Amgen's Third Quarter 2009 Adjusted Earnings Per Share Increased 21 Percent to $1.49

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Third Quarter 2009 Revenue Decreased 2 Percent to $3.8 Billion

THOUSAND OAKS, Calif., Oct. 21 /PRNewswire-FirstCall/ -- Amgen (Nasdaq: AMGN) reported adjusted earnings per share (EPS) of $1.49 for the third quarter of 2009, an increase of 21 percent compared to $1.23 for the third quarter of 2008. Adjusted net income increased 16 percent to $1,518 million in the third quarter of 2009 compared to $1,308 million in the third quarter of 2008.

Total revenue decreased 2 percent during the third quarter of 2009 to $3,812 million versus $3,875 million in the third quarter of 2008.

"Our third quarter results reflect the continued stability of our core businesses in the face of increased competition," said Kevin Sharer, chairman & chief executive officer. "We are pleased by the results of clinical studies for denosumab and Vectibix that we recently presented at a scientific meeting, and look forward to making these innovative medicines available to patients in their respective indications."

Adjusted EPS and adjusted net income for the third quarter of 2009 and 2008 exclude, for the applicable periods, stock option expense, certain expenses related to acquisitions, a strategic decision to change manufacturing processes and the resolution of certain non-routine transfer pricing issues with the Internal Revenue Service (IRS), and certain other items. In addition, adjusted EPS and adjusted net income for the third quarter of 2009 and 2008 exclude the incremental non-cash interest expense resulting from a change in accounting for convertible debt as discussed below. These expenses and other items are itemized on the attached reconciliation tables.

On a reported basis and calculated in accordance with United States (U.S.) Generally Accepted Accounting Principles (GAAP), Amgen's GAAP EPS were $1.36 in the third quarter of 2009, a 30 percent increase compared to $1.05 in the same quarter last year. GAAP net income increased 24 percent to $1,386 million in the third quarter of 2009 from $1,121 million in the third quarter of 2008. GAAP net income for the third quarter of 2008 was negatively impacted by an $84 million inventory write-off resulting from a strategic decision to change manufacturing processes. Effective Jan. 1, 2009, Amgen adopted a new accounting standard which changed the method of accounting for the Company's convertible notes. In addition, as required, the Company also revised its previously reported financial statements to apply this change in accounting to prior periods. Under this new accounting method, the Company's GAAP EPS and net income have been reduced as a result of recognizing incremental non-cash interest expense. In connection with adopting this new accounting standard, Amgen recorded $63 million and $59 million of additional non-cash interest expense in the third quarter of 2009 and 2008, respectively. In addition, the Company's previously reported GAAP EPS and net income for the third quarter of 2008 have been reduced by $0.04 per share and $37 million to $1.05 per share and $1,121 million, respectively, as a result of adopting this new accounting method.

Product Sales Performance

During the third quarter of 2009, total product sales decreased 1 percent to $3,736 million from $3,784 million in the third quarter of 2008. Sales in the U.S. totaled $2,918 million in the third quarter of 2009, relatively unchanged versus $2,929 million in the third quarter of 2008. International sales decreased 4 percent to $818 million versus $855 million for the third quarter of 2008. The decline in third quarter 2009 international sales reflects the unfavorable impact of changes in foreign exchange, which were in aggregate approximately $76 million. Excluding the impact of foreign exchange, total product sales increased 1 percent and international product sales increased 5 percent.

Worldwide sales of Aranesp(®) (darbepoetin alfa) decreased 19 percent to $685 million in the third quarter of 2009 versus $845 million during the third quarter of 2008. In the U.S., Aranesp sales decreased 27 percent to $333 million in the third quarter of 2009 versus $458 million in the third quarter of 2008. U.S. sales of Aranesp in the third quarter of 2008 were positively impacted by $54 million due to a change in the accounting estimate related to product sales return reserves. Excluding the positive impact of this prior year change in the accounting estimate, U.S. sales of Aranesp decreased 18 percent in the third quarter of 2009 versus the prior year. The decrease was driven by a decline in demand reflecting the negative impact, primarily in the supportive cancer care setting, of additional product label changes which occurred in August 2008, and a decrease in average net sales price. In addition, the decrease in sales also reflects, to a lesser degree, a slight loss of segment share. International Aranesp sales decreased 9 percent to $352 million in the third quarter of 2009 versus $387 million in the third quarter of 2008 due to the unfavorable impact of changes in foreign exchange, which were in aggregate approximately $29 million and, to a lesser extent, segment decline. Excluding the impact of foreign exchange, international Aranesp product sales decreased 2 percent. Excluding the impact of the change in the accounting estimate related to product sales return reserves and foreign exchange, worldwide product sales decreased 10 percent in the third quarter of 2009 versus the prior year.

Sales of EPOGEN(®) (Epoetin alfa) increased 5 percent to $663 million in the third quarter of 2009 versus $634 million in the third quarter of 2008 due to an increase in demand. The increase in demand is principally due to patient population growth and, to a lesser extent, increases in average net sales price and dose/utilization.

Combined worldwide sales of Neulasta(®) (pegfilgrastim) and NEUPOGEN(®) (Filgrastim) increased 2 percent to $1,210 million in the third quarter of 2009 versus $1,192 million for the third quarter of 2008. Combined sales of Neulasta and NEUPOGEN in the U.S. were $897 million in the third quarter of 2009 versus $856 million in the third quarter of 2008, an increase of 5 percent due primarily to an increase in demand. The increase in demand was driven by an increase in units sold and an increase in average net sales price. Combined international sales decreased 7 percent to $313 million in the third quarter of 2009 versus $336 million for the third quarter of 2008. This decline is due to the unfavorable impact of changes in foreign exchange, which were in aggregate approximately $33 million, partially offset by an increase in demand driven by segment growth and by the continued conversion from NEUPOGEN to Neulasta. Excluding the impact of foreign exchange, combined worldwide product sales of Neulasta and NEUPOGEN increased 4 percent and international product sales increased 3 percent.

Sales of Enbrel(®) (etanercept) increased 3 percent in the third quarter of 2009 to $924 million versus $893 million in the third quarter of 2008, driven primarily by an increase in demand, partially offset by a favorable change in the accounting estimate recorded in the third quarter 2008 related to accruals for sale incentives. The increase in demand was principally due to a high single digit increase in the average net sales price partially offset by a decrease in units sold due to share declines as a result of increased competitive activity in dermatology. ENBREL continues to maintain a leading

position in both the rheumatology and dermatology segments.

Worldwide sales of Sensipar(®) (cinacalcet) increased 2 percent to $165 million in the third quarter of 2009 versus $161 million during the third quarter of 2008, primarily as a result of increased international demand. U.S. sales declined 3 percent driven by a decrease in units sold.

Vectibix(®) (panitumumab) sales for the third quarter of 2009 were $58 million as compared to $41 million in the third quarter of 2008. Sales growth for the third quarter was driven by international demand as a result of recent launches of Vectibix in Europe. U.S. sales declined 12 percent driven by a decrease in units sold.

Operating Expense Analysis on an Adjusted Basis:

Cost of sales decreased 8 percent to $542 million in the third quarter of 2009 versus $590 million in the third quarter of 2008 primarily driven by lower royalty expenses, lower excess inventory write-offs, and lower excess capacity charges partially offset by higher fill and finish costs resulting from lower utilization at our manufacturing facility in Puerto Rico.

Research & Development (R&D) expenses decreased 12 percent to $613 million in the third quarter of 2009 versus $700 million in the third quarter of 2008. This decrease was primarily driven by lower clinical trial costs and lower staff-related expenses, due in part to the optimization of our clinical supply network.

Selling, General & Administrative (SG&A) expenses increased 3 percent to $913 million in the third quarter of 2009 versus $890 million in the third quarter of 2008. This increase was due to increased spending for activities in anticipation of the approval and launch of Prolia(TM) (denosumab), higher promotional expenses for marketed products, and higher expenses associated with the Pfizer (formerly Wyeth) profit share due to higher ENBREL sales partially offset by lower litigation expenses, lower staff related expenses, and expense recoveries associated with the GlaxoSmithKline collaboration agreement for Prolia in postmenopausal osteoporosis (PMO) in Europe, Australia, New Zealand, and Mexico.

Excluding expenses associated with the Pfizer profit share of $306 million and $298 million in the third quarter of 2009 and 2008, respectively, adjusted SG&A expenses in the third quarter of 2009 increased 3 percent versus the same quarter last year.

The adjusted tax rate in the third quarter of 2009 was 12.9 percent compared to 22.7 percent in the third quarter of 2008. The decrease in the adjusted tax rate is primarily due to the favorable impact of settling IRS and California tax audits for prior years, the impact of which is specific to the third quarter. In addition, the adjusted tax rate is lower due to an increase in bulk manufacturing and profits in Puerto Rico and the fact that the Federal R&D tax credit had not been extended in the third quarter of 2008. The third quarter adjusted tax rate is not indicative of the anticipated full year rate, which is expected to be approximately 18 percent.

Average diluted shares for adjusted EPS in the third quarter of 2009 were 1,021 million versus 1,063 million in the third quarter of 2008.

Capital expenditures for the third quarter of 2009 were approximately $130 million versus $159 million in the third quarter of 2008. Worldwide cash and marketable securities were $14.0 billion and adjusted outstanding debt was $12.2 billion at the end of the third quarter of 2009. The Company's adjusted outstanding debt excludes the impact of adopting a new accounting standard on the carrying values of its convertible debt. The Company's outstanding debt presented in accordance with GAAP was $11.5 billion at the end of the third quarter of 2009.

2009 Guidance Update

The Company reaffirmed that revenues for 2009 are trending towards the upper end of the current guidance range of $14.4 to $14.8 billion. Amgen now expects 2009 adjusted EPS to be in the range of $4.90 to $5.05, an increase from the previous range of $4.80 to $4.95, excluding stock option expense, certain expenses related to acquisitions, the income tax benefit, net as a result of resolving certain non-routine transfer pricing issues with the IRS, the incremental non-cash interest expense resulting from the change in accounting for convertible debt, and certain other items itemized on the reconciliation table below.

The Company still expects 2009 capital expenditures to be less than $600 million.

Third Quarter Product and Pipeline Update

The Company provided updates on selected products and clinical programs.

Prolia: The Company reviewed the Complete Response Letter that the U.S. Food and Drug Administration (FDA) has issued for the Biologic License Applications (BLA) for Prolia in the treatment and prevention of PMO. The Complete Response Letter on the Prolia PMO applications requested several items, including further information on the design and background adverse event rates that will inform the methodology of Amgen's previously submitted post-marketing surveillance program. This letter does not require additional pre-marketing clinical trials to complete the review of the PMO treatment indication. The FDA has requested a new clinical program to support approval of Prolia for the prevention of PMO indication. The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for Prolia and must include a medication guide, a communication plan, and a timetable for submission of assessments of the REMS. The FDA acknowledged receipt of Amgen's previously submitted proposed REMS materials. The FDA has also requested all updated safety data related to Prolia.

The Company also announced that it has received a Complete Response Letter issued by the FDA for the BLA for Prolia in the treatment and prevention of bone loss due to hormone ablation therapy (HALT) in breast and prostate cancer patients. The Complete Response Letter on the Prolia HALT applications requested additional information regarding the safety of Prolia in patients with breast cancer receiving aromatase inhibitor therapy and patients with prostate cancer receiving androgen deprivation therapy. Specifically, the FDA has requested results from additional adequate and well-controlled clinical trials demonstrating that Prolia has no detrimental effects on either time-to-disease progression or overall survival.

Amgen is reviewing both Complete Response Letters and will work with the FDA to determine the appropriate next steps regarding these applications.

The Company announced it expects that data from a study of the effect of denosumab on skeletal-related events in patients with bone metastases from prostate cancer will be available in the first quarter of 2010. The Company also announced that it will include results from all three of its skeletal-related events studies (breast, solid tumors or multiple myeloma, and prostate cancer) in its regulatory filings for marketing approval in the oncology setting next year.

Aranesp: The Company discussed the large, randomized, double-blind, placebo-controlled, Phase 3 study of patients with chronic kidney disease (CKD) (not requiring dialysis), anemia and type-2 diabetes (the *T*rial to *R*educe Cardiovascular *E*ndpoints with *A*ranesp(®) *T*herapy, or TREAT). Treatment of anemia with Aranesp to a hemoglobin target of 13 g/dL had no statistically significant effect on either of two primary endpoints compared with placebo treatment. The two primary endpoints were a composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia) and a composite of time to all-cause mortality or chronic renal replacement therapy. Among the components of the TREAT outcomes measures, stroke, which has been noted in the Aranesp label since 2001, was more likely to occur in the patients who received Aranesp (101 patients [5.0 percent] vs. 53 patients [2.6 percent]; hazard ratio, 1.92; 95 percent CI, 1.38 to 2.68; P