



FORM 10-Q

AMGEN INC – amgn

Filed: November 09, 2005 (period: September 30, 2005)

Quarterly report which provides a continuing view of a company's financial position

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON D.C. 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2005

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 000-12477

AMGEN INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

95-3540776

(I.R.S. Employer Identification No.)

One Amgen Center Drive, Thousand Oaks, California

(Address of principal executive offices)

91320-1799

(Zip Code)

Registrant's telephone number, including area code

(805) 447-1000

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No
As of October 14, 2005, the registrant had 1,234,319,868 shares of common stock, \$0.0001 par value, outstanding.

AMGEN INC.

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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.

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-effects, we may voluntarily withdraw, or regulatory authorities may mandate the withdrawal, of such product from the market for some period or permanently. Further, regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain or maintain approval of our products and/or product candidates or require significant additional costs to obtain or maintain such approvals. We currently manufacture and market all our approved principal products, and we plan to manufacture and market many of our potential products. (See "—Difficulties, disruptions or delays in manufacturing may limit supply of our products and limit our product sales." and "—We may be required to perform additional clinical trials or change the labeling of our products if we or others identify side effects after our products are on the market.") Even though we have obtained regulatory approval for our marketed products, these products and our manufacturing processes are subject to continued review by the FDA and other regulatory authorities. In addition, ENBREL® is manufactured both by us at our Rhode Island manufacturing facilities and by third-party contract manufacturers, including Boehringer Ingelheim Pharma KG ("BI Pharma").