AMGEN INC
Form 8-K
September 16, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of

The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)

September 16, 2008

AMGEN INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-12477**	**95-3540776**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One Amgen Center Drive

Thousand Oaks, CA	**91320-1799**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code

805-447-1000

N/A

(Former name or former address, if changed since last report)

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

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On September 16, 2008, the Company will present additional data from its pivotal fracture trial (the Pivotal Fracture Trial) evaluating its receptor activator of nuclear factor kappa B (RANK) Ligand inhibitor, denosumab, in the treatment of postmenopausal osteoporosis. This data will be presented at the annual meeting of the American Society of Bone and Mineral Research in Montreal, Canada, and may include data set forth in this Periodic Report on Form 8-K.

Pivotal Fracture Trial Results: In the Pivotal Fracture Trial, 7,808 women with osteoporosis were randomized to receive either a 60 mg subcutaneous injection of denosumab (N=3,902) or a matching placebo injection (N=3,906) every 6 months for three years. The mean age of the study participants was 72.3 years, and the mean baseline Bone Mineral Density (BMD) T-scores of the subjects was -2.8 at the lumbar spine, -1.9 at the total hip and -2.2 at the femoral neck. Approximately 24% of subjects had prevalent vertebral fractures at baseline. Approximately 83% of the subjects completed the three-year study (denosumab N=3,272; placebo N=3,206). Through month 36 of the study, treatment with 60 mg of denosumab every six months reduced the risk of new vertebral fractures by 68% versus placebo (2.3% denosumab versus 7.2% placebo; P<0.0001), a statistically significant result. Treatment with denosumab also reduced hip fracture risk by 40% (0.7% denosumab versus 1.2% placebo, P=0.036) and nonvertebral fracture risk by 20% (6.5% denosumab versus 8.0% placebo, P=0.011) during the 36 month period, both statistically significant results. Adverse events reported included infections characterized as adverse events (52.9% denosumab, 54.4% placebo), infections characterized as serious adverse events (4.1% denosumab, N=159; 3.4% placebo, N=133), delayed fracture healing (0.1% denosumab, N=2; 0.1% placebo, N=3), stroke (1.4% denosumab, N=56; 1.4% placebo, N=54), coronary heart disease events (1.2% denosumab, N=47; 1.0% placebo, N=39), atrial fibrillation characterized as serious adverse events (0.7% denosumab, N=29; 0.7% placebo, N=29) and new primary malignancy (2.4% denosumab, N=93; 2.2% placebo, N=84). Adverse events reported for at least 2% of subjects and for which P<0.05 included fall (denosumab 5.3%, N=205; placebo 6.4%, N=250) and flatulence (denosumab 2.2%, N=84; placebo 1.4%, N=53), and serious adverse events reported for at least 0.1% of subjects and for which P<0.01 included concussion (denosumab <0.1%, N=1; placebo 0.3%, N=11) and erysipelas (denosumab 0.2%, N=7; placebo 0%, N=0). Additionally, deaths occurred in 1.8% of the denosumab subjects (N=70) and 2.3% of the placebo subjects (N=90). No cases of osteonecrosis of the jaw, or ONJ, were seen in either study group.

SIGNATURES

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

AMGEN INC.

Date: September 16, 2008

By: /s/ David J. Scott
Name: David J. Scott
Title: Senior Vice President,
General Counsel and Secretary