial Statements and Exhibits

- (a) Financial statements of business acquired.
  - (1) Immunex's audited consolidated balance sheets at December 31, 2001 and 2000 and audited consolidated statements of income, cash flows, and shareholders' equity for each of the three years in the period ended December 31, 2001 and notes thereto and report of Independent Auditors.
  - (2) Immunex's unaudited consolidated condensed balance sheets at March 31, 2002 and December 31, 2001 and unaudited consolidated condensed statements of income and cash flows for the three month period ended March 31, 2002 and 2001 and notes thereto.
- (b) Pro forma financial information:
  - (1) Amgen's unaudited pro forma condensed combining balance sheet as of March 31, 2002 and unaudited pro forma condensed combining statements of operations for the year ended December 31, 2001 and the three months ended March 31, 2002.
- (c) Exhibits see Exhibit Index

**SIGNATURES**

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: July 16, 2002

By: /s/ Steven M. Odre

Name: **Steven M. Odre**

Title: **Senior Vice President, General Counsel and Secretary**



**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Document Description</b>
2.1	First Amendment to Amended and Restated Agreement and Plan of Merger dated as of July 15, 2002, by and among Amgen Inc., AMS Acquisition Inc. and Immunex Corporation (filed as Exhibit 2.2 to Post-Effective Amendment No. 1 to Form S-4 Registration Statement (File No. 333-81832) on July 15, 2002 and incorporated herein by reference)
21	Subsidiaries
23.1	Consent of Ernst & Young LLP, Independent Auditors
99.1	Press release dated July 16, 2002
99.2	Immunex's audited consolidated balance sheets at December 31, 2001 and 2000 and audited consolidated statements of income, cash flows, and shareholders' equity for each of the three years in the period ended December 31, 2001 and notes thereto and report of Independent Auditors (filed as Exhibit 99.3 to Current Report on Form 8-K filed on May 22, 2002 and incorporated herein by reference)
99.3	Immunex's unaudited consolidated condensed balance sheets at March 31, 2002 and December 31, 2001 and unaudited consolidated condensed statements of income and cash flows for the three month period ended March 31, 2002 and 2001 and notes thereto (filed as Exhibit 99.3 to Current Report on Form 8-K filed on May 22, 2002 and incorporated herein by reference)
99.4	Amgen's unaudited pro forma condensed combining balance sheet as of March 31, 2002 and unaudited pro forma condensed combining statements of operations for the year ended December 31, 2001 and the three months ended March 31, 2002 (filed as Exhibit 99.1 to Current Report on Form 8-K filed on May 22, 2002 and incorporated herein by reference)
99.5	Factors That May Affect Amgen